U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Food and Drug Administration

FDA EMERGENCY OPERATIONS PLAN

Version 1.1

August 2010

OFFICE OF CRISIS MANAGEMENT

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A MESSAGE FROM THE COMMISSIONER

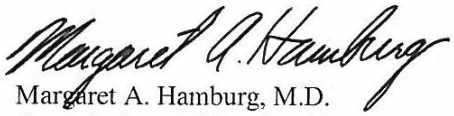
As part of the Food and Drug Administration's mission to promote and protect the public health, the agency must be prepared to respond to a multitude of different types of emergencies that can involve, impact, or require the use of FDA-regulated products. The ***FDA Emergency Operations Plan*** *(FDA EOP)* and its Incident-Specific Annexes are intended to provide a framework for the agency to prepare for, prevent, respond to, and assist the country in recovering from emergencies. Whether a natural disaster, foodborne illness outbreak, contaminated drug or biologic, faulty medical device, harmful pet food, influenza pandemic, or supporting a national event, such as the Presidential inauguration, FDA must provide a coordinated response across field and headquarters organizational components.

This plan describes the agency's overall role and responsibilities as well as those of its individual Centers and Offices relative to emergencies. It addresses routine emergency operations procedures and contemplates a state of readiness relating to the monitoring of potential public health risks associated with FDA-regulated products. The *FDA EOP* also outlines what the agency's procedures are for responding to and managing complex and life threatening incidents which require more resources and coordination.

A new feature of the plan is that it implements Homeland Security Presidential Directive 5 (HSPD-5), *Management of Domestic Events.* HSPD-5 calls for the establishment of a single, comprehensive, national incident management system. As a result, the Department of Homeland Security released the National Incident Management System (NIMS), and required all Federal agencies to incorporate and utilize NIMS for incident response. NIMS is a comprehensive, standardized, scalable, and flexible system that is being used by all levels of government to manage and coordinate emergencies and other significant incidents. The *FDA EOP* incorporates NIMS principles and the FDA's incident command structures, bringing the agency into compliance with HSPD-5 and NIMS.

With FDA's unique combination of public health and regulatory response roles, there are few types of emergencies that would not call for some level of involvement on the part of FDA. Effective response hinges upon well-trained leaders and responders who have invested in preparedness; therefore I strongly urge agency staff to become familiar with this plan before the next emergency occurs. Those who study the plan will be prepared to service the public with a greater understanding of the Agency's roles and responsibilities associated with an emergency or significant incident.

The *FDA EOP* will be treated as a living document to be updated regularly to reflect organizational and policy changes, improvements in national incident management best practices and structures, and lessons learned from real world incidents and exercises. An electronic version of the *FDA EOP* and its Incident-Specific Annexes can be found on the Inside FDA Web site at http://www.fda.gov/EmergencyPreparedness/EmergencyResponse/default.htm.



Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

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Record of Changes

Change #	Page #	Section	Change Description	Change Made By	Date
1	72/299	D.2.1.4	Updated wording to reflect current operations.	Office of External Affairs	1/26/11
2	73/299	Figure D-4	Moved location to top of D.2.1.4.1 and updated graphic.	Office of External Affairs	1/26/11
3	75/299	D.2.1.4.5.	Added Technical Information Group and renumbered the other groups.	Office of External Affairs	1/26/11
4	81/299	D.2.3	Added Office of External Affairs Associate Commissioner to the list of members of the AEG.	Office of External Affairs	1/26/11
5	36/298	B.2.2.2	Edited Operating Status for Operational Levels 2 & 1 and added examples of Operational Level 2 incidents.	Office of Crisis Management/Office of Emergency Operations	3/2/11
6	37/298	B.2.2.2	Updated wording to reflect FDA EOC coordination role.	Office of Crisis Management/Office of Emergency Operations	3/11/11
7	37/298	B.2.2.2.1	Added sentence related to establishment or activation of Center/Office situation room or Field IMT in response to an incident.	Office of Crisis Management/Office of Emergency Operations	3/11/11
8	38/298	B.2.2.2.2	Changed the tense on the 2nd bullet and the punctuation on the 6th bullet.	Office of Crisis Management/Office of Emergency Operations	3/11/11

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U.S. Food and Drug Administration

FDA EMERGENCY OPERATIONS PLAN

August 2010

OFFICE OF CRISIS MANAGEMENT

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A INTRODUCTION

For purposes of this plan and its supporting annexes:

An ***incident*** is defined as: An occurrence or event, natural or manmade, that requires the attention of the U.S. Food and Drug Administration (FDA). At the incident level, FDA is aware of the circumstances, is monitoring and assessing the situation, and is determining whether it has regulatory authority over the incident. FDA may initiate response operations as described in this plan, as appropriate. Any incident may evolve into an emergency.

An ***emergency*** is defined as: An unforeseen occurrence or a combination of circumstances that poses a significant risk to public health and that involves the safety, efficacy, and security of human and veterinary medicines, biological products, medical devices, our Nation's food supply, cosmetics, products that emit radiation, and tobacco products that call for immediate actions by FDA staff.

Since each emergency situation is unpredictable and dynamic, and any incident has the potential to escalate into an emergency, this plan will use the terms incident and emergency interchangeably.

Emergencies and disasters, whether natural or manmade, accidental or intentional, have the potential to cause adverse health and safety effects for large segments of the human and animal populations. In order to mitigate the consequences of such incidents, FDA must possess the resources and capabilities necessary to prevent, prepare for, protect against, and rapidly and effectively respond to and recover from all hazards. A planned and coordinated approach to emergency operations by FDA organizational components in support of Federal, State, tribal, territorial, and local government, with assistance, when appropriate from foreign counterparts and international partners, can save lives and ensure that critical public health and medical needs are met.

The *FDA Emergency Operations Plan and Annexes (EOP)* is an all-discipline, all-hazards plan that establishes a single, comprehensive framework for the agency's management of incidents. It provides the measures, operating structures, roles and responsibilities, and mechanisms for direction and coordination of FDA resources before, during, and after disease outbreaks, terrorist attacks and other criminal acts, natural disasters, and any other incidents associated with FDA-regulated products that pose a risk to human or animal health.

The *FDA EOP* is compatible with the scalable, flexible, and adaptable Federal Government emergency coordinating structures of the *National Response Framework (NRF)*; is consistent with the concepts, principles, and terminology of the *National Incident Management System (NIMS);*[1] and it fulfills the requirements of the *Post-Katrina Emergency Management Reform Act of 2006 (PL 109-295)*; *Homeland Security Presidential Directive (HSPD) 8, National Preparedness*; the *Federal Emergency Management Agency (FEMA) Comprehensive Preparedness Guide 101: A Guide for All-Hazard Emergency Operations Planning*; and the U.S. Department of Homeland Security's (DHS') *Integrated Planning System (IPS) of 2009*. The *FDA EOP* is to be used to assist FDA in conducting response operations for all types of incidents.

A.1 MISSION

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary medicines, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation, and by regulating tobacco products. Additionally, FDA advances public health by helping to speed innovations that make foods safer and medical products more effective, safer, and affordable and by helping the public get the accurate scientific information they need to use medical products and foods to improve their health.

[1] For more information on the *NRF* and *NIMS*, refer to the "Authorities and References" section of this Plan.

FDA must continue to meet its mission during emergency and disaster situations, under adverse conditions, and/or from alternate locations as needed. In addition to day-to-day activities, FDA activities may expand to include performance of specific, incident-related functions, such as:

- Assisting and supporting the U.S. Department of Health and Human Services (HHS) in public health- and medical-related efforts to prevent, respond, mitigate, and recover from an incident
- Conducting inspections and investigations, and assessing damage to FDA-regulated industry in impacted areas
- Coordinating the tracing (forward and backward) of the distribution of any potentially contaminated FDA-regulated products and initiating seizures or recalls, as appropriate
- Collecting and analyzing product samples
- Providing technical assistance or subject matter expertise related to food and feed, human and animal drugs, medical devices, biologics, radiation-emitting devices, and tobacco products
- Conducting assessments of food retail establishments in impacted areas
- Conducting assessments of tobacco product retail establishments nationwide
- Conducting reviews of all adverse event reports related to FDA-regulated products
- Assisting with surveillance efforts to determine product integrity of foods, pharmaceuticals, medical supplies, equipment, and tobacco products
- Authorizing the use of an unapproved medical product (drug, biologic, and device) or the unapproved use of an approved medical product (i.e., Emergency Use Authorization [EUA])
- Issuing safety alerts, health information advisories, warnings, and advice and guidance to consumers and industry
- Requiring product manufacturers to make safety-related changes to prescribing information or labeling
- Detaining or removing contaminated or unfit merchandise from the market and/or restricting those marketing it

A.2 PURPOSE

The purpose of the *FDA EOP* is to provide for a coordinated and consistent agency approach to preparing for, preventing, protecting against, responding to, and recovering from incidents involving or impacting FDA-regulated products.

To accomplish this, the *FDA EOP*:

- Serves as the single, overarching FDA-wide operational plan to address the full spectrum of natural and technological hazards and terrorist threats and the "umbrella plan" into which all supporting agency emergency plans, procedural documents, and other guidance integrate
- Defines the FDA emergency operating structure and assigns essential tasks to all FDA organizational components involved in prevention, protection, response, and recovery efforts
- Provides mechanisms for vertical and horizontal command, control, coordination, and communications
- Integrates FDA emergency response operations into the Federal coordinating structure and ensures consistency with nationally recognized incident management policy and guidance

A.3 SCOPE AND APPLICABILITY

The *FDA EOP* covers the full range of complex and constantly changing requirements in anticipation of or in response to all "incidents" that FDA manages or participates in, including the following:

- Complaints, adverse events, recalls, or unintentional contamination involving FDA-regulated products that present a threat of serious adverse health consequences or death to humans or animals
- Natural disasters (e.g., hurricanes, tornadoes, severe storms, floods, fires, earthquakes, volcanic eruptions, tsunamis, and landslides)
- Naturally occurring disease and foodborne illness outbreaks, epidemics, and pandemics
- Manmade accidents, such as hazardous materials releases or spills; air, land, or water contamination; and utility outages
- Terrorist or criminal acts, including the threat or intentional use of chemical, biological, radiological, nuclear, or high-yield explosive (CBRNE) weapons against human or animal populations or FDA-regulated products

The *FDA EOP* establishes intra- and interagency mechanisms for FDA involvement in domestic and international incident management operations. These mechanisms include coordinating structures and processes for incidents requiring agency support for consumer protection and to other Federal Agencies; States and territories, tribal nations, and local governments; foreign governments; and international organizations. It is applicable to all FDA headquarters and field organizational components that may be required to provide assistance or conduct emergency operations in the context of actual or potential incidents. In these cases, FDA may use the Incident Command System (ICS) to facilitate command and coordination.

A.4 PLANNING ASSUMPTIONS

The *FDA EOP* is based on the following planning assumptions:

- Incidents, including large-scale emergencies and major disasters, will require full coordination of FDA operations and resources, and may:
  - Occur at any time with little or no warning in the context of a general or specific threat or hazard
  - Involve one or more FDA organizational component(s), and span a single or multiple region(s)
  - Require significant information sharing, resource coordination, and/or assistance across FDA organizational components; Federal, State, territorial, tribal, and local agencies, the private sector, and foreign governments
  - Result in numerous casualties, fatalities, displaced people, property loss, significant damage to the environment, and disruption of economy and normal life support systems, essential public services, and critical infrastructures
  - Require extremely short-notice FDA response times, and prolonged, sustained recovery operations and support activities
- All FDA emergency-related activities will be initiated and conducted in accordance with the principles, concepts, and terminology established within the NIMS.
- Regardless of incident characteristics or requirements, FDA continues to be responsible for consumer products under its jurisdiction while coordinating response operations with other interagency public health and medical partners.

- An emergency or disaster that overwhelms the capabilities of State and local governments may require FDA and/or other Federal Agencies to assist in meeting public health and safety needs. FDA assets will supplement the response, as directed or requested, when an incident affects an FDA-regulated product, or requires the provision of subject matter expertise or use of specific medical countermeasures. As such, the agency will participate in incident command or unified command systems to manage multi-agency emergencies.
- Contamination of the Nation's human and animal food or medical products supply may initially be indistinguishable from a naturally occurring event. Moreover, depending upon the particular agent and associated signs or symptoms, several days or weeks could pass before authorities suspect terrorism may be the cause.
- Response to a chemical, biological, radiological, or nuclear (CBRN) incident suspected of being deliberate in origin or a terrorist act requires consideration of special law enforcement and homeland security requirements as well as international legal obligations and requirements.
- The combined expertise and capabilities of government at all levels, industry, and nongovernmental organizations will be required to respond to incidents of catastrophic proportions. During such periods, FDA will provide emergency support as directed by the Commissioner, the Secretary of the HHS, and/or the Secretary of Homeland Security, through the coordinating mechanisms established within the *NRF*.
- Supporting documentation (e.g., standard operating procedures [SOPs], operations and procedural manuals, and field guidance) has been developed and made available to designated FDA emergency staffs in order to provide detailed instructions during performance of specific functions or incident-related actions.
- As part of its Emergency Support Function (ESF) #8 functions, FDA can provide State, tribal, territorial, and local agencies with activities related to regulated product support at the national level. For example, FDA can provide assistance to State and local agencies in ensuring the safety of food products at retail food establishments and drug and medical products in pharmacies.
- To ensure the capability to implement the *FDA EOP*, each FDA headquarters and field organizational component tasked with emergency roles and responsibilities, as identified in this basic plan or any of its annexes, may develop and maintain individual emergency plans and procedures that identify the critical and time-sensitive missions, functions, assignments, and processes to be performed during all hazards. These documents shall be consistent with this Plan and available to all agency personnel.

A.5 ACTIVATION

While many parts of this plan may be used routinely to manage FDA's emergency operations, the full plan will be activated when certain events occur such as, but are not limited to the following:[2]

- A determination has been made by the Commissioner of Food and Drugs (the Commissioner) or other FDA senior official(s) as delegated by the Commissioner that agency emergency actions are warranted to prevent, prepare for, protect against, respond to, or recover from a threat or hazard.
- The Secretary of the HHS (the Secretary) has directed FDA to provide emergency support to maintain the safety, efficacy, and security of drugs, biologics, medical devices, radiation-emitting devices, the food supply, or cosmetics.

[2] Regional Food and Drug Directors, District Directors, and Center/Office Directors may activate their individual organizational component's EOP without activation of the FDA EOP.

- The Secretary of the HHS (the Secretary) has directed FDA to provide emergency support to protect the public health in the event of tobacco product adulteration.
- The Secretary of Homeland Security has raised the Homeland Security Advisory System level across all national critical infrastructure sectors or specifically for the food and agriculture and/or healthcare and public health sectors.
- The President has declared an emergency or major disaster exists within an affected State or States under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, PL 100-707, as amended, and *NRF* coordinating mechanisms, in whole or in part, have been activated.
- The President has declared a national emergency exists under the National Emergencies Act, 50 U.S.C. 1601-1651, in the event that the Nation is threatened by crisis, exigency, or emergency circumstances (other than natural disasters, war, or near-war situations).
- The Secretary has determined that a disease or disorder presents a public health risk, or a public health emergency—including significant outbreaks of infectious diseases or bioterrorist attacks—otherwise exists under the Public Health Service Act.

A.5.1 Activation of EOP Annexes

A decision on whether an EOP annex is to be implemented in response to an incident is made by the Office of Crisis Management (OCM) Director in consultation with the Counselor to the Commissioner and senior officials of the Center(s) involved or in a meeting requested by the Commissioner, a Center Director, the Associate Commissioner for Regulatory Affairs (ACRA), the Director of OCM, or some other top official specifically to discuss a particular incident or problem. If an annex(es) is to be activated, the OCM Director will notify the involved FDA parties (through electronic mail, if available).

A.6 SUPERSEDENCE

The *FDA EOP* supersedes the following emergency plans:

- *FDA Emergency Response Plan* (February 2005)
- *FDA Chemical and Biological Emergency Response Plan* (April 2004)
- *FDA Bovine Spongiform Encephalopathy Emergency Response Plan* (April 2004)

The *FDA EOP* Annexes supersede the following emergency plans:

- *FDA Radiological Emergency Response Plan* (April 2004)
- *FDA Pandemic Influenza Emergency Response Plan* (December 5, 2007)
- *Crisis Management Plan* (November 5, 2004)

B CONCEPT OF OPERATIONS

The scope of FDA emergency operations is as wide as the array of products the agency regulates. FDA actions impact the Nation's quality of life on a daily basis through its regulation of food, drugs, medical devices, radiation emitting products, biologics, veterinary drugs, and tobacco products. For this reason, FDA's successful and efficient handling of emergencies and disasters is especially important in fulfilling its mission to maintain not only the public's health, but also its trust and confidence as well. The following concept of operations (CONOPS) describes the principal authorities' governing agency emergency functions and the phases within which FDA conducts incident-related operations.[3]

B.1 EMERGENCY AUTHORITIES

Statutory authorities relevant to FDA emergency preparedness and response are described below under the general categories of safety and medical countermeasures. In addition certain FDA regulations in Title 21 of the Code of Federal Regulations may apply in an emergency situation.

1) Safety of FDA-regulated products:

- Under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., as amended, FDA regulates the safety of, among other things, food, including dietary supplements, infant formula, and animal feed; human and animal drugs; medical devices; electronic products emitting radiation; and tobacco products.
- Under the Public Health Service Act (PHSA), 42 U.S.C. 262, FDA will only approve a biologics license application upon a demonstration that the biological product is safe, pure, and potent. In addition, under the PHSA, 42 U.S.C. 264, FDA may issue and enforce regulations necessary to prevent the spread of communicable disease.

2) Medical countermeasures:

- Under the FFDCA, FDA generally approves drugs and devices that have been shown to be safe and effective. Under the PHSA, FDA licenses biological products based upon a determination that they are safe, pure, and potent.
- Section 561 of the FFDCA: Expanded Access to Unapproved Therapies and Diagnostics allows FDA to permit the treatment of a patient with an investigational medical countermeasure under certain circumstances, even though the safety and effectiveness of the drug have not been fully established.
- Section 564 of the FFDCA, as amended by the Project BioShield Act of 2004, allows FDA to authorize the emergency use of drug(s), device(s), or biological product(s) during a declared emergency under certain circumstances.
- The Public Readiness and Emergency Preparedness Act (PREP Act) of 2005, "PREP Act," (42 U.S.C. 247d-6d), concerns, among other things, liability protection for the use of designated medical countermeasures.

[3] For detailed information on the actions performed during specific incidents, refer to the FDA EOP, Incident Annexes.

B.2 EMERGENCY OPERATIONS PHASES

The following three phases comprise the entire spectrum of FDA emergency operations: ***Prevention and Protection, Response, and Recovery.*** Although emergency operations may involve each of these phases over the course of any multitude of incidents, the nature and severity of an event and the FDA organizational component(s) responding will determine the specific order, actions, and responsible parties required for each.[4]

B.2.1 Prevention and Protection

FDA participates in a number of planning subcommittees under the Federal Radiological Preparedness Coordinating Committee (FRPCC), which coordinates all Federal responsibilities for assisting State and local governments in their emergency planning and preparedness for peacetime radiological emergencies, developing protective action recommendations for human and animal feed, providing guidance on radioprotective substances and prophylactic drugs to reduce radiation dose, and providing medical and mental health support through ESF #8. FEMA is the chair of the FRPCC.

The FRPCC performs the following functions:

- Assisting the Director of FEMA in providing policy direction with respect to Federal assistance to State and local governments in their radiological emergency planning and preparedness activities
- Establishing subcommittees to aid in carrying out its functions; current subcommittees include Training, Offsite Instrumentation, Transportation, and Federal Response.
- Assisting FEMA in resolving issues relating to granting final approval (under 44 Code of Federal Regulations [CFR] 350) of a State radiological emergency preparedness plan
- Coordinating research and study efforts of its member agencies relative to State and local government radiological emergency preparedness to ensure minimum duplication and maximum benefits to State and local governments

The FRPCC works directly with HHS and FDA, seeking guidance for State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g., potassium iodide, Radiogardase) to reduce the radiation dose to specific organs, including dosage and projected radiation exposures.

The "prevention and protection" phase of FDA emergency operations includes those actions taken to avoid an incident or intervene to stop an incident from occurring, or to mitigate its effects on FDA-regulated products and the community, during periods of increased risk or heightened threat conditions.[5] It involves immediate steps to protect consumers; ensure the safety and defense of food and animal feed, medical products (e.g., blood donations and diagnostic devices), cosmetics, field operations, and toxicological research; and apply intelligence and other information to a range of directed countermeasures. Upon preliminary determination of an incident, FDA conducts the following preventive/protective measures:

- Increasing ***surveillance and detection*** of adverse events, disease outbreaks, natural disasters, and other emerging public health concerns
- Heightening ***consumer product protection*** measures against the adverse effects of naturally occurring and man-made hazards

[4] Refer to Section C, "Organization and Assignment of Responsibilities," of this Plan for an overview of FDA organizational component roles and responsibilities during all hazards. Refer to the FDA EOP, Incident Annexes for incident-specific Center/Office actions.

[5] Examples of high-risk situations include: designated National Special Security Events (NSSEs), developing public health emergencies and natural disasters, and elevated Homeland Security Advisory System condition levels.

- Ensuring the availability of ***medical countermeasures*** that prevent, diagnose, or treat the effects of disease outbreaks; biological, chemical, or radiological agents; and natural disasters
- Increasing ***surveillance of FDA regulated products*** used to prevent or mitigate adverse health effects related to the actual or potential incident

B.2.1.1 Surveillance and Detection

Within the context of this Plan, increased risk-based "surveillance and detection" is defined as an increase in the frequency, quantity, or detail of the ongoing, systematic collection, analysis, and interpretation of public health data essential to the planning, execution, and evaluation of FDA emergency operations, closely integrated with the timely dissemination of these data to those responsible for prevention and control. FDA uses accumulated data from a variety of sources (i.e., international, Federal, State, territorial, tribal, and local public health agencies; consumer complaints; regulatory inspections, investigations, and sampling; and laboratory testing) for passive and active surveillance of regulated products and other public health concerns during day-to-day situations and for targeted preventive actions. The focus of these systems is to detect a "signal" to allow for additional information gathering and analysis or to track and trace a suspected or confirmed event within the agency's jurisdiction. They support FDA's primary mission, including identifying and reviewing adverse events and tracking and tracing product problems, and are used to facilitate counterterrorism and product safety and security activities, as appropriate.

The Emergency Operations Center (EOC), staffed by OCM's Office of Emergency Operations (OEO), is in a constant state of readiness during routine agency operations, maintaining 24 hours-a-day, 7 days-a-week monitoring capability for surveillance and detection. OCM/OEO staff members assist with the detection of signals either as the direct point of contact (POC) for outside stakeholders or in support of the Centers and Office of Regulatory Affairs (ORA) and participate in meetings for identifying emerging threats. After hours, FDA's Call Center serves as an additional resource to the EOC, monitoring complaints and reports of problem products and triaging phone calls back to the EOC to be assessed by OCM/OEO staff to determine potential public health threats.

In addition, several databases and electronic information exchanges enable responsible FDA organizational components to collect and report out-of-the-ordinary information, monitor potential and ongoing situations, and determine whether agency emergency response activities are warranted (**Table B-1**).

Table B-1. FDA Surveillance and Detection Systems

System	Description	Sponsoring Agency	FDA POC
Adverse Event Reporting System (AERS)	The AERS is a computerized information database designed to support FDA's post-marketing safety surveillance program for all approved drug and therapeutic biological products. FDA uses AERS to monitor for new adverse events and medication errors that might occur with these marketed products.	FDA	Center for Drug Evaluation and Research (CDER)
Biological Product Deviation Reporting (BDPR) System	The BDPR System reports errors and accidents in manufacturing of products, including testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product or a blood or a blood component, in which the safety, purity, or potency of a distributed product may be affected. Also, it includes deviations in manufacturing of human cells, tissues, and cellular and tissue-based products that relate to the prevention of communicable disease transmission, contamination, or other unexpected events.	FDA	Center for Biologics Evaluation and Research (CBER)
BioWatch	BioWatch is a detection system for the release of biological agents in the air through a comprehensive protocol of monitoring and laboratory analysis	Centers for Disease Control and Prevention (CDC)	OCM

System	Description	Sponsoring Agency	FDA POC
Center for Devices and Radiological Health (CDRH) Product Availability (Shortages) Database	The Shortages Database identifies and monitor s supplies of certain devices that are or have the potential to be in demand.	FDA	CDRH
Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS)	The CAERS receives and monitors all post-marketing surveillance adverse events reports that directly affect CFSAN. These adverse event reports include foods, dietary supplements, cosmetic products, and food and color additives.	FDA	CFSAN
Counterfeit Alert Network (CAN)	The CAN is a coalition of health professional and consumer groups to disseminate educational guidance and alert messages about counterfeit drug incidents and measures to take to prevent exposure.	FDA	Office of Regulatory Affairs (ORA)/ Office of Criminal Investigations (OCI)
Electronic Laboratory Exchange Network (eLEXNET)	The eLEXNET is an integrated, Web-based information network that allows health officials at multiple government agencies engaged in food safety activities to coordinate and share laboratory analysis findings. It provides the necessary infrastructure for an early warning system that identifies potentially hazardous foods and enables health officials to assess risks and analyze trends. eLEXNET is the data capture and communication system for the Food Emergency Response Network (FERN) and is supported by the U.S. Department of Agriculture (USDA) and the U.S. Department of Defense (DoD).	FDA	ORA/Office of Regional Operations (ORO)/ Division of Field Science (DFS)
Emergency Operations Network Incident Management System (EON IMS)[6]	The EON IMS serves as the central hub for exchanging and relaying all incident-related information within the agency. Managed by OCM, this system integrates multiple data streams from other electronic systems, such as the FERN, eLEXNET, Epi-X, and from FDA laboratories and investigators and external agencies, into a coherent fashion during critical decision points. The EON IMS creates a safety net that significantly reduces the probability that incidents will prevent FDA from accomplishing its objectives and minimizes the impact of these events on normal operations.	FDA	OCM
Epidemic Information Exchange (Epi-X)	The Epi-X is a secure, Web-based communications network that provides public health officials with up-to-the-minute information, reports, alerts, and discussions about terrorist events, toxic exposures, disease outbreaks, and other public health events. It provides a flexible search interface for researching outbreaks and unusual health events and for tracking information for outbreak investigations and response.	CDC	OCM
Foodborne and Diarrheal Diseases Outbreak Summaries	FDA receives the weekly summaries on outbreaks from the CDC Foodborne and Diarrheal Diseases Branch to document ongoing investigations, current outbreaks, State(s) where the outbreak is occurring, and the serotype of the causal microorganism.	CDC	CFSAN
Foodborne Diseases Active Surveillance Network (FoodNet)	The FoodNet is a collaborative project of the CDC, 10 State Emerging Infections Program sites, the Food Safety and Inspection Service (FSIS) of the USDA, and FDA. It consists of active surveillance for foodborne diseases and related epidemiologic studies designed to help public health officials better understand the epidemiology of foodborne diseases in the United States.	CDC, USDA, FDA, State health departments	CFSAN

[6] For more information on EON IMS, refer to Section E "Communications" of this plan.

System	Description	Sponsoring Agency	FDA POC
FERN	FERN is a network of Federal and State laboratories that analyze food samples in the event of a biological, chemical, nuclear, or radiological incident or large-scale contamination. FERN Federal partners include FDA, USDA, CDC, DHS/U.S. Customs and Border Protection (CBP), and the U.S. Environmental Protection Agency (EPA).	FDA and USDA	ORA
Health Alert Network (HAN)	The HAN provides rapid and timely access to emergent health information and evidence-based practices and procedures for effective public health preparedness, response, and service on a 24 hours-a-day, 7 days-a-week basis. It includes all 50 States, 3 large city health departments, 3 county health departments, 8 territories, the District of Columbia, and multiple health organizations and major hospital networks.	CDC	OCM
Homeland Security Information Network (HSIN)	HSIN is a comprehensive, nationally secure, and trusted Web-based platform able to facilitate Sensitive But Unclassified information sharing and collaboration between Federal, State, local, tribal, private sector, and international partners. It interfaces with existing information sharing networks to support the diverse Communities of Interest engaged in preventing, protecting from, responding to, and recovering from all threats, hazards, and incidents. HSIN provides a collaborative environment that interoperates with mission area systems developed and managed by Federal, State, and local partners.	Department of Homeland Security (DHS)	Centers, ORA, OCM
Integrated Consortium of Laboratory Networks (ICLN)	The ICLN was established to coordinate the nation's laboratory networks to improve the response to acts of terrorism and other events requiring an integrated laboratory response. One outcome of the ICLN is the creation of an Integrated Response Architecture that provides, among other things, event notifications and updates, preparedness alerts, and situational reports through a secure web portal.	Department of Homeland Security (DHS)	ORA
Laboratory Response Network (LRN)	The LRN is a network of over 150 Federal, State and local, military, food testing, environmental, veterinary, and international laboratories that are fully equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies.	CDC	ORA and CFSAN
Manufacturer and User Facility Device Experience System (MAUDE)	MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports, user facility reports, distributor reports, and manufacturer reports. The online search allows you to search CDRH database information on medical devices that may have malfunctioned or caused a death or serious injury.	FDA	CDRH
MedWatch	MedWatch, the FDA Safety Information and Adverse Event Reporting Program, provides important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products. It allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices that they prescribe, dispense, or use.	FDA	CDER
Mobile Laboratories (ML)	FDA operates Mobile Labs (MLs): • A Microbiology Lab to detect foodborne microbiological pathogens in food and drugs • A Chemistry ML to detect pesticides, poisons, toxins, or other chemicals that could be used to deliberately contaminate food or drugs The ML allows FDA to transport and establish laboratory capabilities virtually anywhere in the continental U.S. and is capable of functioning as a self-contained regulatory laboratory. The Microbiology ML tests products using enzyme-linked immunosorbent assay test kits and instrumentation and molecular Real-Time Polymerase Chain Reaction technologies. The Chemistry ML contains sophisticated instruments to	FDA	ORA

System	Description	Sponsoring Agency	FDA POC
	detect sub ppm residues of pesticides or poisons in food. The ML has also received samples from State and local health departments as well as from other Federal and military branches of the Government. While the ML is a screening platform, all of the methods have been validated for the specific products and analytes/organisms tested. A fixed-site FDA laboratory supports further testing and confirmation of mobile lab results.		
National Biosurveillance Integration System (NBIS)	The NBIS integrates all of the U.S. biosurveillance programs into a single system for providing a comprehensive integrated biosurveillance and situational awareness for detecting agents and disease trends.	DHS	OCM/OEO
National Consumer Complaint System	FDA uses the National Consumer Complaint System to collect complaints from consumers about FDA-regulated products. Consumer Complaint Coordinators at FDA headquarters and Regional Offices throughout the United States review complaints to determine trends and potential emerging public health issues.	FDA	OCM/OEO
New Drug Application (NDA) Field Alert Program	The NDA Field Alert Program is used to quickly identify drug products that pose potential safety threats. All drug manufacturers with approved NDAs and Abbreviated New Drug Applications (ANDAs) are required to submit Field Alert Reports to FDA if they find any significant problems with an approved drug.	FDA	CDER, ORA
The Pet Event Tracking Network (PETNet)	PetNet is a collaborative project between FDA and Federal and State government partners to provide a secure reporting/notification system, accessible by State and Federal government officials, which will allow for the exchange of information early in a disease outbreak that is associated with the consumption of adulterated pet food.	FDA	CVM
PulseNet	PulseNet is a national network of laboratories that performs DNA "fingerprinting" on foodborne bacteria. The network permits rapid comparison of patterns through an electronic database, helping to better detect the source of bacteria in foods. PulseNet helps public health authorities recognize when cases of foodborne illness are occurring at the same time in geographically separate locales.	CDC	CFSAN
Recall Enterprise System (RES)	RES is used by Center and District Office recall personnel to submit, update, classify, publicize, and terminate recalls. This online, searchable database allows users to enter real-time data on a recall event as it becomes available and track information and generate and disseminate reports of recall activities.	FDA	ORA
Safety Reporting Portal (also Reportable Food Registry) [RFR]	RFR is is an electronic portal for an owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the U.S. to file a report about a product that is suspected will cause serious adverse health consequences of death to humans or animals. Initial RFR reports are sent to EON IMS.	FDA	OCM/OEO, CFSAN
Vaccine Adverse Event Reporting System (VAERS)	The VAERS is a national vaccine safety surveillance program to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events (possible side effects) that occur after the administration of U.S. licensed vaccines.	FDA, CDC	CBER
Veterinary Adverse Drug Experiences (ADE) Reporting System	The ADE Reporting System provides early warning to FDA for adverse effects not detected during pre-market testing of FDA-approved animal drugs. Reports of adverse clinical events from veterinarians and animal owners are entered into a computerized database for use by scientists to make decisions about product safety, which may include changes to the label or other regulatory action.	FDA	Center for Veterinary Medicine (CVM)

B.2.1.2 Consumer Product Protection

Prior to confirmation of an incident, FDA may employ a number of activities designed to deter intentional and unintentional acts against FDA-regulated products and protect consumers from potential public health hazards.[7] Through heightened and targeted preventive measures at various points in the processing and distribution chains, and by exercising the systems and networks to be used during emergency response operations, FDA can protect the safety and security of regulated products and protect consumers from harm. Activities in support of this effort, conducted in cooperation and collaboration with applicable FDA organizational components; Federal, State, territorial, tribal, and local partners; industry; academia; foreign governments; and, international organizations include, but are not limited to, the following:

- Implementing risk communications with government and industry partners
- Prioritizing examination of food commodities based on potential for contamination (as determined by vulnerability assessments previously undertaken by FDA)
- Identifying entities handling specific FDA-regulated consumer products
- Conducting targeted inspections and investigations and collecting samples[8]
- Readying laboratory response and other scientific capabilities to analyze/test for chemical and microbiological agents
- Tracing and intercepting specific imported and domestic products
- Requesting the recall of drugs, biologics, medical devices, radiation-emitting devices, the food supply, or cosmetics that predictably could cause serious health problems or death ("Class I") or such products that might cause a temporary health problem or pose only a slight threat of a serious nature ("Class II")[9]
- Requesting the recall of tobacco products containing a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death
- Providing additional guidance to food producers, processors, transporters, importers, retailers, food service establishments, and cosmetic processors on security measures to take to minimize the risk of tampering or other intentional contamination/adulteration and protect against the damaging effects of diseases and natural disasters
- Working, as permitted, with Federal, State, territorial, tribal, and local government agencies, and international partners
- Issuing warnings, alerts, advisories, and other advice to consumers, industry, foreign counterparts, and other international partners regarding food, drug, medical device, biological product, and tobacco product safety and animal health and soliciting feedback

The FDA system for responding to the increased risk of an emergency or disaster impacting FDA-regulated products provides a significant increase in coverage, awareness, and preparedness through targeted preventive measures implemented by both headquarters and field offices and in coordination with other intergovernmental public health and medical partners. Collectively, these additional consumer

[7] Incident confirmation includes conclusive laboratory analysis, field investigations, epidemiological data, or reliable information from other government agencies that triggers emergency response operations.

[8] Detailed Agency investigation/inspection procedures can be found at www.fda.gov/ora/inspect_ref. Compliance references are located at www.fda.gov/ora/compliance_ref.

[9] Recalls of products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws ("Class III"), will not by themselves activate this Plan.

protection activities provide for more protected supply and distribution chains and a better prepared national network capable of responding to an identified threat or hazard.[10]

B.2.1.3 Medical Countermeasures

FDA plays a vital and multifaceted role in securing the homeland through its broad regulatory oversight, monitoring infrastructure and responding to terrorist attacks and naturally occurring emerging threats with timely and appropriate countermeasures. FDA fosters the development of safe and effective medical countermeasures to mitigate the effects of such threats by actively engaging industry, academia, and government partners. While all the FDA Centers and Offices have a role in the agency's counterterrorism mission, the three product centers (CBER, CDER, and CDRH), as well as ORA and various organizations within the Office of the Commissioner, play critical roles in ensuring the safety, effectiveness, quality, and availability of medical countermeasures.

B.2.1.4 Increased Surveillance of FDA-Regulated Medical Products

Depending on the nature of an incident, FDA may increase its surveillance of FDA-regulated medical products used to prevent or mitigate adverse health effects related to the actual or potential incident. Such increased surveillance could be a result of conditions such as the use of a product by a larger or different population, the use of products for other than their labeled indication, or concerns about the potential development of resistance to a product such as antivirals or antibiotics.

B.2.2 Response

The "response" phase of FDA emergency operations includes those immediate and sustained actions to ensure the safety, efficacy, and availability of FDA-regulated products and protect the public's health throughout the duration of an incident. This phase generally involves the following four elements (**Figure B-1**):

1) **Gain and Maintain Situational Awareness**
   - **Alert and Notification.** Receiving information or intelligence confirming the development or occurrence of an incident and issuing notifications to agency stakeholders and partners
   - **Assessment and Monitoring.** Performing initial and ongoing situation analysis, monitoring, and reporting
2) **Activation and Deployment of Resources and Capabilities.** Directing and mobilizing FDA headquarters and field resources and capabilities, including EOC operational level changes and establishment of the ICS in the field and/or headquarters
3) **Coordination of Response Actions.** Conducting rapid and synchronized emergency response activities at headquarters and field locations
4) **Demobilization.** Standing down FDA emergency response resources (personnel, facilities, equipment, and other materials support) and returning them to their original location and status

[10] For more information on FDA protection measures as part of the Nation's larger critical infrastructure protection efforts, refer to the "Agriculture and Food Critical Infrastructure and Key Resources Sector-Specific Plan" to the *National Infrastructure Protection Plan*, located at: www.dhs.gov/xlibrary/assets/nipp-ssp-ag-food.pdf.

Figure B-1. FDA Emergency Response Elements

B.2.2.1 Gain and Maintain Situational Awareness

B.2.2.1.1 Alert and Notification

FDA may be alerted to a threat, hazard, or other significant event through a variety of means, including the surveillance systems discussed in Table B-1 and/or directly from external Federal Agencies (e.g., the HHS Secretary's Operations Center (SOC), CDC, USDA, DHS, and/or the Federal Bureau of Investigation (FBI)); international, State, territorial, tribal, and local public health agencies; industry; consumers; news media; and internal FDA organizational components. Any or all agency organizational components may receive word of a problem depending on the event's scope and magnitude. Recipients of such information must handle it properly to ensure FDA is able to track and evaluate the situation. Failure to handle a report in a timely fashion may delay emergency response and potentially exacerbate the incident.

The EOC serves as the agency's focal point for monitoring and coordinating agency response activities related to developing and ongoing emergency situations, 24 hours a day, 7 days a week. The EOC is staffed by OCM/OEO staff members who work with the Centers and ORA to review information that may indicate potential or actual incidents, as well as quickly detect similarities in seemingly unrelated reports, and ensure that incident reports are treated in a consistent manner across FDA. The EOC also provides or acquires from a variety of sources the resources and capabilities necessary for FDA headquarters-level and interagency coordination that may be necessary when emergencies or disasters cross geographic and/or jurisdictional boundaries.

All reports of large-scale natural and manmade emergencies, and significant alleged or actual adverse effects associated with FDA-regulated products, require prompt reporting to the EOC staff of OCM/OEO. Upon receipt of an alert or warning, the EOC OCM/OEO staff will notify internal and external partners via a pre-developed, prioritized notification list specific to each particular emergency situation.

Certain types of incidents typically, but not necessarily always, should be reported to EOC staff of OCM/OEO as potential emergencies. These include incidents that:

- Involve life-threatening adverse events or deaths possibly related to use of drugs, biologics, medical devices, radiation-emitting devices, the food supply, or cosmetics
- Involve life-threatening adverse events or deaths possibly related to use of an adulterated tobacco product containing manufacturing or other defects not ordinarily contained in tobacco products on the market
- Involve a contaminant or pathogen associated with FDA-regulated products
- Involve product distribution and/or injury, illness, or death across multiple States or geographic regions

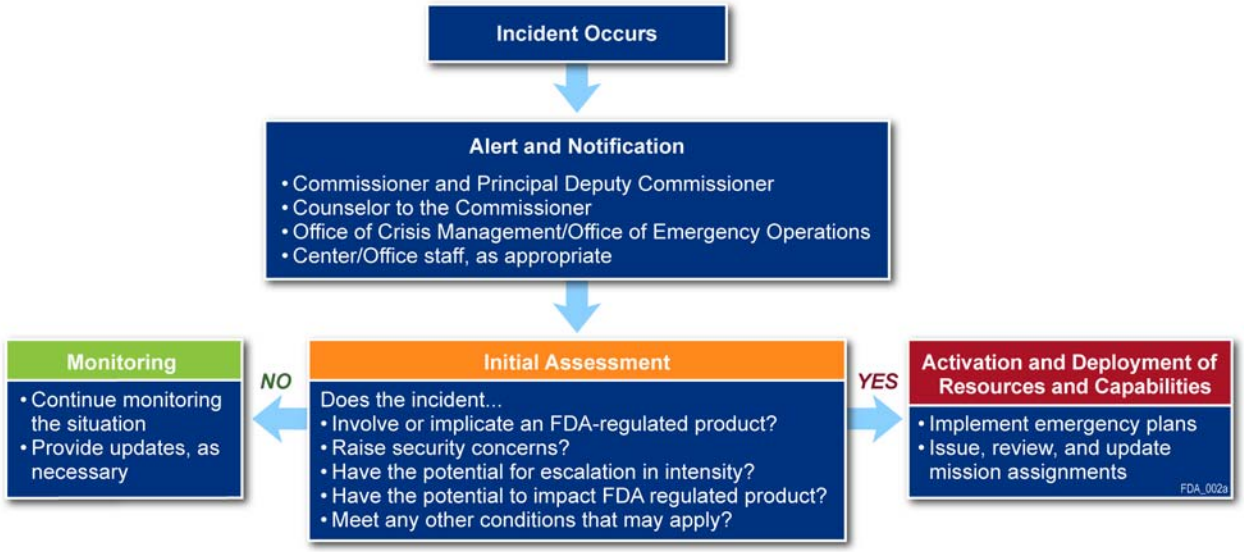
- Involve a considerable number of producers or manufacturers, or a firm of considerable size and extensive product distribution
- Arise in circumstances in which it is difficult to quickly identify the source of the problem

B.2.2.1.2 Assessment and Monitoring

Once FDA officials receive word of an impending, ongoing, or resurgence of an emergency situation, they must gather enough information to determine the validity and extent of the threat or hazard and the agency's roles and responsibilities within the situation. FDA headquarters and field organizational components work collaboratively with one another and with other government agencies and industry to rapidly evaluate the situation and make these determinations.

OCM/OEO is responsible for coordinating with applicable FDA headquarters and field units and external partners to formulate an initial incident assessment.[11] Results of this assessment may include a variety of situation and status reports, healthcare records, research and analyses, maps, and surveillance information. This critical information is passed through established reporting channels to allow agency decisionmakers to develop situational awareness and establish a "common operating picture." Based on initial analysis of the threat or hazard, FDA will take steps to monitor the situation, identify and prioritize requirements, and/or activate available resources and capabilities. **Figure B-2** depicts the methodology agency officials use to assess an incident and determine whether additional response activities are warranted.

Figure B-2. FDA Emergency Response Decision Tree



Determining Regulatory Authority. It is important to note that a reported incident may or may not be subject to FDA authority. Therefore, one of the first discussions to take place will include a determination of whether FDA has regulatory authority. Some of the criteria potentially used in the assessment include:

- Whether an FDA-regulated product is implicated as the cause of the incident
- Whether it is confirmed that FDA-regulated products have been or may be affected
- Whether medical countermeasures are expected to be used in response
- Whether interstate commerce of FDA-regulated products, as defined under the various statutes FDA enforces, is involved

[11] At the time of the initial notification, an FDA organizational component or another government agency may already have completed a preliminary assessment of the emergency.

- Whether Federal, State, territorial, tribal, or local agencies and/or foreign governments have formally requested FDA assistance

Once FDA determines that it has regulatory authority, it may manage the incident internally or function in a supporting role.[12] Although the agency may make an initial determination regarding authority and jurisdiction, it may continue to review and reconsider regulatory authority throughout an incident as it evolves, expands, or contracts.

B.2.2.2 Activation and Deployment of Resources and Capabilities

As the agency's central coordination point for emergencies, the FDA EOC operating status generally falls into one of three levels depending on the severity or potential consequences of an incident or perceived threat (**Table B-2**). Confirmation of an incident with potential or confirmed public health impact may require activating a change in the EOC operational level from a readiness state of Operational Level 3 to Operational Level 2 or 1, depending on the scope of the incident. Center and Regional/District Office Situation Rooms, Command Centers, and Emergency Response Coordination Centers may follow the EOC operating levels or activate according to their individual emergency plans and procedures, as appropriate.

Table B-2. FDA Incident Levels and Emergency Operations Center Operation Levels

Operational Level	Operating Status	Criteria	Examples
3	• Routine Awareness and Response Operations • Normal staffing • Regular work hours • Readiness State	Incident(s) involving FDA-regulated product(s) that, from a response and coordination viewpoint, are limited in complexity and scope such that the resources needed for response and/or coordination do not significantly impact normal operations for response/coordination. OCM and OCM/OEO coordinate with ORA and Center Emergency Coordinators. Generally, FDA's response and coordination actions are sufficient to respond effectively to the incident with no or limited internal and/or external coordination necessary.	• Single person illness, injury, or consumer complaint with no or very few similar complaints in FDA systems • Foodborne illness reports associated or implicated with FDA-regulated products • Planning for National Special Security Events
2	• Increased Response Operations • Augmentation of EOC staffing may be necessary • Extended work hours as needed • Center Situation Room activation may be necessary • Establishment of an Incident Management Group (IMG) may be necessary (EOC serves as resource to IMG)	Incident(s) involving FDA-regulated products(s) that, from a response and coordination viewpoint, are of moderate complexity and scope such that resources needed for an effective response and/or coordination are beyond those ordinarily provided within the average workday and/or beyond average staffing levels. The incident may require periodic or ongoing coordination with other external entities, in which case FDA may or may not be the "lead" responding agency for the incident. If additional staff and resources are not provided, response and coordination efforts would be somewhat adversely impacted, most likely in terms of response timeliness.	• CDC report of microbial contamination in pharmacy-compounded drugs • Ongoing foodborne illness outbreak involving one or more States or regions – *S.* Montevideo outbreak 2009-10 and *S.* Enteriditis outbreak 2010 • H1N1 response 2009 • National Special

[12] Refer to the FDA EOP Appendix A and B of this Plan for detailed information on how the FDA supports other Federal Agencies under the *NRF*.

Operational Level	Operating Status	Criteria	Examples
			Security Events • National-level or full-scale agency exercises
1	• Escalated Response Operations • Additional personnel (support and subject matter experts [SMEs]) • Extended work hours likely, 24-hour operations possible (8- to 12-hour shifts) • Possible engagement of Crisis Management Team as appropriate • Center Situation Room provides EOC daily situation reports (SITREPs)	Incident(s) involving FDA-regulated product(s) that, from a response and coordination viewpoint, are of substantial complexity and scope such that the resources needed for an effective response and/or coordination exceed the Level 2 capability. Staffing levels, hours, and operations will likely be substantial to mount an effective response (prevent or mitigate public health impact). Incidents may require significant coordination with external entities to optimize response. FDA may be the "lead" responding agency and/or may have a substantial support role to provide to another 'lead' agency. Both field and headquarters response operations and/or coordination activities may require the establishment of formal organizational restructuring, e.g., ICS, to respond optimally.	• Hurricane Katrina • Ongoing foodborne illness outbreak or food contamination involving multiple States and increased complexity in product tracing, involving multiple agencies • Unknown contaminated drug product with serious adverse event • Pet food contaminated human food or animal feed • Terrorist event

Depending on the anticipated or actual size and complexity of an incident, activation of FDA emergency management resources may be required. The EOC staffed by OCM and OCM/OEO (typically Operational Level 3), coordinate with ORA's headquarters and field components and the appropriate Center(s) in the review and analysis of information about threats and hazards, and assists in the early recognition of emergencies, outbreaks, natural disasters, and terrorism or other criminal acts which may affect an FDA-regulated industry or product. This agency-wide coordination involves information collection and distribution, triaging complaints and alerts, issuing mission assignments to organizational components, identifying and tracking needed resources, and communicating with external partners as they request technical and material support. Additionally, the FDA EOC serves as the central link for coordination between FDA components and the HHS SOC, the CDC's EOC, USDA's EOC and/or FSIS Situation Room, and other Federal Departments/Agencies as appropriate.

B.2.2.2.1 Authority to Activate Emergency Operations Center Operational Levels

The authority to activate a change in the operational level of FDA's EOC resides with the OCM Director, OCM/OEO Director, or his/her designee. The Commissioner or the Secretary also may request a change in the operation level of the FDA EOC.[13] Other agency emergency coordination units, such as Centers, shall activate their situation rooms at the discretion of their senior management, such as the Center Director. Regional and District Offices shall establish Incident Management Teams (IMT) at the discretion of the Regional Food and Drug Director or District Director. FDA's EOC (OCM/OEO) shall be made aware when a situation room or IMT is established or activated in response to an incident. An increase in the EOC operational level may lead to the establishment of an IMG to bring together additional resources and expertise to assume overall coordination for the response.

[13] The FDA Principal Deputy Commissioner, Deputy Commissioners, and Associate Commissioner for Regulatory Affairs also are authorized to activate the FDA EOC when normal channels of direction are disrupted.

B.2.2.2.2 Conditions for Operational Level Change

Any of the following conditions could affect the operational levels of the EOC or establishment of the FDA IMG:

- FDA has received credible intelligence or other confirmed information that an FDA-regulated product is the specific target of terrorism or other serious criminal activity.
- An incident involves a single or multiple FDA-regulated product(s) covering a large geographic or population area (more than one State), and requires the coordination of multiple agency organizational components.
- Two or more significant events have occurred at the same time.
- FDA-regulated products or facilities have been impacted by a natural or manmade disaster.
- A natural or manmade incident has triggered activation of the *NRF*, in whole or in part, and State or Federal Agencies have formally requested assistance from FDA.
- Deliberate or accidental contamination of the human or animal food, medical products, or tobacco products supply has caused widespread illness, injury, or death to consumers.
- A widespread epidemic or pandemic disease outbreak or other public health emergency for which FDA has a designated support responsibility has occurred or is highly probable.
- DHS has raised the Homeland Security Advisory System level to High Condition (Orange) "*high risk of terrorist attack*," based on intelligence that the food and agriculture sector is at risk, or to Severe Condition (Red), "*severe risk of terrorist attack*," to prevent/protect against a credible threat.

B.2.2.2.3 Activation

The FDA EOC will notify appropriate agency organizational components, the HHS SOC, and other key Federal partners when the EOC has been activated and an IMG has been established in response to an emergency.[14] This activation announcement may include a status report explaining the rationale for the decision to activate the EOC and establish an IMG, a description of operating hours and staffing levels, and situation reporting requirements. After activation procedures commence, FDA may request additional resources and capabilities to augment emergency operations. This includes prioritizing and clearly communicating specific incident requirements to mobilize and deploy Emergency Response Staff to both internal and external locations. Requests for staffing will be made in writing by the OCM Director, OCM/OEO Director, or someone higher in the Office of the Commissioner, to Center and Office Lead Emergency Coordinators or other senior officials within the organization. Representatives from specific headquarters Centers and Offices may be directed to relocate to the FDA EOC, other designated FDA locations, or other Federal Departments or Agencies. Interagency partners may also send representatives to the FDA EOC or other agency organizational components to perform liaison roles under existing memorandums of understanding (MOUs).[15] In addition, FDA field organizations, such as Regional Offices, District Offices, branches, and resident posts may send personnel and specialized equipment to the FDA EOC, incident site(s), laboratories, or other designated locations to provide subject matter expertise and advice, conduct investigations and inspections, collect and analyze samples, and/or detain or destroy contaminated product(s).[16]

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[14] For detailed information on emergency alert and notification procedures, refer to Section E, "Communications and Information Management," of this Plan.

[15] For more information on MOUs, refer to the FDA EOP Appendix I or J

[16] Refer to Section D, "Direction, Control, and Coordination," of this Plan for more information on Agency emergency position assignments.

Emergency Operations Center Operations during Voluntary Isolation. The physical staffing of the incident management group may take place within the location of the EOC or another designated location, such as the Commissioner's Situation Room. However, various conditions associated with a pandemic (i.e., quarantine, social distancing practices, and the need for staff to care for seriously ill family/friends), natural disaster, or other event impacting EOC members' ability to physically staff the EOC, may make it necessary at times for IMG or EOC assigned staff personnel to carry out their duties from a remote location, such as their residence. The authority to operate the FDA EOC under "virtual" conditions resides with the OCM Director, OCM/OEO Director, or his/her designee.

B.2.2.3 Coordination of Response Actions

FDA personnel must perform a number of tasks and functions when responding to an incident. Some of these basic tasks may include performing initial and ongoing planning, managing and performing mission assignments, coordinating team response operations and resources, performing research and decisionmaking, and documenting and reporting information. Although FDA personnel accomplish most of these basic tasks over the course of the incident, their order of execution, the exact activities performed, and the individual or organization responsible will vary depending on the type and severity of the threat or hazard. Each involved FDA organizational component will be responsible for performing certain emergency actions based on its assigned mission and functions.[17]

FDA organizes emergency response operations in accordance with the concepts, principles, and terminology of the ICS, as defined within *NIMS*.[18] Incident Command and subordinate Planning, Operations, Logistics, and Finance/Administration functions lay the foundation for the agency's implementation of the ICS during all-hazards response, at headquarters and field levels, and across geographic divides. The inherent design of this system enables rapid, scalable, and flexible agency-wide emergency management activities.

This section describes each of the components of a coordinated FDA emergency response. The agency's response strategy, while containing certain core activities, must be tailored to the specific requirements of each incident. (Refer to the Incident Annexes of this plan for detailed information on FDA functions, activities, and organizational constructs for individual hazards.)

B.2.2.3.1 Initial and Ongoing Response Planning

FDA conducts planning to organize its response structure, identify objectives and performance metrics, and coordinate the delivery of resource support. Planning is ongoing throughout the lifecycle of any incident and is adjusted as necessary to meet changing demands. It involves a blend of prescribed actions drawn from existing FDA emergency plans and procedural documents (i.e., hazard-specific incident annexes, SOPs, operations manuals, field guides, etc.) and real-time determination of the necessary course(s) of action. An agency Incident Action Plan (IAP) may be developed based on these actions in order to provide operational and tactical direction to FDA emergency personnel when responding.

The IAP is generally crafted by holding regular planning meetings throughout the incident, both in-person and via conference calls, with responsible headquarters and field units. Planning meetings seek to accomplish the following goals:

- Gathering, recording, analyzing, and distributing incident information in a manner that will facilitate: 1) increased situational awareness of the magnitude, complexity, and potential impact of the incident, emergency, or crisis; and 2) the ability to determine the resources required to resolve the situation

[17] Refer to Section C, "Organization and Assignment of Responsibilities," of this Plan for more information on individual Center/Office roles and responsibilities.

[18] For more information on the ICS, refer to www.training.fema.gov/EMIWeb/IS/ICSResource/index.htm.

- Formulating and prioritizing measurable incident objectives and identifying an appropriate response strategy that conforms to the legal obligations and management objectives of all FDA organizational components and/or external agencies involved
- Determining the tactical direction, reporting mechanisms, timeframes, and specific resource requirements (i.e., personnel, specialized equipment, facilities, training and expert knowledge, and funding) for implementing selected strategies during the response period

Through these planning meetings, the agency can coordinate the execution and evaluation of emergency activities, promote and maintain situational awareness (a "common operating picture"), track the progress of ongoing initiatives, and modify plans and procedures based on new and emerging information.

B.2.2.3.2 FDA Field Response

For the majority of incidents involving FDA-regulated products, one or more FDA field offices may be involved in the response. The districts in which the event is occurring (e.g., the physical location where people have been affected) will obtain necessary information for FDA to confirm the health hazard. In addition, the field offices will determine, plan, and conduct tasks and assignments over the course of the response.

Incident Management Team. A decision can be made to respond by implementing an ICS at the field level, which involves the establishment of an Incident Management Team(s) (IMT). Criteria for activating an IMT will be based on the conditions described in Section A.3 Scope and Applicability. The authority to mobilize an IMT resides with senior field officials in consultation with senior ORA officials. An IMT may also be mobilized at the request of or in consultation with a headquarters incident management group.

The IMT will be responsible for tactical operations (i.e., perform investigations/inspections, collect samples, and/or detain or destroy contaminated product) in accordance with the IAP it develops. In addition, as the IMT conducts its follow-up efforts, field offices will communicate investigational/ inspectional findings of other potentially affected establishments with the firms' home districts and FDA headquarters emergency response entities described in the following section.

The IMT is led by a designated Incident Commander (IC) (see *FDA EOP*, Section D.1., for organizational elements). The field IC reports directly to the FDA Area Command if set up and provides continuous situational awareness to FDA's EOC or an FDA headquarters IMG (see *FDA EOP*, Section B.2.2.3.3 for IMG description) through teleconference calls, e-mails, Internet Service Provider (ISP), and/or SITREPs. The IMT is responsible for managing the District's or Region's emergency response effort; coordinating actions and resources needed to follow up on the incident; and channeling all necessary communications to/from deployed field elements. Depending upon the nature and severity of the incident, additional field IMTs may be established to support geographically distant or functionally different emergency response operations.

Generally, the field IMT's location could be set up at any of the FDA field offices near the site of investigational or inspection activities because of the accessibility to records and the availability of dedicated communications/information systems equipment. However, if the incident has destroyed or otherwise negatively impacted, or is projected to impact, the lead District's office, or appropriate facilities are not available, consideration may be given to relocating the ICP to an alternate facility, such as a pre-designated District Office continuity of operations (COOP) site or other FDA District or Regional Office. A notification for reallocation of field staff between or among Districts shall be directed to ORA/ORO.

B.2.2.3.3 FDA Headquarters Response

Dependent on the nature and complexity of the agency's response to an incident, an intra-agency approach may be used to coordinate resources and incident-related information and to support incident

management and agency policies. Depending on the scale of the incident, coordination will occur through the EOC of an IMG co-located in the EOC.

- **Incident Management Group.** An IMG under an FDA ICS is typically established when an incident involves multiple FDA organizational components or involves complex incident management/coordination. The authority to establish FDA's incident management structure, IMG, resides with the OCM Director, OCM/OEO Director, or his/her designee in consultation with the Counselor to the Commissioner and appropriate senior Center and ORA officials. The IMG may be a hybrid structure conducting coordination and command dependent on the scope of the event. It is staffed by agency headquarters representatives (i.e., from the Office of the Commissioner (OC), ORA, and/or the FDA product Centers) and, as appropriate, FDA field staff and/or external agency liaisons. The IMG staffing is organized consistent with the principles of the NIMS. An Agency Incident Coordinator (AIC) is designated to oversee the development and implementation of a headquarters IAP and the coordination of FDA headquarters resources and capabilities to respond to the event, as needed. Subordinate Command and General Staffs, comprising representatives from headquarters Centers and Offices, are also established to assist the AIC in executing emergency functions under the specific conditions at-hand.[19] The AIC reports directly to the Commissioner or the Commissioner's designee such as the Agency Executive Group. An Agency Executive Group (AEG) may be set up for policy input. For a further description of the AEG, see Section *D. Direction, Control, and Coordination.*

  The scope of the incident may call for the establishment of an internal agency Joint Information Center (JIC). This is a physical or virtual co-located group of representatives from Centers and Offices involved in the event that are designated to handle public information needs *further described in Section D.2.2.4.1.*

- **Emergency Operations Center.** EOC is the physical location at which the coordination of information and resources to support incident management activities normally takes place.

FDA Emergency Operations Center. The FDA EOC serves as the agency-wide focal point for emergency operations coordination and dissemination of information whether staffed by OCM/OEO personnel or an IMG. The FDA EOC monitors ongoing events, processes complaints and alerts, issues mission assignments to FDA organizational components, coordinates overall agency emergency management operations, and communicates with interagency partners to provide technical and material support.[20] The FDA EOC staff facilitates contact between applicable headquarters and field emergency personnel and provides frequent and formalized communications/reporting to agency senior officials and organizational components, as well as the HHS SOC and other external partners regarding the status of FDA emergency response activities.

The FDA EOC provides a central location from which headquarters personnel can provide agency-wide coordination and executive decisionmaking in support of the incident response. The FDA EOC staff does not command or control the agency's response, but carries out the coordination function for complex incidents or multiple incidents occurring simultaneously through:

- **Information Collection, Evaluation, and Dissemination.** Collecting, analyzing, interpreting, distributing information from/to various internal and external sources
- **Priority Setting.** Ensuring that agency response systems are interconnected and complementary, reinforcing interoperability among the various organizational components, making the response

[19] For detailed information on how the FDA organizes and staffs emergency response operations, refer to Section D, "Direction, Control, and Coordination," of this Plan.

[20] The composition of FDA EOC staff will change depending on specific incident requirements.

more efficient and effective by coordinating available resources, and making decisions based on agreed-upon policies and procedures

- **Resource Coordination.** Identifying and acquiring needed resources and allocating existing or known resources
- **Communications Facilitation.** Establishing and maintaining intra- and interagency interoperable communications

Centers. The FDA product Centers are responsible for scientific evaluations and for programmatic decisions and policy development within their respective program areas. Their professional staff includes clinical, scientific, and manufacturing process experts. This expertise (analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is routinely utilized for critical consultation and decisionmaking should an incident occur.

Each Center shall maintain a Situation Room or Coordination Center, consisting of Center-selected SMEs, to be led by a Center Emergency Coordinator (CEC) who reports to the Center Director and coordinates directly with the FDA EOC. He/she serves as the focal point for internal and external Center communications during emergencies and disasters and is responsible for providing regular status and SITREPs to the FDA EOC, as requested. FDA Centers participate in agency emergency operations only when the response includes, or may include, regulatory activities or products under their jurisdiction. During some large-scale or catastrophic incidents, CECs may be directed to report to the FDA EOC to support initial or prolonged emergency operations.

For further information about the Center's responsibilities during an emergency, please see Section C.3 of this plan.

Office of Regulatory Affairs. Any information received by ORA regarding the incident or ongoing field activities will be discussed, as appropriate with staffs operating from the FDA EOC and the Commissioner or the Commissioner's designee, as appropriate. Additionally, ORA, working with the responsible Centers and ORO, will develop, issue, and approve any new or revised regulatory policy, which is required during the course of the event.

For further information about ORA's responsibilities during an emergency, please see Section C.2 of this plan.

B.2.2.3.4 Mission Assignments in Support of State and Local Response

Requests for support from State and local agencies can be made directly to the agency or, in the case of a declaration of a major disaster or emergency under the Stafford Act, through the Federal Emergency Management Agency (FEMA). In order to assist States and local agencies with such requests, FDA has developed Pre-Scripted Mission Assignments (PSMAs), which can be used to expedite the submission of such requests. These requests include laboratory analysis, investigational, sampling collection, subject matter expertise, and training related to drugs, biologics, medical devices, radiation-emitting devices, tobacco, the food supply, or cosmetics. See Appendix C for the list of the PSMAs.

B.2.2.3.5 Medical Countermeasures: Emergency Use Authorization and Expanded Access

For certain events, the Commissioner may authorize the use of an unapproved medical product or the unapproved use of an approved medical product during a declared emergency, which may involve a heightened risk of attack against the public or U.S. military forces or has a significant potential to affect national security. This can be due to a naturally occurring disease or a CBRN agent.[21, 22] An EUA may be issued only after the Secretary has an emergency justifying the authorization to use a product, based on an appropriate determination made by the Secretary of Homeland Security, Secretary of Defense, or Secretary of the HHS as required by the Project BioShield Act of 2004.[23, 24]

When a countermeasure has not yet been approved, licensed, or cleared because the safety, effectiveness, and/or quality have not been fully established, FDA may permit the treatment of patients with the medical countermeasure under expanded access mechanisms of Investigational New Drug (IND), Investigational Device Exemption (IDE), or EUA.

The scope of critical medical countermeasures encompasses biological threats defined by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Section 319F(h)(4), as well as additional chemical and biological emergencies as determined by the HHS Secretary. The medical countermeasures directly or indirectly mitigate the public health consequences of a biological or chemical attack.

Although the agency clearly defines most medical countermeasure regulatory jurisdictional responsibilities, several jurisdictional situations require explanation. CBER regulates all vaccines and blood derivatives for human use, and the USDA regulates those for veterinary use. CDER regulates all drugs for human use, and CVM regulates all drugs for veterinary use. CDRH regulates the majority of clinical diagnostics; however, CBER regulates a specialized subset of in-vitro diagnostics involved in the safety of the blood/tissue supply. Therapeutic biologics are regulated by multiple Centers and questions should be addressed to the appropriate Center. In instances where Center-specific jurisdiction within FDA is unclear, the FDA Office of Combination Products will decide which FDA Center possesses regulatory jurisdiction.

During high-risk or threat situations, responsible OC Offices and FDA Centers and Offices shall perform the following general functions related to medical countermeasures:

- Monitoring and updating the status of product availability and relevant manufacturing information
- Facilitating the availability of safe and effective drugs, therapeutic biologics, vaccines, cellular- and tissue-based therapies, diagnostic devices, and other biological products to be used as countermeasures
- Collaborating with, as permitted, Federal, State, tribal, territorial, and local public health agencies and regulated industry regarding product stockpile issues, including labeling, appropriate usage, product performance, monitoring, use in special populations, and other evolving issues

[21] The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the HHS, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies. www.hhs.gov/aspr/barda/

[22] MedicalCountermeasures.gov facilitates communication between Federal Government Agencies and public stakeholders to enhance the Nation's public health emergency preparedness. www.medicalcountermeasures.gov/

[23] The most current FDA guidance on EUAs can be found at www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm.

[24] Federal Food, Drug, and Cosmetic Act, Section 561: Expanded Access to Unapproved Therapies and Diagnostics and 564: Authorization for Medical Products for Use in Emergencies.

- Conducting prospective discussions about emergency use of products and the appropriate regulatory mechanism for their use and the submission of data (e.g., EUA, IND, IDE, or Master File) on the product
- Ensuring that patients will be provided information adequate to obtain informed consent (for IND and IDE products) or to notify patients of the known and potential risks and benefits of a product used under an EUA (does not include EUAs)
- Providing advice on identifying potential contaminants of drugs and therapeutic biological products and advising how to test for quality and purity

B.2.2.4 Demobilization

As the need for full-time incident response coordination wanes, FDA will assess the situation to determine whether to continue or terminate emergency operations.[25] This decision includes identifying whether consumer product safety and security and public health protection objectives were achieved and an orderly, safe, and efficient return of FDA resources (i.e., activated or deployed personnel, facilities, and equipment) to their original locations and/or operating statuses is warranted. In making this decision, FDA coordinates with and seeks input from appropriate experts and stakeholders. As a result, FDA organizational components may resume normal business operations and transition to short- and long-term recovery.

Dependent on the incident, resurgence may occur, and any period of transition back to normal operations could be disrupted. When this occurs, the agency will begin a new "Notification and Alert" period for emergency response and a change in EOC operational levels may occur.

Transition back to normal operations, after initiating and conducting an emergency response, will occur in stages and will correspond to the recovery of affected communities, FDA regulated firms, and the Nation as a whole.

B.2.3 Recovery

During the final phase of emergency operations, the goal of the agency is to recover normal operations and re-establish public confidence in FDA-regulated products. To accomplish this, FDA analyzes the cause or source of the incident to minimize the chance of similar situations reoccurring. By focusing on these goals, the agency maintains its integrity long after the crisis has ended.

Throughout the short-term recovery process, FDA maintains communications with other government agencies, industry, the public, and the media as they may request additional information, particularly concerning any long-term effects associated with the event and the measures being taken to prevent future incidents. All messages are factual and communicate the positive aspects of how FDA addressed the situation. Dependent on the recovery objectives and the level of coordination needed, the FDA IMG will determine if the FDA EOC or the FDA JIC resources are needed to support the functioning of the IMG and recovery efforts.

Some recovery objectives that would support Federal, State, territorial, tribal, or local agencies are:

- Inspect, investigate, or collect samples for the overall recovery operation, as needed (e.g., inspections of retail food establishments and pharmacies)
- Conduct prolonged inspection activities in support of State, territorial, tribal, or local agencies that are specifically related to a disaster but deemed ineligible under the Stafford Act

[25] Only the Commissioner, or his/her authorized designee, and the AIC may formally terminate agency-wide emergency response operations. However, Center Directors, Regional Food and Drug Directors, and District Directors, through their respective Emergency Coordinators, are authorized to demobilize emergency personnel within their organizational components.

- Manage a potentially large number of samples of FDA-regulated products, including long-term sampling associated with natural and nuclear/radiological health disasters, product destruction, and product reconditioning

B.2.3.1 Evaluation of Response

Following any emergency or disaster, agency organizational components will discuss how the agency handled the incident and seek input from appropriate experts and stakeholders. Staffs analyze emergency actions and responsibilities, resolve any deficiencies, mitigate consequences, and anticipate and address any long-term effects of the incident. In addition, organizational policies, plans, and procedures are updated as needed, incorporating lessons learned and best practices captured during the event.

Following the termination of response activities that involved an IMG, the FDA OCM works with stakeholders to conduct a lessons-learned analysis to identify the following:

- Strengths and weaknesses of key response activities performed during the incident, including agency measures to protect public health
- Resource needs—personnel, equipment, training, etc.
- Improvements to emergency response plans and procedures
- Strengths and weaknesses of agency communications, which could include intra-agency and interagency communications as well as communications with specific stakeholder groups, such as industry, consumers, and the news media
- Needed modifications toward regulatory policy, laboratory and field operations, and research activities
- Any other needed improvements to overall preparedness

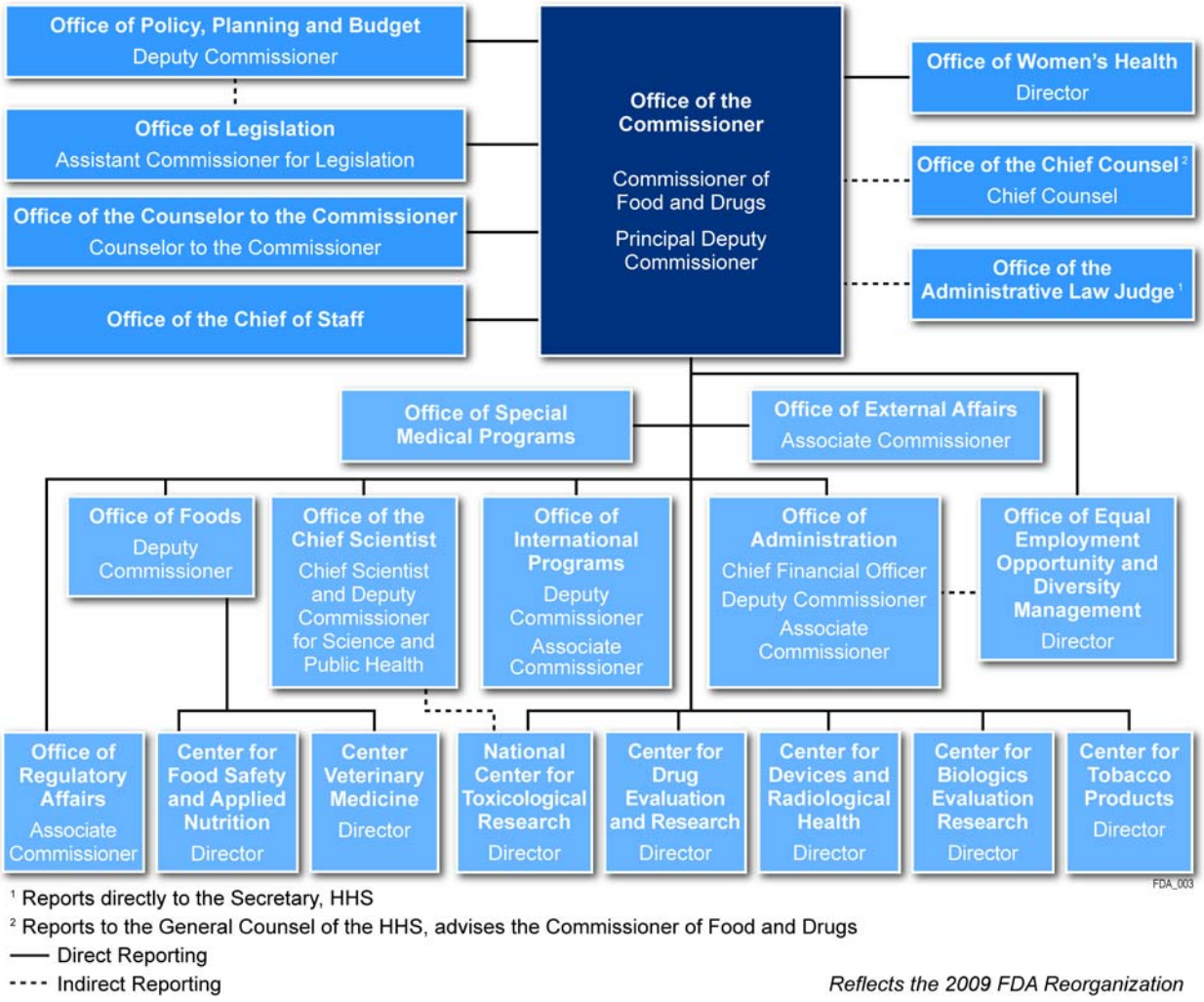
A final lessons-learned report draws conclusions from data collected. All FDA Centers and Offices should submit their input to the FDA OCM Director. All relevant parties within FDA receive the final report. In regards to the recovery of FDA-regulated industry, it may be more appropriate that long-term recovery activities requiring FDA involvement be coordinated by agency components other than OCM/OEO.

C ORGANIZATION AND ASSIGNMENT OF RESPONSIBILITIES

This section identifies the general roles and responsibilities of FDA headquarters and field organizational components, including those that assist in preventing and protecting against, responding to, and recovering from all hazards. FDA staffs work closely with one another and with governmental and industry partners to ensure the safety, efficacy, and security of FDA-regulated products that mitigate the public health effects of an emergency or disaster in the United States or worldwide, using novel and expeditious approaches to product regulation for optimized availability and use in all populations.

Figure C-1 outlines FDA's overall organizational structure, and is followed by a brief description of the emergency functions performed by all responsible organizational components.[26] Refer to individual Center/Office emergency plans and procedural documentation, as applicable, for more detailed information on emergency actions.

Figure C-1. FDA Organizational Chart

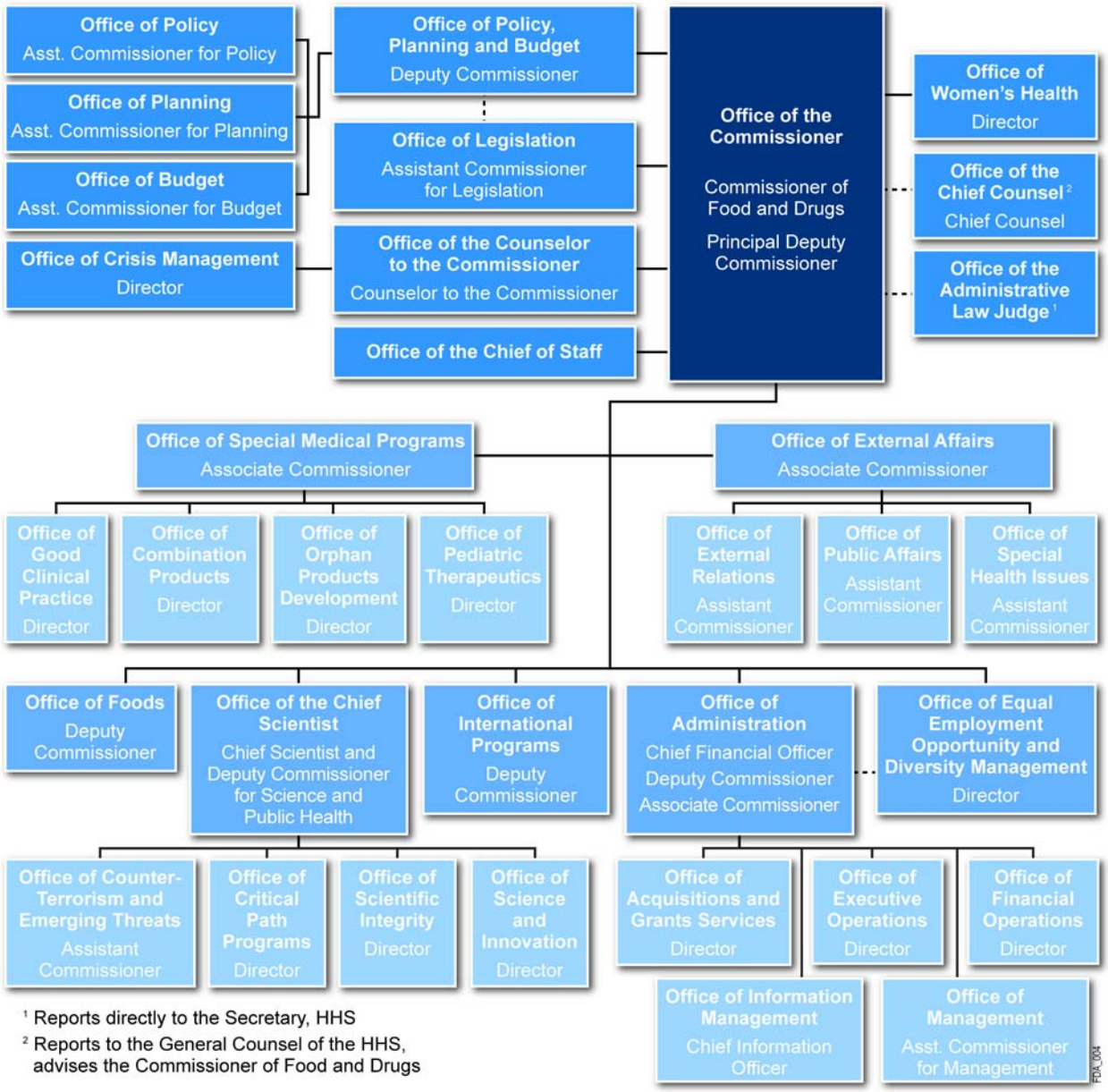


[26] Those FDA organizational components without defined emergency roles or responsibilities are not described within this Plan.

C.1 OFFICE OF THE COMMISSIONER

OC provides centralized direction and management services for agency-wide programs to ensure that FDA's consumer protection efforts are effectively managed within its legal and regulatory framework and those available resources are put to the most efficient use. OC also provides policymaking, program direction, coordination and liaison, and expert advice to agency leadership and programs in support of FDA's science-based work. The Office includes the Commissioner, Principal Deputy Commissioner, and Deputy Commissioners.

Figure C-2. FDA OC Organizational Chart



C.1.1 Office of the Chief Counsel

The Office of the Chief Counsel (OCC) is composed of litigators and counselors. Litigators handle both civil and criminal cases, participating in case development; drafting pleadings, motions, and briefs; and conducting discovery and trials. Counselors provide legal opinions to the major programs of the agency—drugs, foods, biologics, devices, veterinary products, tobacco products, and enforcement. They participate in rulemaking proceedings, legislative matters, policy deliberations, and international negotiations. In addition, FDA attorneys are involved in explaining agency programs to Congress, regulated industry, and the public. In an emergency or disaster, OCC is responsible for, but not limited to, the following activities:

- Providing FDA organizational components with legal counsel on incident-related regulatory activities; examples include EUAs, marketing of medical countermeasures, and human subject protection
- Providing FDA organizational components with legal counsel related to sharing of information with other government agencies and the public, with proper protections (e.g., for trade secrets and confidential commercial information)
- Advising ORA and other relevant agency organizational components on inspections and enforcement matters related to foods, drugs, biologics, medical devices, radiological products, animal drugs/feed, cosmetics, and tobacco products
- Coordinating with the HHS Office of General Counsel (OGC) on FDA-related issues, as appropriate (e.g., on grants and contracts and on legal issues arising from activities of other HHS operating divisions [OPDIVs] in relation to FDA activities)
- Working with other government agencies and their attorneys, Congress, and the U.S. courts on FDA-related issues (e.g., the U.S. Department of Justice [DOJ], FBI, Federal Trade Commission, USDA, EPA, U.S. Department of State [DOS], and U.S. Postal Service; State attorney generals' offices; Congressional oversight and appropriations committees; and Federal and State courts)
- Provides legal advice and assistance to the Office of the Secretary on matters within the expertise of the Chief Counsel

C.1.2 Office of the Chief of Staff

The Office of the Chief of Staff (OCoS) coordinates staff activities in the Office of the Commissioner and serves as the principal liaison to HHS. The Office advises and provides integrated policy analysis and strategic consultation to the Commissioner, Principal Deputy and Deputy Commissioners, and other senior FDA officials on activities and issues that affect significant agency programs, projects, and initiatives. OCoS provides senior-level leadership and guidance on issues and actions tied to the agency's communications with HHS and the White House, including correspondence for secretarial signatures.

C.1.2.1 Executive Secretariat

The Executive Secretariat Office coordinates the agency's communications with HHS and the White House, including correspondence for the Office of the Secretary and the Commissioner of FDA.

The Executive Secretariat Office works with key FDA offices to ensure that the documents prepared for the Commissioner's signature, including EUA, are in the correct format and have been appropriately reviewed and cleared. The Executive Secretariat Office also maintains the agency's archive files of these documents.

C.1.3 Office of Legislation

The Office of Legislation directs and manages FDA's legislative needs, pending legislation, oversight activities, and Congressional relations consistent with the mission of the agency. In an emergency or disaster, the Office of Legislation is responsible for, but not limited to, the following activities:

- Keeping Congress apprised of FDA actions in coordination with the HHS Office of the Assistant Secretary for Legislation
- Responding to Congressional requests for information (RFIs)
- Arranging and supporting Congressional meetings, briefings, and hearings

C.1.4 Office of Policy, Planning, and Budget

The Office of Policy, Planning, and Budget (OPPB) provides advice to the Commissioner and other key FDA officials on matters relating to strategic direction, policy, development of regulations and guidance, legislative issues, planning and evaluation activities, and budget. OPPB manages FDA's advisory committee program, coordinates the publication of agency rules and notices in the *Federal Register*, serves as the agency focal point for policy development, and helps ensure that agency components adhere to FDA policies and regulations. This Office participates with the Commissioner in the formulation of the budget, basic policies, and operational philosophy that guide FDA in effectively achieving its goals and meeting its responsibilities.

C.1.4.1 Office of Policy

The Office of Policy is responsible for advising the Commissioner and other key agency officials on matters relating to agency policy and on regulations and industry guidance development.

C.1.4.2 Office of Planning

The Office of Planning develops programs and systems to evaluate overall FDA program accomplishments against objectives and priorities, recommending changes as necessary.

C.1.4.3 Office of Budget

The Office of Budget (OB) is responsible for developing budget formulation plans, and organizes and carries out annual and multi-year budgeting in support of the nationwide public health protection programs administered by FDA. In coordination with FDA Centers and Offices, OB responds to requests for budget information, special reports, and exhibits, and provides expertise and performs all duties involved with the formulation, justification, and presentation of FDA budget submissions to HHS, the Office of Management and Budget (OMB), and the Congress. In an emergency or disaster, OB is responsible for, but not limited to, the following activities:

- Providing expert advice on and managing supplemental budget requests to support unforeseen expenses during critical periods or events; OB would facilitate this process by working with senior management and Centers to identify resource needs, implementing the process to formulate the budget request, providing essential support during the review and clearance process, and responding to questions from Congressional Appropriations Staff and other stakeholders.
- Facilitating that process by conducting outreach and coordinated communications, gathering information and communicating with senior FDA management, centers, HHS, OMB, and Congressional Appropriations Staff

C.1.5 Office of the Counselor to the Commissioner

The Office of the Counselor to the Commissioner provides a leadership role in advocating for and advancing the Commissioner's priorities. This office provides top-level leadership for the development and management of emergency and crisis management policies and programs for FDA to ensure that a structure exists for FDA to respond rapidly to an emergency or crisis situation in which FDA-regulated products need to be utilized or deployed.

C.1.5.1 Office of Crisis Management

OCM serves as FDA's focal point for coordinating emergency response activities involving FDA-regulated products or in situations when agency resources need to be used or deployed. It coordinates intra- and interagency activities related to emergency preparedness and response and security operations. OCM assists in the development, management, and coordination of incident management policies and programs for FDA to ensure that a structure exists to respond rapidly and effectively to all hazards. OCM consists of a Director, Immediate Office, and OCM/OEO. The Immediate Office staff included an EOC Manager, Geographical Information System (GIS) Mapping Specialist, after hours Call Center, and staff responsible for emergency plans, exercises, and evaluation. Additionally, OCM serves as a coordinator to the HHS Office of the Assistant Secretary for Preparedness and Response, providing situational awareness of all FDA-related emergencies, and ensures that FDA's emergency operations procedures are in alignment with national and HHS procedures. During an emergency response, OCM supports the agency with the following activities:

- Provides Offices and Centers GIS maps created by the EON IMS' GIS mapping component for use in strategic planning of agency emergency response activities
- Oversees the FDA Emergency Call Center, which provides after normal hours service for responding to public inquiries and reports related to FDA-regulated products as well as surge capacity service for managing increased volumes of inquiries due to an event involving an FDA-regulated product
- Manages FDA's EOC, staffing it with personnel from OCM/OEO; when the EOC is activated, OCM augments EOC operations with personnel from relevant Centers and Offices to monitor emergency situations, triage complaints and alerts, issue mission assignments to organizational components, coordinate overall agency response operations, and communicate with external partners requesting technical and material support.
- Coordinates agency evaluation of emergency responses and crisis situations to determine appropriate internal and external referral for further action and recommended changes in agency procedures

C.1.5.1.1 Office of Emergency Operations

OCM/OEO is staffed with Agency Emergency Coordinators and serves as the central coordination point for the agency's response to adverse events, foodborne illnesses, injuries, product tampering, and manmade and natural hazards. It serves as the agency focal point for emergency preparedness and response operating the 24 hours-a-day, 7 days-a-week emergency response system. OEO reviews and assists in the analysis of preliminary information about threats and hazards and assists in the early recognition and agency notification of emergencies, outbreaks, natural disasters, and terrorism or other criminal acts. Part of OEO responsibilities is to manage the National Consumer Complaint System, which monitors reports of problems with FDA-regulated products for potential emergencies. Another is to participate in daily National Biosurveillance Integration Center conference calls sponsored by the DHS to provide a secure forum for interagency information sharing for early recognition of biological events of national concern, both natural and man-made, to make a timely response possible.

In an emergency or disaster, OCM/OEO's staff members are responsible for, but not limited to, the following activities:

- Tracking trends and potential threats associated with FDA-regulated products such as after-hour calls and consumer complaints
- Triaging consumer complaints and emergency alerts
- Coordinating, monitoring, documenting, and reporting on all agency response activities and interagency communications
- Coordinating resource requirements with headquarters Centers and Offices and issuing assignments to the field
- Communicating with Federal Agencies (e.g., HHS SOC, CDC, USDA, DHS, National Oceanic and Atmospheric Administration [NOAA], EPA) as they request technical and material support from FDA
- Providing core staff for the operation of FDA's EOC and liaisons to the HHS Secretary's Operations Center

C.1.6 Office of Special Medical Programs

The Office of Special Medical Programs (OSMP), Immediate Office, oversees and coordinates the program offices that comprise OSMP. The Immediate Office:

- Provides leadership and direction in the coordination of internal and external review of pediatric science, safety, ethics, and international issues in accordance with laws and regulations
- Oversees the implementation of the Orphan Products provisions of the Federal Food, Drug, and Cosmetic Act to encourage the development of drugs of limited commercial value for use in rare diseases and conditions to promote the public health; the Immediate Office provides leadership in developing and communicating agency policy on orphan product activities, including protocol assistance, designation, exclusivity, and grants and contracts.
- Provides leadership and direction on Good Clinical Practice (GCP) and Human Subject Protection (HSP) regulation, policy, harmonization, and outreach activities; the Immediate Office oversees development of regulations and policy to help ensure protection of human subjects involved in FDA-regulated research and the integrity of data resulting from such trials.
- Provides leadership and direction on issues involving the regulation of combination products, the classification of human medical products, and jurisdiction over human medical products; the Immediate Office oversees development of regulations, policy, procedures, and processes to facilitate classification of human medical products and the agency's regulation, review, and oversight of combination products.
- Provides leadership in management and oversight of FDA Advisory Committees to provide consistent application of laws and policies applicable to such committees; the Immediate Office oversees development of policy, procedures, and processes to maintain and improve the agency's advisory committee program.
- Evaluates and responds to appeals involving product classification decisions, assignment of combination product decisions, and orphan product designations

C.1.6.1 Office of Good Clinical Practice

In general, the mission of the Office of Good Clinical Practice (OGCP) focuses on longer-term policy/ regulation development and intra-agency coordination of issues related to the conduct of clinical trials and

the protection of the rights, safety, and welfare of subjects in FDA-regulated studies. There are, however, several mission-critical areas for which OGCP is responsible that require daily attention and which may have heightened importance during an emergency situation, particularly an emergency that directly impacts the conduct of ongoing clinical trials. These areas include addressing clinical trial/human subject protection inquiries, questions related to emergency or compassionate use of investigational articles, trial-specific concerns, EUAs, and coordination of interagency GCP/HSP issues. Should the emergency situation have a major impact on the conduct of clinical trials in one or more areas of the country, OGCP could potentially establish an emergency-specific hot-line, as was done in the aftermath of Hurricane Katrina. Major concerns regarding subject safety could include identification of an accessible clinical site(s) for continued subject care depending on the specific situation.

C.1.6.2 Office of Combination Products

The Office of Combination Products (OCP) ensures the prompt assignment of combination products to agency Centers, the timely and effective premarket review of such products, and consistent and appropriate post-market regulation of like products subject to the same statutory requirements to the extent permitted by law. In addition, OCP is responsible for determining whether articles are drugs, devices, biological products, or combination products if their classification is unclear or in dispute. In an emergency or disaster, OCP is responsible for, but not limited to, the following activities:

- Classifying articles as drugs, devices, biological products, or combination products
- Assigning an FDA Center to have primary jurisdiction for review of a combination product
- Ensuring consistency and appropriateness of post-market regulation of combination products
- Updating agreements, guidance documents, or practices specific to the assignment of combination products during the incident
- Working with FDA Centers to implement guidance or regulations to clarify the agency regulation of combination products
- Serving as a focal point for combination products issues for internal and external stakeholders

C.1.6.3 Office of Orphan Products Development

This Office develops and communicates agency policy and makes decisions on approval of sponsor requests and incentives, including orphan product protocol assistance, orphan product designation, orphan product exclusivity, and orphan product grants and contracts, to support clinical research and other areas of agency policy related to the development of products for rare disorders. It reviews investigational new drug and biologics applications and investigational device exemptions to locate the existence of products under investigational study that show promise for effectiveness for rare or common diseases but lack commercial sponsorship. It assists sponsors, researchers, and investigators in communicating with agency regulatory officials and expediting solutions to problems in obtaining investigational exemptions or premarket approval status.

C.1.6.4 Office of Pediatric Therapeutics

The Office of Pediatric Therapeutics (OPT) coordinates and facilitates all activities of FDA that may have any effect on a pediatric population or the practice of pediatrics or may in any other way involve pediatric issues. In an emergency or disaster, OPT is responsible for, but not limited to, the following activities:

- In direct coordination with CDER's Office of Surveillance and Epidemiology and CDER's Pediatric and Maternal Staff (within the Office of New Drugs), and in consultation with CDER's Office of Counterterrorism and Emergency Coordination, review and address all adverse event reporting involving drugs used in the pediatric population

- In direct coordination with CDRH's pediatric steering committee and Medical Product Surveillance Network (MedSun), address emergency issues related to device use in pediatrics
- Provide consultation and coordination on pediatric issues across Centers and with external groups and agencies as well as provide representation on groups such as the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) working group

C.1.6.5 Advisory Committee Oversight and Management Staff

The Advisory Committee Oversight and Management Staff (ACOMS) coordinates and facilitates all activities of FDA that are related to the establishment and operations of FDA's advisory committees. ACOMS is responsible for seeing that all statutory and regulatory requirements and agency policies are met when conducting all advisory committee meetings, including the screening of members for potential financial conflicts of interests. In an emergency or disaster, ACOMS is responsible for the following activities, among others:

- Overseeing the operations of the Centers to obtain the appropriate experts to attend a meeting
- Assisting the Centers, if necessary, in procuring a space to hold the meeting
- Assisting the Centers, the Regulations Policy Management Staff, and the Associate Commissioner for Special Medical Programs in publishing public meeting announcements in the *Federal Register* and on the FDA Web site
- Reviewing the financial interests of all individuals invited to participate in the meeting for potential financial conflicts of interest. (This is conducted with the assistance of the Centers, the Ethics and Integrity Staff, and the Associate Commissioner for Special Medical Programs. If any members require waivers to participate, ACOMS coordinates disclosure with the FOI staff and the FDA Web staff.)

C.1.7 Office of External Affairs

The Office of External Affairs (OEA) is responsible for the following activities:

- Advises the Commissioner and other key agency officials on FDA's communications to the media and the general public on issues that affect agency-wide programs, projects, strategies, partnerships and initiatives
- Advises and assists the Commissioner and other key officials on all public information programs; acts as the focal point for disseminating news on FDA activities and as a liaison with the Public Health Service and HHS on public information programs
- Advises the Commissioner, Deputy Commissioners, and other senior staff throughout FDA on sensitive and controversial programs and initiatives that impact external stakeholder groups
- Serves as a liaison between FDA and health professional and patient advocacy organizations to solve problems and address concerns these groups have with agency policies and programs related to human medical product development and safety

C.1.7.1 Office of External Relations

The Office of External Relations (OER) during an emergency supports the agency with the following activities:

- Advises the Commissioner, Deputy Commissioners, and senior staff throughout FDA on sensitive and controversial programs and initiatives that impact external stakeholder groups

- Oversees and directs the agency's stakeholder-related communication functions to ensure coherence in decisionmaking and the efficient operation of these functions internally and across agency jurisdiction
- Serve as the agency's focal point for national consumer groups, academia, trade associations, ethnic and minority groups, and tribes
- Assists in the programmatic design, development, and planning with internal and external organizations regarding educational and informational activities intended to educate regulated industry

C.1.7.1.1 Consumer Health Information Staff

- Serves as the agency's focal point for consumer health communications activities. As such, manages the consumer health information section of the FDA Web site, www.fda.gov
- Creates and disseminates FDA consumer health information to empower consumers
- Works closely with FDA Centers and Offices on developing effective consumer health communications strategies and programs
- Establishes and maintains partnerships with external organizations and conducts other activities to increase the reach of FDA consumer health information
- Acts as the agency's public information liaison with HHS for all publications and audiovisual needs; provides prepublication clearance of publications, exhibits, and audiovisual materials in accordance with procedures established by the agency, PHS, HHS, OMB, and the White House

C.1.7.2 Office of Public Affairs

C.1.7.2.1 Media Relations Staff

The Media Relations staff serves as FDA's primary liaison with the news media and develops much of the material the agency uses to communicate its public health and consumer protection messages to the public. In an emergency or disaster, the Office of Public Affairs (OPA) is responsible for, but not limited to, the following activities:

- Developing, clearing, and issuing press releases, talk papers, and other public statements
- Responding to media requests
- Arranging and supporting media interviews
- Coordinating with public affairs specialists within FDA organizational components to provide education materials explaining steps consumers can take to protect themselves during the incident
- Taking guidance from and working closely with the HHS Office of the Assistant Secretary for Public Affairs (ASPA) in publicizing public health messages
- Developing a Critical Media Distribution List, containing contact information via e-mail notification

C.1.7.2.2 Web Communications Staff

OPA's Web Communications Staff oversees the content, design, and management of FDA's external Web site (www.fda.gov). As partners, staff personnel work closely with the FDA Office of Information Management (OIM), which is responsible for the technical operations of FDA's Web site. The Web Communications Staff coordinates Web postings and page development with Web staffs in the agency's organizational components and ensures that information is presented to the public via the FDA Web site

in a timely and usable manner. In an emergency or disaster, the Web Communications Staff is responsible for, but not limited to, the following activities:

- Posting vital and important information, emergency messages, and other communication information quickly to users via the FDA Web site
- Directing and coordinating Web communications on the FDA Web site homepage and other major touchpoints across the FDA organizational components to ensure consistent information that meets FDA's incident objectives
- Coordinating Web communications with HHS, other Federal Agencies, and State and local partners to ensure a comprehensive approach that reduces duplication of messages
- Ensuring agency adherence to governance, policies, and procedures across the FDA Web site
- Collaborates with Offices/Centers to coordinate domestic and international communications with stakeholders and response activities related to emergencies that impact the safety, efficacy, integrity, or availability of FDA-regulated products or that require FDA's investigational or laboratory support to other government agencies

C.1.7.3 Office of Special Health Issues

The Office of Special Health Issues (OSHI), Office of the Chief Scientist (OCS), coordinates and integrates agency policy/program, scientific, and public health issues related to AIDS, cancer, neurological disorders, MedWatch, and other special health issues. OSHI is responsible for engaging, collaborating, and communicating with health professionals, patients and patient advocates, and other special interest populations about FDA regulatory decisions and policies. Of particular importance in emergencies are two of the e-lists managed by the office, including the "FDA Updates for Health Care Professionals" E-list, with more than 25,000 subscribers, and the MedWatch E-list, with over 140,000 subscribers. Both lists provide important, timely FDA information to stakeholders.

C.1.8 Office of Foods

The FDA Foods Program includes three major operating units —CFSAN, CVM, and the foods-related activities of ORA — and draws on the resources and expertise of FDA's National Center for Toxicological Research (NCTR) and key Office of Commissioner staff offices.[27]

The Office of Foods (OF) is responsible, on behalf of the Commissioner, for providing all elements of FDA's Foods Program leadership, guidance, and support to achieve the agency's public health goals. The Office is also the focal point for planning implementation of the recommendations of the President's Food Safety Working Group for any new food safety authorities enacted by Congress.

The FDA Foods Program protects and promotes the health of humans and animals by:

- Posting vital and important information, emergency messages, and other communication information quickly to users via the FDA Web site in coordination with OPA
- Ensuring the safety of foods for humans, including dietary supplements
- Ensuring the safety of animal feed and the safety and effectiveness of animal drugs
- Setting science-based standards for preventing foodborne illness and ensuring compliance with these standards
- Protecting the food and feed supply from intentional contamination
- Ensuring that food labels contain reliable information consumers can use to choose healthy diets

[27] See FDA EOP, section C.2, C.3.4. C.3.5 and C.3.7 for a description of Centers, ORA, and NCTR.

C.1.9 Office of the Chief Scientist

OCS serves as the agency's focus for scientific, medical, and related activities within the Office of the Commissioner. OCS provides strategic leadership, coordination, and expertise to support scientific excellence, innovation, and capacity to achieve FDA's public health mission. The offices within OCS are as follows: the Office of Counter-Terrorism and Emerging Threats (OCET), the Office of Critical Path Programs, and the newly established Offices of Scientific Integrity and Science and Innovation. Additionally, NCTR has a direct reporting relationship to OC and an indirect reporting relationship to the Chief Scientist.

OCS also supports science and public health activities by effectively anticipating and responding to counterterrorism and emerging deliberate and natural threats (e.g., CBRN) to U.S. and global health and security, including through OCET.

C.1.9.1 Office of Counterterrorism and Emerging Threats

OCET protects the public health through the development and implementation of agency policies and plans that safeguard food and medical products from adulteration or disruption of supplies due to terrorist activities and that facilitate the availability of safe and effective public health emergency medical countermeasures. It also develops and implements comprehensive crosscutting policies, including policies that facilitate the availability of safe and effective medical countermeasures against CBRN agents. In an emergency or disaster, OCET is responsible for, but not limited to, the following activities:

- Implementing a comprehensive FDA strategy for counterterrorism and other emerging threats
- Policy leadership, including ensuring performance of counterterrorism and emerging threats goals
- Facilitating intra- and interagency communications on policies and plans for counterterrorism and other emerging threats
- Coordination and implementation of FDA's EUA and emergency use of medical countermeasures activities

C.1.9.2 Office of Critical Path Programs

Supports cross-center bioinformatics activities, including activities related to data management and analysis and safety surveillance of FDA-regulated products

C.1.10 Office of International Programs

The Office of International Programs (OIP) serves as the agency focal point for international issues. The Office leads, manages, and coordinates all of FDA's international activities to: effect an affirmative and strategic public health agenda in the international area; enhance and maximize FDA's communications and interactions globally, ensuring they reflect the agency's policies and best scientific, legal, and policy thinking; ensure that FDA international communications and interaction are consistent with HHS public health objectives; and leverage resources with counterpart foreign agencies and international organizations in meeting FDA's public health mission. In an emergency or disaster, OIP is responsible for, but not limited to, the following activities:

- Coordinating FDA communications with the DOS, including U.S. embassies abroad, foreign governments, and international organizations, including foreign embassies and consulates in the United States
- Exchanging information, and advising on clearing such, with foreign counterparts and other international partners to ensure compliance with laws and policies and consistency in responses

- Assessing, in real-time and in-country, where possible conditions and events in those areas might have an impact on the safety, quality, and availability of FDA-regulated products exported to the United States
- Engaging more proactively and consistently with various international communities in strategic regions abroad, including foreign governments, foreign regulatory counterparts, international organizations, other U.S. Government (USG) colleagues working abroad, industry, and the academia/research community; such engagements are intended to help FDA better accomplish its mission to collaborate with foreign regulatory authorities to reduce regulatory burdens, harmonize regulatory requirements, and establish appropriate reciprocal arrangements in order to promote and protect the public health of the United States by obtaining better information to help FDA Centers, ORA, and OC make better informed regulatory and other decisions.
- Managing formal arrangements with foreign governments, e.g., MOUs, mutual recognition agreements, exchange of letters, and confidentiality commitments to facilitate rapid and efficient information exchange and other cooperation
- Facilitating international technical cooperation and assistance activities and capacity building for emergency collaborations
- Implementing policies and procedures pertaining to emergency international travel and processing international travel requests
- Facilitating international visitors, as needed

C.1.11 Office of Administration

The Office of Administration (OA) provides executive direction, leadership, coordination, and guidance for the day-to-day operations of FDA; manages overall budgets and resources; oversees management and business activities across all FDA headquarters and field offices. OA also ensures that proper conduct of FDA's administrative and financial management activities, including budget, finance, acquisitions, information technology (IT), human resources (HR), organization, methods, and similar support activities, effectively support program operations. The Offices under OA that report to the Deputy Commissioner for Administration are: Acquisitions and Grants Services, Financial Operations, Information Management, Management, and Executive Operations.

C.1.11.1 Office of Acquisitions and Grants Services

The Office of Acquisitions and Grants Services (OAGS) is responsible for negotiating, awarding, and managing all contracts, Cooperative Agreements, interagency agreements, grants, administration of the purchase card program for the FDA, MOU, and technology transfers. OAGS is also responsible for writing acquisition policy, providing strategic business advice and support to our stakeholders, and liaising with the HHS' Senior Procurement Executive.

Administrative functions, such as payroll, travel, and timekeeping, will be provided by the administrative officer, director's administrative assistant, and other administrative support personnel.

C.1.11.2 Office of Financial Operations

Offices that comprise the Office of Financial Operations (OFO) plan, direct, and coordinate a comprehensive financial management operations program for FDA, encompassing the areas of budget analysis, execution, automated financial systems, fiscal accounting, internal financial audit, financial services related to accounts payable, travel support and payroll liaison, and financial reporting.

C.1.11.2.1 Office of Financial Management

The Office of Financial Management (OFM) is FDA's steward of financial assets and resources. OFM performs the following essential functions to support FDA's response to an emergency:

- **Budget Execution.** Apportions funds appropriated by Congress among components and oversees transfers of funds between components; this includes processing User Fees.
- **Accounts Receivable – User Fees.** Receives User Fee payments, which allows FDA's certification process to continue
- **Financial Statements and Reports.** Prepares the agency's financial statements and maintains its general ledger

C.1.11.2.2 Office of Financial Services

The Office of Financial Services is responsible for the following activities:

- Directs and coordinates operations for financial services related to accounts payable, travel support, and payroll liaison
- Monthly, Quarterly, and Yearly Closing – coordinates month-end, quarter-end, and year-end close of financial operations within Unified Financial Management System
- Maintains liaison with the Program Support Center (PSC) and the Defense Financial Accounting System (DFAS) representatives on issues relating to pay and leave and monitors the processes to ensure the successful payment to employees
- During an event when necessary, the Division of Travel Services may oversee the following: processing of vouchers and traveler's reimbursements; the GovTrip system; the agency's Travel Card and Centrally Billed Account Programs; and travel process for all State employees working in tandem with ORA employees.

C.1.11.3 Office of Information Management

OIM enables FDA's strategic efforts to transform and improve the information systems and infrastructure needed to support critical agency operations. The Office implements and enhances common systems to support FDA's regulated products. It also maximizes the availability and use of information technologies that increase or enhance electronic access for the public, as well as the full span of FDA's external and internal customer base, while maintaining effective security. OIM aligns IT investments to business goals that fully support core mission and business priorities and reduces costs of existing legacy systems. The Office consolidates, modernizes, and optimizes FDA's IT infrastructure, and provides the platform required for the agency to meet IT initiatives and to move towards the bioinformatics era of science-based decisions.

In an emergency or disaster, OIM is responsible for, but not limited to, the following activities:

- Ensuring the command and control of all reporting to OIM
- Ensuring computer room facilities (White Oak, Wiley, 2098 Gaither, Parklawn, and the managed hosting facility in Ashburn, VA) are functioning and coordinating with the appropriate building management to determine the building status
- Ensuring IT security services are available that are essential to protect FDA's IT assets and identifying and applying patches that will address the most critical security vulnerabilities
- Ensuring the availability of FDA local area network/wide area network (LAN/WAN) that will be critical for both field and local users to access agency IT resources

- Maintaining Internet services that are critical to the agency's ability to communicate with regulated industry and providing access to FDA's internal and external IT resources
- Ensuring Active Directory availability to provide authentication services when users log onto FDA systems
- Ensuring telephone availability, Voiceover Internet Protocol (VoIP) customer support, and continuity of agency e-mail/ BlackBerry services
- Monitoring the availability of agency Outlook Web Access (OWA)
- Managing and maintaining IT Help Desk and Application Support services
- Ensuring a Special Routing Arrangement Service (SRAS) infrastructure that will support 16,000 concurrent broadband users and approximately 350 dial-in users
- Ensuring FDA staff can perform non-standard queries and data extractions
- Ensuring agency computer application and file/print services
- Monitoring and maintaining the availability of applications and databases
- Procuring additional contract services or information system hardware/software components, as appropriate

C.1.11.4 Office of Management

The Office of Management (OM) is responsible for facility management and docket management. In an emergency or disaster, OM is responsible for, but not limited to, the following activities:

- Reviewing employee issues related to leave, flexiplace, social distancing, and other human resource issues; assessing the impacts of related decisions, such as building closures; issuing clear guidance consistent with the Office of Personnel Management (OPM), HHS, and other administration directives and policies while integrating program priorities and mission requirements; maintaining a clear line of communication on both an agency and individual level so that the implementation of policies is consistent and well understood across FDA
- Managing coordination of timekeeping functions and liaising with the Rockville Human Resource Center and the PSC to ensure FDA employees continue to receive compensation
- Ensuring that FDA facilities are safe and available for staff, and acquiring temporary facilities, if necessary
- Posting critical public information to the *Federal Register*
- Responding to Freedom of Information Act (FOIA) inquiries in accordance with Federal law
- Providing professional library research service support to FDA employees through the FDA Biosciences Library
- Ensuring effective employee administrative support through Employee Resource and Information Center (ERIC) call center operations
- Providing leadership and direction regarding all aspects of agency-wide human resources management
- Formulating policy and procedures necessary to maintain the integrity of privileged and trade secret information submitted by industry

- Providing coordination between FDA management and the Assistant Secretary for Health's Commissioned Corps programs; serving the FDA Centers, special assignments, and details to other organizations and initiatives
- Providing direct interface with the General Services Administration (GSA) for White Oak services

C.1.11.4.1 Office of Security Operations

The Office of Security Operations (OSO) has responsibility for agency-wide physical and personnel security programs, including the suitability and National Security Information program. In an emergency or disaster, OSO is responsible for, but not limited to, the following activities:

- Ensuring that the national security clearances of personnel assigned to various EOCs as part of a response are either sent to or received by the appropriate EOC
- Providing guidance on the proper handling, marking, processing, and storage of classified materials
- Coordinating agency COOP activities, which addresses how to continue agency operations when the availability of FDA facilities to accomplish agency work has been impacted by an emergency
- Ensuring the physical security of all nationwide FDA facilities; the Physical Security Branch may coordinate with on-duty security guard personnel regarding any temporary staff deployment issues that may arise during an emergency.

C.2 OFFICE OF REGULATORY AFFAIRS

ORA, led by the Associate Commissioner for Regulatory Affairs (ACRA), protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products. ORA is the lead office for all agency field activities and is composed of four headquarters offices—Resource Management, Criminal Investigations, Enforcement, and Regional Operations—as well as five Regional and 20 District Offices. In an emergency or disaster, ORA is responsible for, but not limited to, the following activities:

- Coordinating, interpreting, and evaluating the agency's overall compliance efforts, and advising and assisting the Commissioner and other key officials on regulations and compliance-oriented matters related to the incident
- Stimulating an awareness within the agency of the need for prompt and positive action to assure compliance by regulated industries, and working to assure an effective and uniform balance between voluntary and regulatory compliance and agency responsiveness to consumer needs
- Evaluating and coordinating all proposed legal actions to ascertain compliance with incident-related regulatory policy and enforcement objectives
- Executing direct line authority over all agency field operations; developing, issuing, approving, or clearing proposals and instructions affecting field activities; and serving as the central point within the agency through which headquarters offices obtain emergency field support services
- Providing direction and counsel to Regional Food and Drug Directors in the implementation of policies and operational guidelines that form the framework for emergency management of agency field activities
- Developing and/or recommending to the Commissioner emergency policy, programs, and plans for activities between the agency and State and local governments, administering the agency's overall Federal-State program and policy, and coordinating the program aspects of agency contracts with State and local counterpart agencies

- Evaluating the overall management and capabilities of the agency's field organization and initiating action to improve the management of incident-related field activities

C.2.1 Office of Regional Operations

ORO coordinates and manages all agency field operations, including the Prior Notice Center (PNC) on behalf of the ACRA. Any part of agency field operations or PNC may be called upon to respond to an emergency. ORO develops, issues, approves, and clears proposals and instructions affecting field activities and serves as the central point within the agency through which headquarters offices obtain field support services. ORO is composed of five divisions: Federal-State Relations, Field Investigations, Field Science, Import Operations, and Policy and the Prior Notice Center. Working together with the field, these divisions handle FDA's day-to-day and emergency operations at five Regional Offices, 20 District Offices, more than 165 resident posts, and 13 field laboratories, which comprise ORA's National Laboratory Resource. In an emergency or disaster:

- The Division of Federal-State Relations (DFSR) is responsible for, but not limited to, maintaining FDA's rapid communication system to State governments, major municipalities, and poison control Centers.
- The Division of Field Investigations (DFI) is responsible for, but not limited to, providing guidance and assistance in coordinating emergency field investigations.
- The Division of Field Science (DFS) is responsible for, but not limited to, preparing ORA laboratory response and monitoring surveillance database, and activation of FERN.
- The Division of Import Operations and Policy (DIOP) is responsible for, but not limited to, monitoring and controlling import and export activity associated with implicated product(s), countries, foreign manufacturers and shippers, filers, importers, and/or consignees; and coordinating targeted surveillance of imported products with the CBP.
- The PNC is responsible for, but not limited to, security monitoring of shipments of food for potential contamination with CBRN agents, identifying shipments with potential terrorist connections, and coordinating specific actions against suspect shipments with FDA field personnel, OCI and DHS CBP.

C.2.2 Office of Resource Management

Office of Resource Management (ORM) plans, manages, and evaluates field office operations. It also is responsible for the communications and information systems supporting field personnel. In an emergency or disaster, ORM is responsible for, but not limited to, the following activities:

- Advising the ACRA and Regional Food and Drug Directors on all areas of field office management, including financial management, management analysis, and administrative operations
- Providing technical input for ORA quality assurance program as it pertains to the consistency and adequacy of incident-related field investigational and inspectional operations
- Adjusting overall field manpower allocations based on incident requirements
- Implementing nationwide information storage and retrieval systems for data originating in the field offices

- Analyzing and evaluating field performance data and overall accomplishments and generating after action reports (AARs) pertaining to field resources used during emergency response operations[28]

C.2.3 Office of Criminal Investigations

OCI has primary responsibility for all criminal investigations conducted by FDA, including suspected tampering incidents and counterfeit products.[29] Similarly, OCI is the primary POC for all law enforcement and intelligence issues pertaining to threats or perceived threats against FDA-regulated products. It has special agents at FDA headquarters and in field offices nationwide. In addition, OCI maintains a full-time presence at the National Counter Terrorism Center (NCTC), the FBI's National Joint Terrorism Task Force (NJTTF), and the DHS. In an emergency or disaster, OCI is responsible for, but not limited to, the following activities:

- Advising and assisting the ACRA and other key FDA officials on regulations, criminal, counterterrorism, and intelligence matters
- Maintaining classified electronic connectivity with the U.S. Intelligence Community
- Directing FDA criminal investigation activities in coordination with other agency components and with other Federal, State, and local law enforcement agencies
- Implementing and enforcing agency policy related to criminal investigations
- Through field offices located throughout the United States, initiating and conducting criminal investigations under all statutes administered by FDA and coordinating assignments involving undercover and surveillance personnel and activities
- Ensuring coordination of criminal investigation activities with FDA Regional and District Offices and adherence to agency's enforcement priorities through cooperative relationships with field and headquarters organizational components
- Providing recommendations to OCC on referrals of criminal cases to the DOJ for further investigation and/or prosecution, or directly to the U.S. Attorney when such direct reference is authorized
- Maintaining automated data processing systems to be used for criminal investigations and related enforcement matters
- Participating in Grand Jury investigations and serving as agents of the Grand Jury

C.2.4 Office of Enforcement

Office of Enforcement (OE) advises and assists the ACRA and other key FDA officials on regulations and compliance matters that impact policy development, implementation, and long-range goals. The OE also coordinates, interprets, and evaluates FDA's overall compliance efforts and, as necessary, establishes compliance policy and recommends policy to the ACRA. This Office acts as liaison with other Federal Agencies on compliance matters, evaluates proposed legal actions, coordinates these actions with ORO and OCC, and handles appeals of proposed compliance actions which are disapproved by the Centers or OCC. In an emergency or disaster, the OE is responsible for, but not limited to, the following activities:

[28] Evaluation of field emergency operations occurs via the FDA Field Accomplishments and Compliance Tracking System (FACTS). Predefined Program Assignment Codes exist in FACTS that enable the monitoring of accomplishments and resources expended during a brief or extended response period.

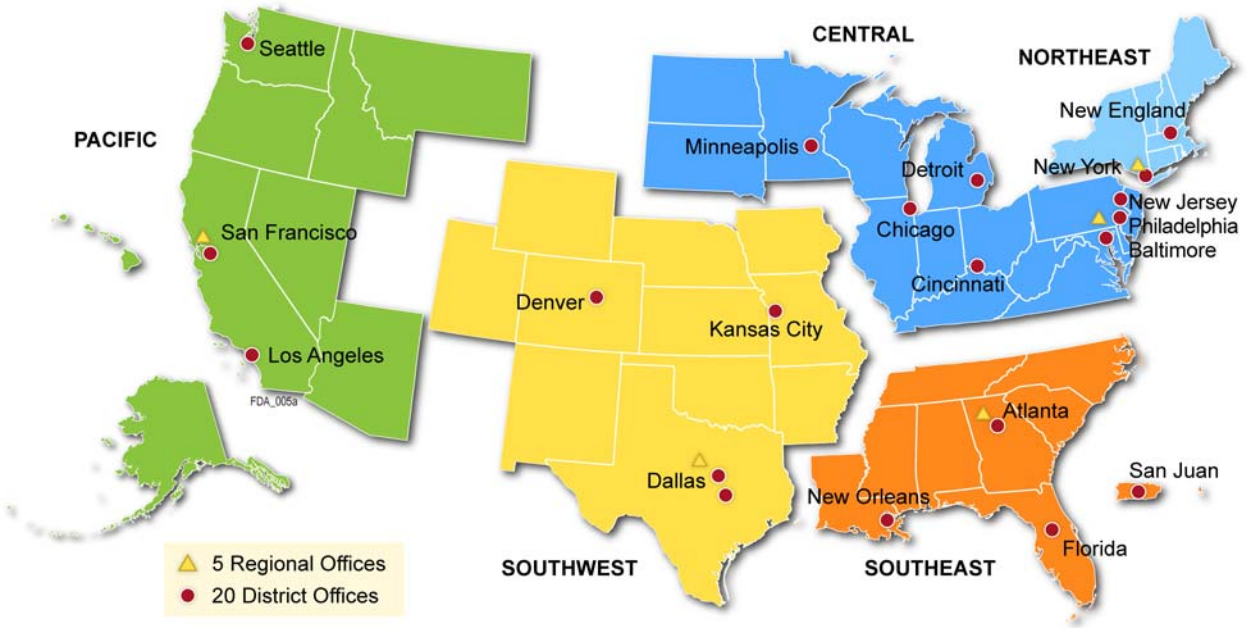
[29] Any deliberate contamination of an FDA-regulated product is a criminal act under Title 18 of the United States Code (USC), Section 1365 (tampering with consumer product).

- Developing compliance policy and recommending policy to the ACRA
- Serving as FDA's focal point for guidance on recall plans and procedures. Directing and coordinating field activities in support of all product recalls. Maintaining liaison with other FDA components, industry, and other Government agencies to ensure proper implementation and completion of recall plans and activities
- Coordinating multi-district or multi-Center enforcement actions against individuals and companies that violate the Federal Food, Drug, and Cosmetic Act
- Identifying unapproved, fraudulent, harmful, or ineffective FDA-regulated health products and initiating investigations, advisory or enforcement actions, and outreach activities when appropriate
- Serving as the FDA focal point for activities relating to the Federal Medical Products Quality Assurance Program and maintaining liaison with other Government agencies procuring medical supplies; issuing final administrative approval for quality assurance of specific products/firms

C.2.5 Regional and District Offices

FDA's field organization is divided into Regional and District Offices responsible for performing inspections, sample collections and analyses of both domestic and imported products, responding to local emergencies, and initiating enforcement actions for all of the agency's major product areas—foods, human drugs, biologics, animal drugs and feeds, and medical devices and radiological products. Five Regional Offices (Northeast, Central, Southeast, Southwest, and Pacific) are under the control of Regional Food and Drug Directors who report directly to the ACRA. Each Regional Office supervises two to seven District Offices, each led by a Director. There are currently 20 District Offices located in major cities around the country. **Figure C-3** illustrates the FDA Regional and District Offices across the Nation.

Figure C-3. FDA Nationwide



In addition to conducting normal surveillance over regulated products, FDA Regional and District Offices serve a critical emergency response function by immediately mobilizing to investigate reports of product

problems. These field organizations work to verify product information and secure any suspect products. They obtain additional information by reviewing records and examining products to focus follow-up actions and may collect samples for laboratory analysis. The Field staff also work with other Federal, State, tribal, territorial, and local agencies to detain, seize, and/or embargo products in support of public health protection and State and local government agencies; request State officials to hold suspect products; issue requests for voluntary holds or suspension of operations of industry; request and monitor industry recalls; conduct necessary inspections; conduct traceback[30] investigation work; and monitor the effective disposition of adulterated/misbranded product.

C.2.5.1 Forensic Chemistry Center

The Forensic Chemistry Center (FCC) located in the Central Region of ORA, reports directly to the Regional Director. Its personnel perform laboratory research and analyses on a day-to-day basis, regularly providing expert technical support for FDA's OCI as its primary laboratory. The laboratory also provides forensic analyses of samples for the rest of ORA, the Office of the Commissioner, CFSAN, CDER, CVM, CDRH, and other Federal and State agencies. The FCC plays a major role in many programs initiated by FDA, particularly anti-counterfeiting, anti-tampering, and counterterrorism.

C.2.5.2 Winchester Engineering and Analytical Center

Winchester Engineering and Analytical Center (WEAC) located in the Northeast Region of ORA, reports directly to the Regional Director. WEAC hold FDA's U.S. Nuclear Regulatory Commission's Materials License, and its personnel perform radionuclide-related laboratory research and analyses on a day-to-day basis. WEAC serves as FDA's sole radiation analytical laboratory and provides radioanalytical analyses for samples as well as lead responsibilities for the radiation safety program for ORA field offices.

C.3 FDA PRODUCT CENTERS

The FDA product Centers are responsible for the regulation of a defined set of products. Their professional staff includes both clinical and scientific experts. This expertise (analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is available for critical consultation should an emergency or disaster occur. They are responsible for scientific evaluations, decisions in conjunction with ORA in response focus based on scientific evaluations, and policy decisions within their respective program areas. FDA product Centers participate in emergency operations when the agency response includes, or may include, regulatory activities or products under their jurisdiction. The Centers are each led by a Director, reporting directly to the Commissioner, and include: the Center for Biological Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Center for Food Safety and Applied Nutrition, the Center for Tobacco Products, and the Center for Veterinary Medicine.

C.3.1 Center for Biologics Evaluation and Research

CBER ensures the safety, efficacy, and quality of biological products (including blood and blood products, vaccines, tissues, and cellular and gene therapies) potentially used as medical countermeasures. In an emergency or disaster, CBER is responsible for, but not limited to, the following activities:

- Providing sponsors and other stakeholders with guidance on the use of biological products as medical countermeasures
- Using sound science and regulatory expertise to review, evaluate, and license new biological products that are safe, effective, and of high-quality standards

[30] For more information on how the FDA conducts traceback investigations, refer to the FDA EOP Appendix H, "Domestic and International Traceback/Traceforward."

- Facilitating the availability of safe and effective vaccines, blood and blood products, cells, tissues, gene-therapies, devices, and other biological products used to prevent and treat disease outbreaks
- Collaborating with public health agencies regarding biologics stockpile issues, including labeling, appropriate usage, product performance, monitoring, use in special populations, and other evolving issues
- Ensuring compliance with current good manufacturing practices (GMP) for all regulated manufacturers
- Providing regulatory guidance on the use of unapproved products or unapproved uses of approved products
- Processing EUA requests for biological products after a public health emergency is declared by the Secretary
- Providing information regarding manufacturers' compliance with current GMP and other relevant product quality issues
- Assisting in the assessment of potentially contaminated biological products
- Assessing the availability, production capacity, and surge capacity for biologic products used as medical countermeasures and providing information on alternative sources of critical medical countermeasures in shortage situations
- Managing CBER laboratory testing and lot release capabilities
- Communicating information, including risk information, about biological products to industry, consumers, State, territorial, tribal, and local governments, and other stakeholders
- Conducting post-marketing surveillance and enforcement activities relating to biological products

C.3.2 Center for Drug Evaluation and Research

CDER ensures the safety, efficacy, and quality of drugs (including prescription and over-the-counter drugs, both brand name and generic) and therapeutic biological agents for use as medical countermeasures. In an emergency or disaster, CDER is responsible for, but not limited to, the following activities:

- Providing sponsors and other stakeholders with regulatory guidance on the development and use of medical countermeasures against CBRNE agents or emerging infectious threats (e.g., severe acute respiratory syndrome [SARS] and 2009 H1N1) when there is no FDA approval for the product or proposed indication or when another issue would cause the product to be considered adulterated or misbranded
- Facilitating communications with manufacturers on adverse event reporting during an emergency
- Collaborating with public health agencies regarding drug and therapeutic biologic product stockpile issues, including labeling, appropriate usage, product performance, monitoring, use in special populations, product expiry (e.g., the Shelf Life Extension Program), and other evolving issues
- Processing EUA requests for drugs and therapeutic biologic agents after a public health emergency is declared by the Secretary
- Providing information to manufacturers regarding compliance with GMP and other relevant product quality issues, including extension of product expiry

- Assessing the availability, production capacity, and surge capacity of drugs and therapeutic biologic products used as countermeasures and providing information on alternative sources of critical medical countermeasures in shortage situations
- Managing CDER laboratory capabilities
- Monitoring media and marketplace for counterfeit or violative drugs (or advertising) of particular relevance to the emergency
- Enhanced monitoring and evaluation of adverse events associated with products relevant to the emergency
- Reviewing public communications related to CDER-regulated products relevant to the emergency

C.3.3 Center for Devices and Radiological Health

CDRH ensures the safety, efficacy, and quality of medical devices, including in-vitro diagnostics and radiological products. In an emergency or disaster, CDRH is responsible for, but not limited to, the following activities:

- Processing EUA requests for medical devices (diagnostics, personal protective equipment [PPE], and radiological products) after a public health emergency is declared by the Secretary
- Facilitating the development, regulatory review, and production of diagnostic devices, PPE, and other devices that may be needed
- Conducting post-market surveillance to monitor the safety and effectiveness of devices used, including for diagnosis, therapeutics, PPE, and supportive care
- Supporting efforts to ensure an adequate supply of devices through cooperative interactions with manufacturers and distributors and coordination with the Strategic National Stockpile (SNS) to determine the adequacy of stocks and actions required to meet targeted amounts
- Using an emergency shortages database to identify and monitor supplies of certain devices that are or have the potential to be in demand
- Educating device users on how to use devices in a safe and effective manner
- Collaborating with public health agencies regarding product stockpile issues, appropriate usage, labeling, product performance, monitoring, use in special populations, and other evolving issues
- Communicating information, including risk information, about medical devices and radiation-emitting products to industry; consumers; State, territorial, tribal, and local governments; and other stakeholders

C.3.4 Center for Food Safety and Applied Nutrition

CFSAN, in conjunction with the agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the Nation's food supply is safe, sanitary, wholesome, and honestly labeled and that cosmetic products are safe and labeled properly. CFSAN has the authority to regulate food producers and distributors involved in interstate commerce. It also determines whether data collected by another agency or organization are adequate for FDA decisions regarding food and cosmetic issues. In an emergency or disaster, CFSAN is responsible for, but not limited to, the following activities:

- Collaborating with other public health agencies and industry regarding food contaminants and other monitoring programs for foodborne illness

- Providing critical information on food safety and regulatory issues to consumers, industry, and other Federal, State, local, territorial, and tribal governmental and international entities (all levels of the food chain)
- Protecting human health through regulatory, legal, and administrative actions
- Participating actively in legal proceedings critical to the safety and defense of the food supply
- Using import alerts to prevent unsafe food and cosmetic products from entering the United States
- Facilitating coordination of food contamination investigations between FDA and the States
- Identifying foods that are at elevated risk of contamination and investigating the effectiveness of food processing and preparation practices
- Developing and disseminating recommendations on measures to prevent the contamination of FDA-regulated foods and cosmetics
- Developing and evaluating analytical methods for identifying food and cosmetic contaminants
- Critically reviewing cases and other regulatory actions sent from the Office of Compliance to evaluate whether proposed regulatory action is supported by findings and providing policy and technical input to FDA field investigations
- Identifying and training a cadre of CFSAN personnel for potential rapid deployment to the FDA EOC, to HHS, and to external organizations to provide support for contingency functions

C.3.5 Center for Tobacco Products

CTP is responsible for protecting the public's health by restricting the marketing and access of tobacco products to minors; regulating the manufacturing, distribution, and labeling of tobacco products; setting tobacco products standards; requiring registration of tobacco manufacturers; and requiring ingredient and constituent listings for tobacco products. In an emergency or disaster, CTP is responsible for, but not limited to, the following activities:

- Collaborating with other public health agencies to communicate information regarding tobacco product contaminants and to coordinate monitoring for patterns of exposure and illness
- Protecting human health through regulatory, legal, and administrative actions
- Participating actively in legal proceedings critical to ensuring compliance with tobacco product regulatory standards
- Facilitating coordination of tobacco product contamination investigations between FDA and State, territorial, local, and tribal governmental and international entities
- Identifying tobacco products that are at elevated risk of contamination and investigating the effectiveness of tobacco processing and preparation practices
- Developing and disseminating recommendations on measures to prevent the contamination of tobacco product
- Developing and evaluating analytical methods for identifying tobacco product contaminants
- Critically reviewing cases and other regulatory actions sent from the Office of Compliance to evaluate whether proposed regulatory action is supported by findings and providing policy and technical input to FDA field investigations
- Enhanced monitoring and evaluation of adverse events associated with products relevant to the emergency

- Communicating information, including risk information, about tobacco products to industry; consumers; State, territorial, tribal, and local governments; and other stakeholders
- Ordering a stop to the distribution of a tobacco product and recalling a tobacco product relevant to the emergency

C.3.6 Center for Veterinary Medicine

CVM ensures the safety, efficacy, and quality of drugs for animals, including food-producing and companion animals, animal food and feed, and medical devices used on animals potentially threatened by an incident. In an emergency or disaster, CVM is responsible for, but not limited to, the following activities:

- Protecting animal and human health through regulatory, legal, and administrative actions
- Actively participating in legal proceedings critical to the safety of the food and feed supply
- Using import alerts to prevent unsafe products from entering the United States
- Facilitating coordination of meat and milk residue investigations between FDA and the States
- Providing sponsors and other stakeholders with guidance on the use of animal drugs that serve as potential medical countermeasures in animals
- Providing information on critical safety and regulatory issues to stakeholders, consumers, industry, veterinarians and other government officials
- Collaborating with public health agencies regarding feed contaminant, tissue residue programs, and other monitoring programs for meat and poultry products
- Providing information regarding manufacturers' compliance with GMP and other relevant animal drug product quality issues
- Providing technical advice and assistance in the assessment of animal drug or feed product possibly affected
- Assessing the availability, production capacity, and surge capacity of animal drugs, and providing information on alternative sources of critical products in shortage situations
- Providing an assessment on the diversion of contaminated human food for animal feed use
- Providing advice to pet owners regarding animal safety measures

C.4 FDA Research Center

C.4.1 National Center for Toxicological Research

NCTR conducts FDA mission-critical scientific research to support and anticipate FDA's regulatory needs. This research is targeted to understand critical biological events in the expression of toxicity and to develop and characterize methods and incorporate new technologies to improve the assessment of human exposure, susceptibility, and risk. In an emergency or disaster, NCTR is responsible for, but not limited to, the following activities:

- Responding to RFIs from the Commissioner, other FDA Centers, and Federal Agencies
- Providing SME consultations to support informed decisionmaking in responding to health-related issues associated with the incident.

D DIRECTION, CONTROL, AND COORDINATION

FDA organizes emergency response operations in accordance with the concepts, principles, and terminology of the ICS, as defined within *NIMS*.[31] Incident Command and subordinate Planning, Operations, Logistics, and Finance/Administration functions lay the foundation for the agency's implementation of the ICS during all-hazards response, at headquarters and field levels, and across geographic divides. The inherent design of this system enables rapid, scalable, and flexible agency-wide emergency management activities. **Figures D-1 and D-2** depicts FDA's emergency response coordinating structure and is followed by a brief description of each designated ICS position.[32]

Section D describes FDA's application of the ICS. It is important to remember that two key principles of ICS are its scalability and flexibility. Emergency and disaster situations can be unpredictable and dynamic. To accommodate this, the ICS organizational structure was developed to be expanded easily from a very small size for routine operations to a larger organization capable of handling catastrophic events. Therefore, the agency's organizational structure, while containing certain core positions, must be tailored to the specific requirements of each incident. Refer to the *FDA EOP*'s Incident Annexes for detailed information on FDA organizational constructs for individual hazards.

For individual Center/Office emergency response organizations within this basic structure, refer to each organizational component's EOP and/or SOPs.

D.1 FIELD INCIDENT COMMAND

The use of Incident Command in the field is achieved through the establishment of an IMT at appropriate field location(s) to identify field incident response objectives and execute the tactical implementation of headquarters' strategic plan for responding to an incident. IMTs can follow a Regional or District strategic plan in addition to or in the absence of a headquarters plan. An IMG and IMT may or may not mobilize and/or demobilize concurrently.

The Field IC(s) will direct the field personnel to conduct tactical operations to determine the cause/source of the crisis and/or resolve the crisis, in accordance with the incident action plan they develop and, in some cases, based on information, analysis, and direction received from the IMG. Depending on the nature and stage of the emergency, these operations might include, among other things, facility or field inspections, sample collection, laboratory analysis, traceback and traceforward investigations, import-related activities, recall efforts, and enforcement actions. In conducting these operations, Incident Command might interact with regulated entities, FDA headquarters, State and local officials, other Federal Agencies, foreign regulatory authorities, and regional/local news media[33].

When appropriate, the FDA field IC may be part of a Unified Command with multiple ICs representing different agencies (e.g., FDA and a State health agency) or jurisdictions (e.g., Federal, State, and local). The field may also be requested to provide a Liaison Officer to a regional or local Unified Command.

An IMT functions in accordance with ICS principles and is headed by an IC who may establish Operations, Planning, Logistics, and/or Finance/Administration Sections as needed to manage the agency's on-the-ground response (Figure D-1).

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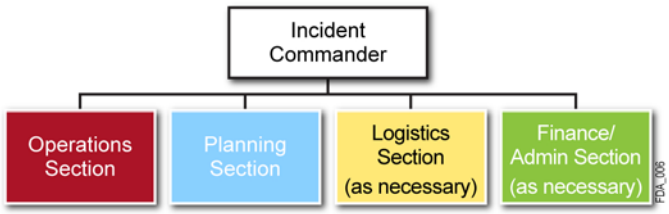
[31] For more information on the ICS, refer to www.training.fema.gov/EMIWeb/IS/ICSResource/index.htm.

[32] Depending on the level and complexity of incident requirements, certain Agency ICS functions and positions may not be necessary. Refer to the FDA EOP, Incident Annexes for specific personnel assignments.

[33] The Public Information Officer (PIO) coordinates development and release of agency public health and consumer protection messages for use with the public, media, and/or other agencies with approval from FDA headquarters and HHS.

Figure D-1. FDA Field Incident Management Team



When multiple district IMTs are involved in responding to the same incident, an Area Command Structure may be established to oversee the management of the incident. When multiple agencies are responding at the field level to the same incidents, a Unified Command may be used in the field to establish a common set of objectives and strategies and a single IAP. If multiple agencies and jurisdictions are responding at field level to the same incident, a Unified Area Command can be used in the field to provide command authority and coordination.

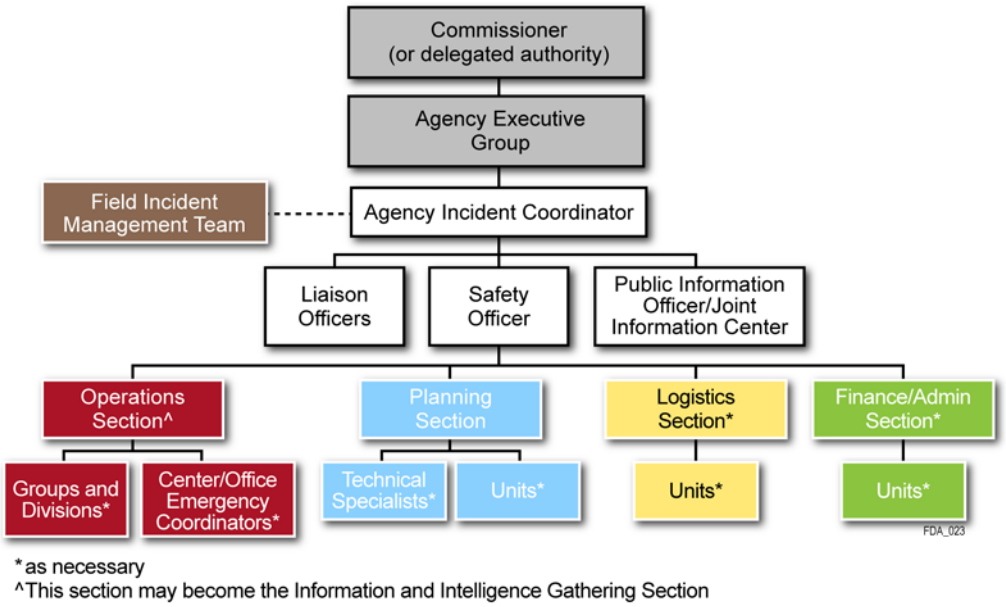
D.2 HEADQUARTERS INCIDENT COORDINATION

When necessary, headquarters will establish an incident coordination structure referred to as the IMG. (See *Section B.2.2.3.3 FDA Headquarters Response – Incident Management Group* regarding what officials have the authority to establish an IMG.) The IMG facilitates the integration of all FDA assets responding to an incident as required by the NRF. As the agency's coordination structure, the IMG serves as the focal point for headquarters-level strategic coordination and provides recommendations for actions to take and the priorities for the use of resources in support of incident management. The IMG has the general oversight of the application of FDA resources in coordination with existing agency and interagency resource management. It provides strategic situational awareness and decision support across the full spectrum of incident management domains—awareness, prevention, protection, response, and recovery.

Because of FDA's unique organizational structure, which involves emergency response resource and capabilities from multiple Centers and Offices, the FDA IMG coordinates unified agency responses to incidents, which is somewhat similar to an area command. The goal of the IMG is to facilitate a comprehensive, integrated, and coordinated approach to domestic and international incident management.

For its coordination structure, FDA may adapt the incident command structure to address the scope of the incident, which at times acts as a hybrid coordination and command structure as in the case of an influenza pandemic response. Figure D-2 is an example of how an IMG may be organized. This structure is flexible and parts of it may be expanded or contracted.

Figure D-2. FDA Headquarters Incident Management Group



D.2.1 Command Staff

D.2.1.1 Agency Incident Coordinator

The AIC has overall delegated authority and responsibility for agency-wide emergency operations and ensures information review for appropriate action, including referral to the Commissioner or AEG for executive-level direction or to headquarters or field units for any necessary follow-up. In addition, the AIC serves as the central point for headquarters coordination regarding issues and decisions involving FDA organizational components, the HHS SOC, other HHS OPDIVs, applicable Federal and State agencies, and foreign governments. The AIC is responsible for assigning the Operations and Planning Section Chiefs, or when these additional persons are not required, personally accomplishing or managing these aspects of the incident organization. This position may operate from his/her normal work location if equipped to address incident requirements or at the FDA EOC. [34] If headquarters ICS is activated, the AIC and designated support staff will be physically located in the EOC.

Until the Commissioner, Deputy Commissioner, or other designated senior agency official appoints an AIC for any emergency or disaster involving multiple FDA organizational components and/or requiring external coordination, the Director of OCM/OEO will serve as the AIC and report to the Commissioner or his/her authorized designee. He/she is responsible for coordinating and providing situational awareness on all incident activities performed at the headquarters and field levels.

The AIC responsibilities are to:

- Develop broad objectives for agency-wide emergency response operations
- Coordinate with engaged headquarters and field Centers/Offices in the development of individual incident objectives and strategies
- Allocate/reallocate agency resources as the established priorities change
- Ensure effective communications between headquarters and field organizational components
- Ensure that overarching incident management objectives are met and do not conflict with each other or with agency policies

[34] Refer to Appendix K, "Job Action Sheets," for the specific time-phased emergency actions of the AIC.

- Identify and report on critical agency resource needs
- Facilitate FDA's transition to full recovery operations

The FDA Command Staff at headquarters and possibly in the field includes a Public Information Officer (PIO) and Liaison Officers who report directly to the AIC. Additional Command Staff positions may be required, depending on the nature, scope, complexity, and number of locations of the incident(s), or according to specific requirements established by the AIC. At headquarters, a Legal Advisor may be assigned to the Command Staff as a technical specialist or to the Planning Section to advise Incident Command on legal matters, such as emergency proclamations, and the legality of emergency use authorizations (legal rights and restrictions pertaining to product use). Similarly, a Medical Advisor or Science Advisor may be designated and assigned directly to the Command Staff to provide advice and recommendations to Incident Command in the context of incidents involving medical and public health response or medical countermeasures considerations. Command Staff positions are discussed below.[35]

D.2.1.2 Liaison Officers

Liaison officers (LNOs) interface or report from external Federal Agencies (i.e., HHS, CDC, USDA, EPA, DHS, FBI, or DOS) as representation to FDA during an incident. These Command Staff members serve as direct links between the AIC and their agency, to provide input on their agencies' policies, activities, concerns, resource availability, and other incident-related matters. These LNOs are responsible for maintaining an awareness of the situation, reporting relevant information, and facilitating communication regarding FDA requests for assistance from the LNO's agency. Staffs assigned to these positions must have the authority to speak for their parent agencies or organizations on all matters, following appropriate consultations with their agency leadership. Assistants and personnel from other agencies or organizations, public or private, involved in incident management activities may be assigned to the LNO to facilitate coordination. There may be a need for a liaison with industry.

Direct liaison with the U.S. Law Enforcement and Intelligence Communities will be coordinated by OCI.

D.2.1.3 Safety Officer

The Safety Officer monitors incident operations and advises the AIC on all matters relating to operational safety, including the health and safety of emergency responder personnel. The Safety Officer is, in turn, responsible to the AIC for the systems and procedures necessary to ensure ongoing assessment of hazardous environments, including the incident Safety Plan, coordination of multiagency safety efforts, and implementation of measures to promote emergency responder safety as well as the general safety of incident operations. The Safety Officer has immediate authority to stop and/or prevent unsafe acts during incident operations. It is important to note that the agencies, organizations, or jurisdictions that contribute to joint safety management efforts do not lose their individual identities or responsibility for their own programs, policies, and personnel. Rather, each contributes to the overall effort to protect all responder personnel involved in incident operations.

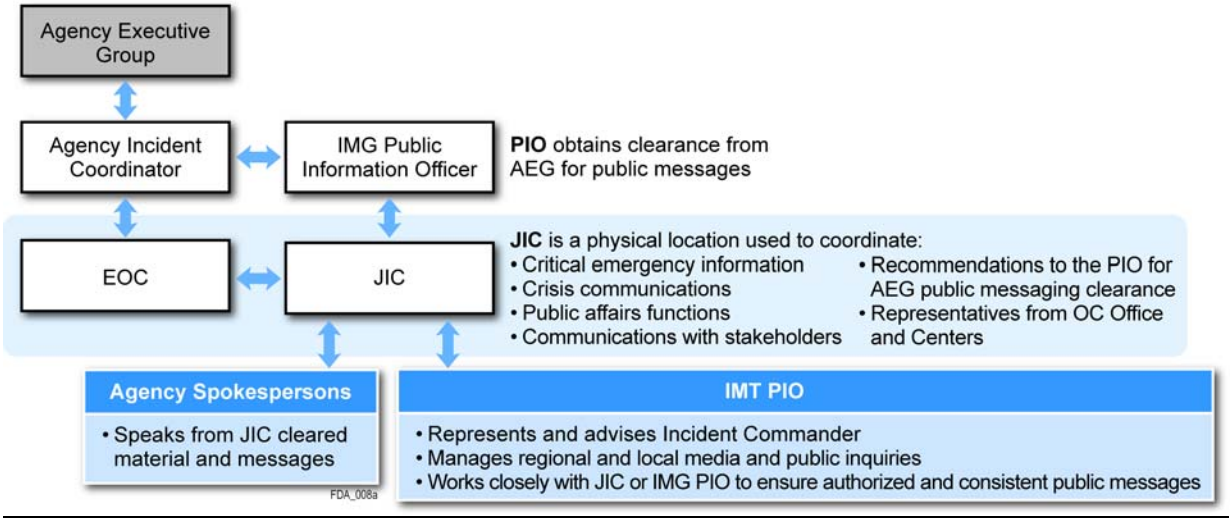
D.2.1.4 Public Information Officer

The headquarters IMG PIO serves as a liaison between the AIC and the agency's primary Office for managing the news media and public messages. The PIO serves as the contact for other governmental organizations PIOs and serves as FDA's lead for the Internal Joint Information Center. The FDA PIO maintains regular communications with OEA as well as other Center and Office (i.e., OER, OPA, and OIP) public affairs and communications staffs and informs the IMG of any associated public information activities, concerns, and information requests. The PIO obtains clearance from the AEG, which the Associate Commissioner for OEA is a standing member of (see Section D.5 for description of AEG), and HHS for public messages. This individual is not necessarily the incident spokesperson but the coordinator

[35] Refer to Appendix K, "Job Action Sheets," for specific time-phased emergency actions of the Command Staff.

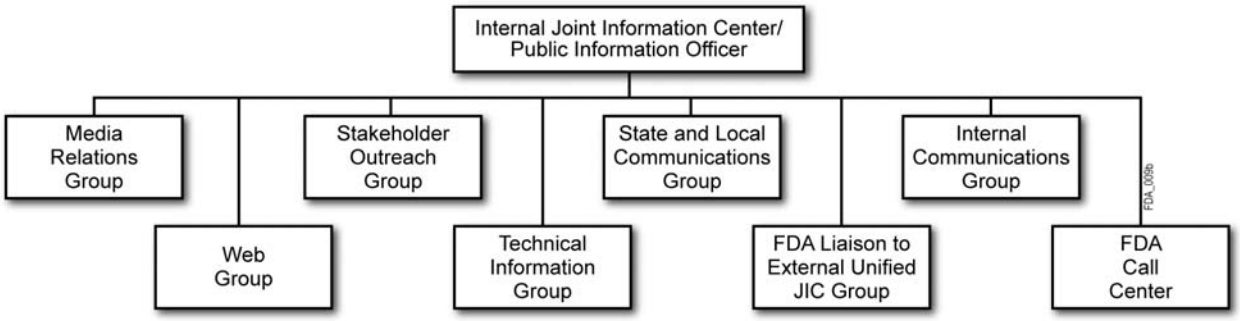
of the message development and dissemination. In addition to the headquarters role, there may be one or morea field IMT PIOs. The relationship between these entities is illustrated in the figure below. Proper media clearance channels through HHS are not superseded by the figure below.

Figure D-3. FDA's Joint Information System



The ICS offers flexibility in determining the right structural approach for the specific circumstances of the incident at hand. The following groups may be activated to support a PIO or as part of a JIC.

Figure D-4. FDA Joint Information Center Possible Structure



D.2.1.4.1 Internal Joint Information Center

Dependent on the incident's strategic communication objectives, the FDA PIO's responsibilities may be shared among other individuals and Offices in a JIC as part of a larger Joint Information System.[36] FDA's

[36] **Joint Information System:** Integrates incident information and public affairs into a cohesive organization designed to provide consistent, coordinated, accurate, accessible, timely, and complete information during crisis or incident operations. The mission of the JIS is to provide a structure and system for developing and delivering coordinated interagency messages; developing, recommending, and executing public information plans and strategies on behalf of the IC; advising the IC concerning public affairs issues that could affect a response effort; and controlling rumors and inaccurate information that could undermine public confidence in the emergency response effort.

JIC is a physical or virtual co-located group of representatives from the FDA Offices and Centers involved in the event, who are designated to handle public information needs. The JIC monitors and assesses the need for and effectiveness of public messaging regarding the incident and FDA's response. The JIC makes recommendations to the PIO for AEG clearance regarding needed public messaging. Public messages include consumer, industry, congress, health professionals, and other targeted audiences.

To facilitate timely communication among its members, the JIC may designate a physical location within FDA facilities. If such an arrangement is not possible, the JIC may function as a group using electronic communications such as conference calls, e-mails, and instant messaging. The FDA JIC will be activated when the PIO and the AIC deem it will benefit the incident objectives to have the communication strategies coordinated in the same physical location or by electronic communications. C/O representatives will be requested to participate in the FDA JIC.

FDA may send a representative to an external unified JIC. This is a co-located or collaborating group of representatives from external agencies and organizations involved in the event, who are designated to handle public information needs. This representative will act as a liaison with FDA's JIC and report back to the FDA PIO (see D.2.1.4.6).

D.2.1.4.2 Media Relations Group

The Media Relations Group typically is composed of staff from the Office of External Affairs, specifically the Office of Public Affairs, the Office of External Relations, and relevant Centers. They are responsible for the following:

- Creating a media list and conducting outreach to members of the media
- Drafting all press material, including but not limited to news releases, media advisories, media statements, fact sheets, and Q&A documents
- Assisting in the development of messages, including the key message platform, talking points, speaker remarks, and internal Q&A documents
- Coordinating media events, including but not limited to media teleconferences, press conferences, and satellite media tours
- Coordinating development of audio and video packages to be posted on FDA.gov and shared with external video Web sites
- Assisting the Communications Chief in coordinating Spokesperson interviews and clearing press materials

D.2.1.4.3 Web Group

The Web Group is typically composed of staff from the OEA/OPA/Web Communications Staff and representative(s) from relevant Center(s) who are responsible for the following:

- Developing a "personalized Web site" for the emergency response effort
- Providing and updating the Web site with all public information about the emergency
- Working with OPA, OER, and OSHI to develop outreach tactics, including but not limited to, blogs, widgets, Really Simple Syndication (RSS) feeds, and mobile communications

D.2.1.4.4 Stakeholder Outreach Group

The Stakeholder Outreach Group is typically composed of staff from OEA's OER, Office of Special Health Issues, and Office of Legislation as well as the relevant Center as needed. It has the following responsibilities:

- Creating a list of interested stakeholders, including but not limited to healthcare providers, patient groups, trade organizations, consumer groups, academics, retail outlets, minority organizations, and industry
- Coordinating outreach to all stakeholders; this includes consumer materials that explain the issue in consumer-friendly language, including but not limited to articles, Q&A documents, and graphics.
- Coordinating stakeholder briefings, roundtable discussions, and teleconferences on the incident

Depending on the nature of the incident, Patient/Healthcare Provider Outreach, Congress, and International Groups may be created to facilitate targeted communications.

D.2.1.4.5 Technical Information Group

The Technical Information Group may be formed to support the JIC PIO and the Media Relations, Web, and Stakeholder Outreach Groups. The Technical Information Group is comprised of staff with technical knowledge specific to the incident and is typically composed of staff from OEA and/or the relevant product Center(s). It has the following responsibilities:

- Developing content that would be used for public and news media materials, including but not limited to news releases, media advisories, media statements, fact sheets, and Q&A documents.
- Researching technical, scientific, industry, audience and regulatory information related to the incident

D.2.1.4.6 State and Local Communications Group

The State and Local Communications Group, typically comprising staff from ORA/DFSR, has the following responsibilities:

- Creating a list of DFSR State/local agencies to conduct outreach with regarding the emergency
- Coordinating briefings and 50-State stakeholder calls
- Providing information and outreach instructions to FDA field Public Affairs Specialist

D.2.1.4.7 FDA Liaison to External Unified Joint Information Center

An FDA Inter-Agency Communications Liaison may be onsite at a unified JIC, a co-located group of representatives with public information responsibilities from agencies involved in the response tasked with performing critical emergency information and public affairs functions. A single unified JIC location is preferable, but a virtual or multiple JIC locations may be used, as required.

FDA's liaison to a Unified JIC is responsible for:

- Establishing and maintaining communications with public information staff from other agencies involved in the response at all levels of government
- Ensuring the delivery of timely, accurate, consistent, and accessible information to the public
- Coordinating with other government departments and agencies at all levels the dissemination of information to the public within jurisdictional areas of responsibility
- Participating in the development, coordination, and dissemination of information to the public and media concerning the emergency; actions being taken to ensure the health, safety, and security of the public; and steps the public should take to protect themselves from harmful product(s)

The establishment of a unified JIC does not interfere with or replace ongoing interagency communications critical to the sharing of information needed for the strategic coordination of response activities.

D.2.1.4.8 Internal Communications Group

The Internal (FDA) Communications Group is responsible for providing updates to FDA staff through Commissioner All-Hands messages and Inside.FDA communications. The Internal Communications Group may comprise staff from the Office of Chief of Staff, Office of Administration, and relevant Centers.

D.2.1.4.9 FDA Call Center

During an emergency, FDA's after-hours call center may be activated during normal business hours to assist with managing a surge of incoming public inquiries and/or reports of illness or injury related to FDA-regulated products. FDA has defined a surge as a 20 percent to 50 percent increase in the normal daily call volume to the Office of Emergency Operation during normal business hours. The average number of calls as defined by FDA is approximately 20 calls per business day between the hours of 8:00 a.m. and 4:30 p.m. EST Monday through Friday. The Call Center Coordinator will work with other members of the FDA JIC to ensure consistency and accuracy in the information disseminated through the Call Center. FDA SMEs may be called upon to support or assist the Call Center.

D.2.1.5 Technical Advisors

Dependent on the incident, other technical advisors to the AIC may be included who are not traditionally part of an incident command structure but whose role would be instrumental with FDA response coordination.

D.2.1.5.1 Legal Advisor

The Legal Advisor provides advice to the AIC on issues that involve application or interpretation of relevant statutes and regulations. For example, in some situations involving possibly adulterated food, the Legal Advisor might advise the IMG on the legal aspects of requesting records from food facilities under Section 414 of the Federal Food, Drug, and Cosmetic Act (the Act). The Legal Advisor also reviews any EUA requests that might be submitted to the agency regarding medical countermeasures needed to protect responders and the public. In addition, the Legal Advisor considers legal issues in media releases and other documents prepared for the crisis response. The Legal Advisor usually is a manager or other senior attorney in OCC.

D.2.1.5.2 Science/Medical Advisor

The Science/Medical Advisor advises the AIC and the Section Chiefs on scientific and/or medical issues that arise during the response. The Advisor will have expertise in the scientific and/or medical aspects of the crises and will typically be a staff member from the lead Center(s) for the emergency.

D.2.1.5.3 International Advisor

The International Advisor, a staff member from OIP, advises the AIC and the Section Chiefs on international issues that arise during the response.

D.2.1.5.4 Emergency Use Authorization/Product Interface Advisor

The EUA/Product Interface Advisor, typically a staff member from OCET, advises the AIC and Section Chiefs on emergency use and other medical countermeasures issues that arise during the response. The EUA/Product Interface advisor also leads the coordination of cross-agency activities related to medical countermeasure use and availability activities.

D.2.2 General Staff

The General Staff is responsible for the functional aspects of any ICS. The General Staff consists of Operations, Planning, Logistics, and Finance/Administration Sections composed of designated FDA headquarters and field emergency staffs. The responsibilities associated with assignments to these sections are discussed more fully below.[37]

D.2.2.1 Operations Section

The Operations Section is responsible for coordinating all agency activities in response to an identified threat or hazard, establishing an agency-wide common operating picture, and restoring normal operations. This section may be composed of a Section Chief, Divisions, and Groups (each led by a designated Supervisor). **Figure D-5** depicts FDA's Operations Section.

Figure D-5. Operations Section Organizational Elements

Expansion or contraction of the Operations Section may vary according to numerous considerations and operational factors associated with an incident. In some cases, a functional approach may be used. In other cases, the organizational structure will be determined by geographical or Center/Office jurisdictional boundaries or a mix of functional and geographical considerations may be appropriate. Information and Intelligence Gathering could be one of these functions that may become its own section. The AIC will determine the appropriate structural approach based on the specific circumstances of the incident at-hand.

D.2.2.1.1 Operations Section Chief

Until the AIC appoints an Operations Section Chief, an Emergency Coordinator from OCM/OEO will fulfill the role. The Operations Section Chief is responsible to the AIC for managing incident activities required in order to implement the agency IAP, as well as providing the AIC with regular status reports. The Operations Section Chief monitors initial and ongoing headquarters and field response activities; advises and assists the AIC on appropriate courses of action; responds to requests for assistance from internal organizational components and external partners; and coordinates regular status/situation updates throughout the lifecycle of the incident. He/she has direct involvement in providing input to and implementing the IAP and serves as the focal point for intra- and interagency coordination and communications. The Operations Section Chief is co-located with the AIC at the FDA EOC.

D.2.2.1.2 Divisions and Groups

Divisions may be established within the Operations Section to assign responsibility based on the physical/geographic location(s) of an emergency or major disaster. Groups may also be assembled to combine similar activities being addressed for a single or multiple incident(s). For example, Geographic Divisions may be created in support of a single or multiple responding FDA Regions/Districts or to coordinate operations when a foreign country is involved. Functional Groups, on the other hand, may include personnel addressing investigations, enforcement, traceback, laboratory analysis, and other issues depending on the nature and scope of the incident. These tasks may be grouped under

[37] Refer to Appendix K, "Job Action Sheets," for specific time-phased emergency actions of the General Staff.

Information/Intelligence Gathering in the Operations Section or become their own section. Divisions and Groups are staffed by representatives from OC, ORA, and Centers and may change both in designation and composition based on the specific incident requirements. They typically operate from the FDA EOC or alternate work space locations as needed. A Supervisor shall be designated for each to oversee operations and provide status/situation reporting to the Operations Section Chief.[38]

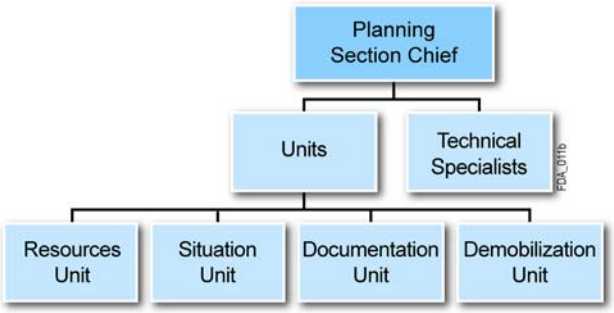
D.2.2.1.3 Center/Office Emergency Coordinators

FDA product Centers and OC Offices shall designate a senior staff member, and alternates, to serve as the Center/Office Emergency Coordinator (C/O EC). The C/O EC is responsible for advising the Center/ Office Director of actions needed to address an incident, supervising and reporting on the Center's/ Office's emergency response activities, and channeling necessary communications between the Center and other FDA organizational components (e.g., other Centers/Offices and the FDA EOC). He/she serves as the focal point for internal and external Center/Office communications during emergencies and disasters and is responsible for providing regular status reports, as requested. During some large-scale or catastrophic incidents, C/O ECs may be directed to report to the FDA EOC to support initial or prolonged emergency operations.

D.2.2.2 Planning Section

The Planning Section is responsible for collecting, evaluating, and disseminating information pertaining to the incident. This section documents and maintains information on the current and forecasted situation, as well as the status of FDA resources assigned to the incident. The Planning Section prepares the IMG IAP, compiles and consolidates FDA-wide SITREPs, and organizes status/situation reporting meetings and teleconferences. As shown in **Figure D-6,** the Planning Section, led by a Section Chief, may include subordinate units (i.e., resources, situation, documentation, and/or demobilization) and technical specialists from FDA headquarters Centers and Offices to assist in evaluating the situation and forecasting requirements for additional agency resource support.

Figure D-6. Planning Section Organizational Elements



D.2.2.2.1 Planning Section Chief

Until the AIC appoints a Planning Section Chief, an Emergency Coordinator from OCM/OEO will fulfill the role. This individual oversees all data gathering and analysis activities regarding incident operations and assigned resources, coordinates planning and status/situation reporting meetings, and prepares the IAP. The Planning Section Chief is co-located with the AIC and Operations Section Chief at the FDA EOC.

[38] Refer to the "Incident Annexes" of this Plan for detailed information on the functional groups established within the Operations Section to address specific incident requirements.

D.2.2.2.2 Units

The Planning Section may have up to four primary Units (described below) that support the Section Chief.[39] Composed of headquarters staffs, each Unit operates from normal work locations unless otherwise directed.

1) **Resources Unit:** Makes certain that FDA resources (personnel, teams, and equipment) are available for assignment to or deployment during an incident
2) **Situation Unit:** Collects, processes, analyzes, and organizes ongoing situation information; prepares situation summaries; and develops projections and forecasts of future events related to the incident
3) **Documentation Unit:** Maintains a record of the major steps taken to resolve the incident and files incident records for legal, analytical, and historical purposes
4) **Demobilization Unit:** Develops an incident demobilization plan that includes specific instructions for agency resources to return to normal operations.

D.2.2.2.3 Technical Specialists

Technical specialists have specialized skills and are activated only when needed.[40] Technical specialists are most often assigned to the specific area (Section, Branch, Unit, Division, etc.) where their services are needed and performed. These headquarters personnel may be assigned to the Planning Section, but may support any ICS function. Technical specialists normally perform the same duties during an incident that they perform in their everyday jobs and operate from normal locations unless directed to report to the FDA EOC by the Planning Section Chief or AIC. The following are examples of the kinds of specialized expertise that may be required during an emergency or disaster:

- Human/veterinary medicine
- Biology
- Chemistry
- Pharmacology
- Epidemiology
- Toxicology
- Statistics
- Engineering
- Data analysis
- GIS
- Legal counsel

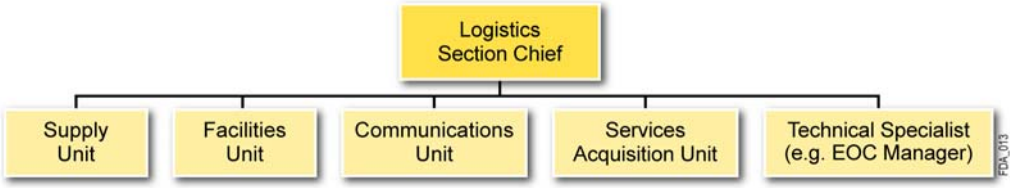
D.2.2.3 Logistics Section

The Logistics Section is responsible for all service support requirements needed to facilitate effective and efficient agency incident management operations. This section provides facilities, transportation, security, supplies, communications, and IT support services to FDA headquarters and field personnel, as required. The Logistics Section is led by a Section Chief. This role is initially filled by an OCM staff member unless designated otherwise by AIC to OM. Support Units may be staffed from OM, OIM, and other headquarters Offices, as appropriate.

[39] The incident itself will primarily dictate the need for Planning Section Units. Refer to the "Incident Annexes" of this Plan for detailed information on the types and composition of Units needed for each situation.

[40] The incident itself will primarily dictate the need for technical specialists. Refer to the FDA EOP, Incident Annexes for detailed information on the types and numbers of technical specialists needed for each situation.

Figure D-7. Logistics Section Organizational Elements



D.2.2.3.1 Units

Units, such as Supply, Facilities, Communications, and Services Acquisition (described below), may be established within the Logistics Section based on the scope and complexity of incident operations. Composed of headquarters staffs, each Unit operates from normal work locations unless otherwise directed. The Logistics Section Chief will determine, given current and anticipated requirements, the need for establishing specific subordinate Units.

1) **Supply Unit:** Coordinates ordering, receiving, processing, storage, inventory management, and distribution of supplies and materials for headquarters personnel
2) **Facilities Unit:** Coordinates headquarters facility operations and building security support services during incident operations
3) **Communications Unit:** Coordinates headquarters IT systems and equipment in support of incident operations and supervises and operates the communications center
4) **Services Acquisition Unit:** Coordinates requirements for contracted services needed during the emergency response

D.2.2.3.2 Technical Specialists

Technical specialists have specialized skills and are activated only when needed. These headquarters personnel are assigned to the Logistic Section, but may support any ICS function. Technical specialists normally perform the same duties during an incident that they perform in their everyday jobs and operate from normal locations unless directed to report to the FDA EOC by the Logistics Section Chief or AIC. OCM EOC Manager is an example of a technical specialist who may be required during an emergency to provide specialized expertise.

D.2.2.3.3 Emergency Operations Center Manager

The EOC Manager can be called up to assist the IMG in performing the emergency response operations, which requires that EOC communication methods be functioning at all times, including access to network, databases, and the Internet. S/he is responsible for the technical requirements during COOP relocations and the operation of the EOC.

In addition, the EOC Manager may assist with the transmission of electronic information during an emergency and analysis of information/data needs for a response. Onsite the EOC Manager coordinates all enhancements of the agency's data information systems, which pertain to critical and time-sensitive information.

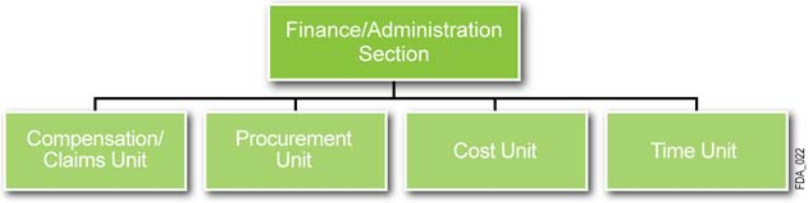
D.2.2.4 Finance/Administration Section

A Finance/Administration Section[41] is established only for those incidents requiring large-scale or extended agency operations or specific financial and administrative support services. Some of the

[41] In certain incidents, the Logistics and Finance/Administration Sections may be collapsed together under one branch. During an influenza pandemic or alert, it is likely that the agency's ICS organizational structure will expand to include Logistics and Finance/Administrative as part of the response.

functions that fall within the scope of this Section are accounting, payment processing, financial reporting, foreign and domestic travel expenditures, employee relocation, payroll liaison, and financial systems management. The Finance/Administration Section is led by a Section Chief designated by ORA and staffed with support personnel from ORA, OFM, and other Centers/Offices, as appropriate.

Figure D-8. Finance/Administration Section Organizational Elements



D.2.2.4.1 Units

Units, such as Time, Procurement, Compensation and Claims, and Cost (described below), may be established within the Finance/Administration Section based on the scope and complexity of incident operations. Composed of headquarters staffs, each Unit operates from normal work locations unless otherwise directed. The Finance/Administration Section Chief will determine, given current and anticipated requirements, the need for establishing specific subordinate Units.

1) **Time Unit:** Ensures proper daily recording of personnel time, in accordance with FDA policies
2) **Procurement Unit:** Administers all financial matters pertaining to vendor contracts, and is modified as needed
3) **Compensation and Claims Unit:** Handles agency injury/illness compensation and claims
4) **Cost Unit:** Provides cost analysis data for the incident

D.2.3 Agency Executive Group

The AEG is established when an emergency calls for the involvement of senior FDA officials with the knowledge and authority to address a wide range of issues. The AEG, whether convened as a collective unit or acting as individual members, serves primarily to provide strategic policy direction and guidance for major agency emergency response activities, and to approve important policy decisions in consultation with the Commissioner and AIC.

Members of the AEG:

- Counselor to the Commissioner
- OCM Director or Designee
- ORA, Associate Commissioner or Deputy Associate Commissioner
- Directors from appropriate Centers or their representatives
- Regional Food and Drug Director(s)
- Office of External Affairs Associate Commisioner
- Other OC representatives as appropriate, i.e. Office of Counterterrorism and Emerging Threats, Office of Chief Counsel, Office of International Programs, the Office of Policy, Planning, and Budget, and Office of Foods

An FDA Crisis Management Team (as described in the Crisis Management Annex) may be established in lieu of an AEG when an incident which poses a significant public health threat exceeds the agency's

ability to respond to the threat through the use of emergency procedures and resources identified in this plan.[42]

D.3 MULTI-AGENCY COORDINATION

Many of the incidents to which FDA responds involve other agencies which have a stake in providing response or needed resources. If the product involved in an incident crosses agency jurisdictional lines, the Multi-Agency Coordination (MAC) System may be used to support a unified coordination of operations. The primary function of the MAC System is to coordinate activities above the field level and to prioritize incident demands for critical or competing resources, thereby assisting the coordination of field operations.

In this unified coordination approach, representatives from each agency meet to set goals and decide how each agency can contribute to the achievement of the goals. There can be strong, formal command and control relationships between and among the agencies, or the command and control linkages can be based on informal but structured arrangements that recognize Federal and State responsibilities. It can be as simple as a teleconference or, alternately, require an assembled group and associated support systems. Such an assembled group comprises senior officials from the agencies involved in the response who are brought together to form a MAC Group, providing executive guidance to individual agency incident command groups on policy, resource allocation, and communications.

A MAC Group may be supported by a MAC Group Coordinator, who may supervise MAC Group Situation Assessment and Resources Information Units that collect and assemble information needed for the MAC Group to fulfill its mission. These units would obtain such information from the agency's IMG/IMT. The MAC Group may also have its own Public Information Unit to coordinate summary information and access to information sources with the media and other governmental entities. This function is often called a JIC.

The results of the MAC Group's deliberations are distributed by its members directly to their own organizations as well as through the normal chain of command (EOCs, Incident Command/Coordination Groups, etc.)

Regardless of the level of government involved in response to an incident, all MAC Groups have five key functions. These functions include:

- **Direction and Control.** Provide indirect control and direction for complex or multi-jurisdictional incidents. Serve as a single POC for prioritizing incidents and for facilitating access to critical resources
- **Information Collection and Evaluation.** Serve as a central point for collecting, analyzing, and interpreting information from a variety of sources
- **Coordination.** Play a key role in coordinating the information flow and resources for complex incidents or multiple incidents occurring simultaneously
- **Priority Setting.** Prioritize incidents and critical resources, using the priorities established by the National Preparedness Goal as well as the priorities used to guide development of incident objectives (Life Safety, Incident Stabilization, and Property and Environmental Conservation), and use these priorities at the policy level
- **Resource Management.** Manage scarce resources, in line with incident priorities; resource management includes identifying and acquiring needed resources in addition to allocating existing or known resources

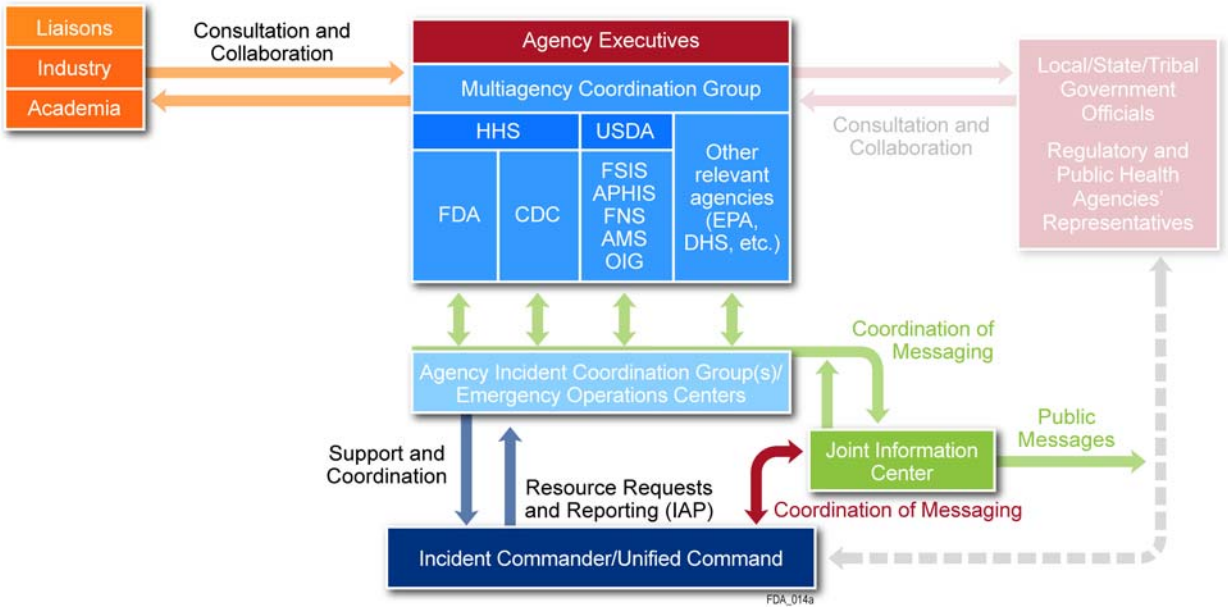
[42] For more information on the CMT and its membership, refer to the *FDA Crisis Management Annex*.

D.3.1 Multiagency Coordination Group for Foodborne Illness Outbreaks [43]

FDA, along with USDA agencies, HHS, and CDC, has created a pre-formed and pre-positioned MAC System for foodborne illness outbreaks. This approach to unified coordination includes a MAC Group that comprises senior officials from each agency, and these personnel provide executive guidance to individual agency incident command groups on policy, resource allocation, and communications. Known as the MAC for Foodborne Illness Outbreaks (MAC-FIO), this MAC Group may be alerted when indicators of a large-scale foodborne illness outbreak potentially involving more than one agency become evident. This pre-alert is intended to ensure the critical coordination among agencies involved under a unified structure for all large-scale foodborne illness outbreaks involving multiple agencies. A formal MAC-FIO in place can also be activated expeditiously to provide the executive guidance to incident command through the agencies' response coordinating bodies and ensure:

- Coordination of the development and implementation of a flexible, scalable, and adaptable response among Federal, State, local, and tribal governments to multijurisdictional foodborne illness outbreaks
- Coordination between law enforcement agencies and public health agencies of investigations of foodborne illness outbreaks due to intentional contamination
- Coordinated communication strategy to the public, industry, and other international and domestic partners
- Coordinated and collaborative efforts among Federal, State, and local governments in identifying the source of the contamination and removal of contaminated products/ingredients through a coordinated traceback and recall of all contaminated food, feed, and ingredients
- Coordinated development of measures to prevent future contamination and illnesses
- Establishment of a systematic and proactive approach for managing incidents across multiple jurisdictions as well as establish a national-level policy coordination structure

Figure D-9. Unified Coordination for Foodborne Illness Outbreaks



[43] Information excerpted from *FACT SHEET: Multi Agency Coordination Group for Foodborne Illness Outbreaks (MAC-FIO)*, March 31, 2010.

E COMMUNICATIONS AND INFORMATION MANAGEMENT

Effective emergency management and incident response activities rely upon flexible communications and information systems that provide for a "common operating picture" across all agency components and staffs. Properly planned, established, and used communications processes and systems enable the vertical and horizontal dissemination of information among and between FDA organizational components; with Federal, State, territorial, tribal, local, and foreign government agencies; and to the news media, industry, and consumers.

E.1 INTRA-AGENCY COORDINATION

During the course of any incident for which an FDA response may be necessary, timely communications and information sharing among agency units is critical to assist FDA leadership and staffs with gaining and maintaining situational awareness and making decisions. Incident information, such as emergency alerts and status/situation reporting, can aid in developing an agency IAP, serve as the basis for releasing public messages, determine the need for involvement of FDA organizational components, and satisfy RFIs. The following are examples of information generated by responsible FDA emergency staffs, and the technological systems they rely upon, for use during an incident to build an agency-wide "common operating picture."

E.1.1 Emergency Alerts

FDA may be alerted to a threat or hazard through a variety of means, including from FDA headquarters Centers/Offices or Regional/District Offices, other government agencies, consumers, and industry. Formal notifications typically occur by phone (primary) to OCM/OEO with appropriate follow-up by e-mail and/or fax referencing the initial emergency alert.

HHS/FDA/OC/OCM/OEO
10903 New Hampshire Avenue
BLDG 32, Room 1395
Silver Spring, MD 20993
Main OCM/OEO
301-796-8240
Toll Free Number
1-866-300-4374
Fax Number
301-847-8545 or 301-847-8544
Emergency.Operations@fda.hhs.gov

An OCM/OEO Emergency Coordinator records the initial call and subsequent follow-up information. After regular duty hours (8:00 a.m. to 4:30 p.m. EST, Monday through Friday, excluding Federal holidays), and when the Office is not operating, an answering service refers all emergency calls via pager to an OEO Late Duty Officer (LDO). Upon receipt, the Emergency Coordinator or LDO uses a pre-developed call-down tree/notification list for internal and external distribution of emergency alerts.

For each incident, OCM/OEO will provide notification about the incident to those appropriate officials and staff of the Centers and Offices who may have a response role in that particular incident.

Also, the Director, OCM/OEO, may send notification of EOC operating status level and additional staffing requirements to all involved parties.

E.1.2 Situation Reporting

Standardized incident reporting and documentation procedures ensure that agency-wide situational awareness is maintained and provide emergency personnel with easy access to critical information. Status reports relay information specifically related to the availability or assignment of agency resources. SITREPs offer a snapshot of each tasked organizational component's emergency operations and contain confirmed information regarding the explicit details of the incident (who, what, when, where, and how). Transmission of this data in a common format, and at pre-designated intervals, enables FDA to rapidly share critical intelligence and information between headquarters and field elements and with external partners, as appropriate.

During an incident, FDA IMT, field offices, and Centers provide regular SITREPs via the EON IMS, which is discussed in-depth below. These SITREPs highlight significant event information and emergency response activities (e.g., investigations, analyses, public affairs, cooperating agencies, scientific data, and legal court matters). District, Regional, and Center Emergency Coordinators are responsible for configuring the SITREP process, defining recipients, and reviewing and accepting inputted information.

Once field SITREPs have been approved/confirmed by Emergency Coordinators, the Planning Section Chief, in coordination with Command and General Staffs located at the FDA EOC, assembles a consolidated SITREP and posts to the EON IMS. This report combines relevant data from field SITREPs for dissemination across the agency and is used to provide operational information to external Federal Agencies.

E.1.3 Emergency Operations Network Incident Management System

In addition to primary modes of voice and data communications (phone and email), the EON IMS[44] serves as the central hub for exchanging, storing, and relaying all incident-related information within the agency. Managed by OCM, this system integrates multiple data streams from other electronic systems, such as the FERN, eLEXNET, Epi-X, and from FDA laboratories and investigators and external agencies, into a coherent fashion during critical decision points. The EON IMS creates a safety net that significantly reduces the probability that incidents will prevent FDA from accomplishing its objectives and minimizes the impact of these events on normal operations. It provides a Web-based connection for all agency organizational components and their partners, through which accurate real-time data about an incident can be shared and discussed, and is used in all situations requiring efficient receipt and dissemination of large volumes of information to FDA stakeholders, including the public and other government agencies.

The EON IMS, which is critical for comprehensive performance of agency incident management functions, has three components: 1) incident tracking and contact management, 2) a collaboration and knowledge management tool for meetings and document management, and 3) a GIS for mapping and impact assessment. Through EON IMS, FDA ensures that its emergency response is uniform, consistent, and coordinated. Participants are able to provide input and access real-time data, agency emergency plans and procedures, contact databases, and analysis tools, which enhance response capabilities.

[44] Additional EON IMS resources (User Manual, Reference Sheets, etc.) may be found on FDA Intranet http://inside.fda.gov:9003/ProgramsInitiatives/EmergencyPreparednessandResponse/EmergencyOperationsNetworkIncidentManagementSystemEONIMSResources/default.htm or by contacting the Office of Crisis Management.

E.1.4 Government Emergency Telecommunications Service

In response to White House guidance, the National Communications System (NCS) developed the Government Emergency Telecommunications Service (GETS) to ensure that key personnel can communicate over local and long distance telephone networks during an emergency. GETS can provide users a high likelihood of call completion during the most severe conditions of network congestion and disruption. There is an additional feature that can be activated on the GETS card called Wireless Priority Service (WPS). WPS allows GETS users to have their official cell phone number associated with their GETS service and ensure cellular communications are also available.

Located on the back of each GETS card are instructions for its use. For questions concerning GETS cards, call the FDA EOC at 301-443-1240 and ask to speak with the GETS card coordinator.

E.2 INTERGOVERNMENTAL COORDINATION

Coordination with responsible government agencies at the Federal, State, territorial, tribal, and local levels must be effective during emergency and disaster situations to ensure that resource allocations are efficient, policy is understood, and that roles are well defined. Considering that Federal Agency responsibility varies from one type of incident to another, and that State and local government organizations differ from those of the Federal Government, the specific agencies that should cooperate in a given situation is highly dependent on the incident at-hand and its location(s) as well. However, specific FDA organizational components are charged with establishing and maintaining communications at the various intergovernmental levels, regardless of incident size, complexity, or geographic location. These headquarters and field organizations are described below.

E.2.1 Communicating with Federal Government Agencies

The FDA EOC staff is responsible for coordinating Federal interagency liaison activities and establishing communications with the headquarters emergency operations offices and staff of Federal Agencies during incidents of varying nature and scope. Through the use of dedicated communications channels, standardized reporting mechanisms, and the deployment of internal and external liaisons, the FDA EOC is able to maintain contact with the HHS SOC, the CDC's EOC, the USDA/FSIS, and other Federal Department/Agency EOCs, as appropriate. Centers may have technical consultation with other government agencies during an emergency and provide updates about significant consults to the agency through the EOC.

The lead District, in coordination with the FDA EOC, is also responsible for communicating with appropriate Federal field offices and incident management field structures, such as the DHS/FEMA Regional Response Coordination Center (RRCC), the Joint Field Office (JFO), and any established disaster recovery centers, as appropriate.

E.2.2 Communicating with States, Territories, Tribal Nations, and Local Governments

During an incident, both the lead District and other investigating Districts are responsible for establishing communications with responsible State agencies. Usually FDA will work through the State in coordinating efforts at the local level or through the use of the State's pre-designated Rapid Response Teams (RRT). However, depending upon the State, it may be more appropriate for FDA District Offices, in coordination with the FDA EOC, to work directly with local government to address the situation.

The DFSR, within ORA, in cooperation with the appropriate FDA Region(s) and District(s), is responsible for managing FDA's field interaction with State, territorial, tribal, and local agencies. The DFSR maintains a rapid communication system to alert officials in State governments, major

municipalities, and poison control centers, and quickly enlist nationwide assistance for the agency's emergency operations. During an incident, the DFSR will:

- Ensure that the appropriate State agencies, such as Agriculture and Health Departments, are notified of significant confirmed incidents within their States or which cross State borders, indicating the potential for problem FDA-regulated products to enter commerce
- Prepare (or distribute) information requested by States during the course of emergency response operations, and assure that they are fully advised as to what action(s) FDA can recommend under the circumstances of the specific incident

E.2.3 Communicating with Foreign Governments

During an incident when commerce with Canada or Mexico is involved, FDA's response coordination will be performed by the EOC in cooperation with OIP. When commerce with other countries is involved, OIP, in direct coordination with the FDA EOC, will establish, supervise, and/or coordinate and maintain appropriate communication channels.

During emergency response operations, a requirement may exist to conduct secure communications with other government agencies. This requires strict adherence to guidelines and regulations for handling, processing, and storing sensitive/classified materials. FDA restricts access to sensitive and classified material to ensure its release to only those agency personnel who possess appropriate security clearances and a need-to-know. OCM/OEO maintains a list of locations and numbers of agency secure voice and data equipment. In direct coordination with OSO, they shall be made available to authorized agency staff on a case-by-case basis.

E.3 PUBLIC MESSAGING

Public messaging consists of the agency processes, procedures, and systems to communicate timely, accurate, and accessible public health and medical information to the media and directly to FDA stakeholders (both directly and indirectly affected). Information must be coordinated and integrated across FDA organizational components at the headquarters and field levels, as well as with other Federal, State, territorial, tribal, and local government agencies and industry partners in order to protect consumer well-being and decrease the risk of illness, injury, disease, or death. Well-developed communications plans and strategies executed by responsible FDA staffs help to ensure that messages, alerts and warnings, educational materials, and situational updates are developed and distributed to numerous audiences in a timely, consistent manner.

E.3.1 Public Affairs

The FDA's OPA, within OEA, is responsible for coordinating the release of information to the public during an emergency or disaster. It serves as the agency's primary liaison with the news media and develops FDA's public health and consumer protection messages. During an emergency, OPA Public Affairs Specialists, in direct coordination with the assigned IMG PIO, Center media representatives, and all responding field offices, issue press releases, media advisories, and other public statements; respond to media requests; and arrange and support media interviews. They also coordinate with other external Federal Agencies to ensure the provision of a common message.

Throughout an incident, OPA will take guidance from and work closely with the HHS Office of ASPA in publicizing public health messages and implementing a strategic communications plan that:

- Coordinates and expedites FDA messages with HHS/ASPA and other partners to ensure consistency

- Coordinates communications activities with the FDA Center and field Public Affairs Staff through OPA
- Disseminates clear and accurate messages that maintain, increase, or restore public trust and confidence
- Uses a variety of vehicles to distribute public health messages

OPA's Web Communications Staff ensures that vital and important information and consumer health messages are expeditiously posted to the agency's Web site (www.fda.gov) and updated as needed. OPA's Web Communications Staff also coordinates Web communications with OPA, the HHS/ASPA, other Federal Agencies, and State and local government to ensure a consistent and comprehensive approach that reduces duplication of messages.

E.3.2 External Relations

FDA's OER develops and promotes FDA consumer health information which consists of time-sensitive public health and product safety alerts and information about FDA's roles and responsibilities in protecting and promoting public health. The goals of this Office during an incident include promoting improved outreach and readership of FDA Consumer Health Information; sharing time-sensitive public health and product safety alerts; and facilitating public understanding of FDA's roles and responsibilities in protecting and promoting public health via the Internet. OER also coordinates Web communications with OPA, the HHS/ASPA, other Federal Agencies, and State and local government to ensure a consistent and comprehensive approach that reduces duplication of messages.

E.3.3 Congress

FDA's Office of Legislation directs and manages FDA's legislative needs, pending legislation, oversight activities, and Congressional relations consistent with the mission of the agency. In an emergency or disaster, the Office of Legislation is responsible for, but not limited to, the following activities:

- Keeping Congress apprised of FDA actions relative to the incident in coordination with the HHS Office of the Assistant Secretary for Legislation
- Responding to Congressional RFIs about the incident related to the incident
- Arranging and supporting Congressional meetings, briefings, and hearings

F PLAN MANAGEMENT

F.1 COORDINATION

The FDA OCM is responsible for the overall management and maintenance of the *FDA EOP* (to include all annexes) and for ensuring that changes and revisions occur, including their preparation, coordination, publication, and distribution. OCM, in consultation with all responsible agency Centers and Offices, coordinates regular plan reviews to address lessons learned from real-world and simulated incidents and incorporates necessary organizational or technological changes.

F.2 MAINTENANCE

Any FDA headquarters or field organizational component may propose changes to the *FDA EOP*. All proposed changes are to be captured within the "Record of Changes" section to this Plan and submitted to OCM for formal review. Approval from the appropriate Center/Office senior official should be secured prior to submitting any proposed change.

Once OCM receives a proposed change to the *FDA EOP,* it will coordinate a review with all applicable Centers and Offices to determine its suitability for inclusion in the plan. Once this coordination has been finalized, OCM will issue an official Notice of Change to those agency components with defined emergency roles and responsibilities.

- The Notice of Change will specify the date, number, subject, purpose, background, and action required, and provide the change language on one or more numbered and dated insert pages that will replace the previous pages in the *FDA EOP*.
- Once published, the changes will be considered part of the *FDA EOP* for operational purposes pending a formal revision and re-issuance of the entire document.

F.3 PROMULGATION

OCM Director is responsible for coordinating annual reviews of the basic plan and all applicable annexes to the *FDA EOP* and for re-adoption and distribution every 4 years, or more frequently as deemed necessary. The annual review will consider lessons learned and best practices identified during responses to simulated and/or actual emergencies and disasters. Any changes that result from annual reviews will be incorporated in the *FDA EOP* and any supporting Center/Office emergency plans and procedures.

Prior to any reissuance of the plan, or at the request of the Commissioner or his/her authorized representative, OCM will convene an *FDA EOP* coordinating committee composed of designated agency headquarters and field emergency coordinators to revise key areas of the plan. OCM will disseminate the final draft of the revised *FDA EOP* for review and concurrence prior to submitting to the Commissioner for approval and promulgation.

F.4 STANDARDS FOR SUPPORTING DOCUMENTATION

The *FDA EOP*, including the basic plan and all annexes, is the core plan for FDA emergency operations, and provides the structures and processes for coordinating agency incident management activities for terrorist attacks and other criminal acts, natural disasters, and other emergencies. It provides an umbrella configuration for existing emergency plans and procedural documents (with appropriate modifications and revisions) as integrated components, supplements, or supporting material.

All agency organizational components must incorporate common principles, concepts, and language when developing or updating individual emergency plans and procedures. Accordingly, all Center/Office emergency documentation shall be compatible with the *FDA EOP*.

F.5 TESTS, TRAINING, AND EXERCISES

FDA shall conduct and/or participate in HHS and other organizations' tests, training, and exercises to ensure that agency personnel are familiar with assigned emergency roles and responsibilities and that the *FDA EOP* can be implemented rapidly and effectively.

Any deficiencies, findings, areas recommended for corrective action, or improvements arising from tests and exercises will be considered by additional training, plan updates, and/or demonstration in any subsequent emergency preparedness event.

F.6 IMPLEMENTATION

The *FDA EOP*, including the basic plan and all annexes, is effective for execution upon and pursuant to approval by the Commissioner.

OCM shall ensure that this Plan is subject to regular maintenance, review, and updates based on selective evaluations, AARs, and new guidance. At any time, responsible Agency Emergency Coordinators, upon approval by the Center/Office senior official, should recommend to OCM improvements and changes thereto which are appropriate. The *FDA EOP* and any approved changes will be forwarded to all organizational components with responsibilities for implementation of the Plan.

This Plan shall be placed on the FDA intranet Web site (inside.fda) and made accessible to all agency employees and authorized contract support providers. It shall not be made publicly available unless specifically authorized by OCM Director.

G AUTHORITIES AND REFERENCES

The legal authorities that guide the structure, development, and implementation of the *FDA EOP* include statutes and regulations, Presidential directives, national strategies, and Federal Government plans and guidance. In addition, internal emergency plans and procedures augment the *FDA EOP* and provide specific guidance to agency personnel during emergencies and disasters. These documents are listed chronologically by category and summarized below.[45]

Authorities and references specific to individual hazards are also included in the *FDA EOP*, Incident Annexes.

G.1 STATUTES AND REGULATIONS

G.1.1 Federal Food, Drug, and Cosmetic Act

FDA's mission is mandated by the FFDCA of 1938, 21 U.S.C. § 301, as amended (www.fda.gov/opacom/laws/fdcact/fdctoc.htm). The following FFDCA provisions govern agency emergency actions:

a. In consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products, FDA is charged with 1) promoting the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner, and 2) with respect to such products, protecting the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled; the public health and safety are protected from electronic product radiation; and tobacco products are properly labeled and are not contaminated.

b. FDA is authorized to inspect any location or facility where foods are manufactured, processed, packed or held for introduction into interstate commerce or after such introduction, and this inspection extends to certain records of such persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, hold, or import food when FDA has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death to humans or other animals.

c. FDA is authorized to collect samples and inspect and copy certain records of persons (excluding farms and restaurants) who manufacture, process, pack, distribute, receive, hold, or import an article of food if FDA has a reasonable belief that the article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

d. FDA is charged with ensuring that safe and effective drugs, biologics, and devices are available for emergency use.

e. If FDA finds a reasonable possibility that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the agency can order that distribution of any such tobacco product immediately cease and can order a recall as necessary. FDA may also provide notice to persons subject to the risks associated with the use of such tobacco product.

[45] This list is not exhaustive, and the associated summaries should not be used as a substitute for the authorities and references themselves.

g. If FDA determines that a tobacco product presents an unreasonable risk of substantial harm to the public health, the agency can provide notice to the public as necessary to eliminate such risk, including issuing public service announcements.

h. FDA is authorized to inspect the records of each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products, if the agency has a reasonable belief that a tobacco product is part of illicit trade, smuggling, or counterfeiting operations.

i. The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when a product has been distributed, which presents a risk of illness or injury or gross consumer deception; when the responsible firm has not initiated a recall of the product; and when an agency action is necessary to protect the public health and welfare. A request by FDA that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

j. Under the Project BioShield Act of 2004 (P.L. 108-276), the FFDCA is amended to allow FDA, in response to a declaration issued by the HHS Secretary, to authorize the use, with appropriate safeguards, of unapproved drugs, devices, or biological products, or the use of approved products for unapproved uses. Before FDA can issue an EUA, the HHS Secretary must declare an emergency justifying the authorization to use the product, based on one of three determinations: a determination by the Secretary of Homeland Security of a domestic emergency, or the significant potential for a domestic emergency, a determination by the Secretary of Defense of a military emergency, or the significant potential for a military emergency, or a determination by the HHS Secretary of a public health emergency under the PHSA.

k. The Pandemic and All-Hazards Preparedness Act (P.L. 109-417), 2006, amends the FFDCA to direct FDA to establish a team of experts on manufacturing and regulatory activities (including compliance with current GMP) to provide both off-site and onsite technical assistance to the manufacturers of qualified countermeasures, security countermeasures, or vaccines, at the request of such a manufacturer and at the discretion of the Secretary, if the Secretary determines that a shortage or potential shortage may occur in the United States in the supply of such vaccines or countermeasures and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.

G.1.2 Public Health Service Act

The Public Health Service Act, Title XXVIII – National Preparedness for Bioterrorism and Other Public Health Emergencies, as amended, charges FDA with assisting the Secretary, other HHS OPDIVs, and Federal, State, territorial, tribal, and local government partners in response to bioterrorism and other public health emergencies. www.fda.gov/opacom/laws/phsvcact/phsvcact.htm

G.1.3 Federal Anti-Tampering Act

The Federal Anti-Tampering Act, 18 U.S.C. 1365, authorizes FDA to investigate any tampering of FDA-regulated consumer products. www.fda.gov/opacom/laws/fedatact.htm

G.1.4 Bioterrorism Act

FDA is responsible for carrying out certain provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, "the Bioterrorism Act," P.L. 107-188 (www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm).

Particularly, Subtitle A (Protection of Food Supply) and Subtitle B (Protection of Drug Supply) of Title III, provide for the following FDA authorizations:

- FDA may detain any article of food found during an inspection, examination, or investigation that presents a threat of serious adverse health consequences or death to humans or animals.

- FDA is authorized to access certain records when there is a reasonable belief that an article of food is adulterated and presents a threat of adverse health consequences or death to humans or animals.
- Owners and operators of foreign or domestic food facilities that manufacture or process, pack, or hold food for human or animal consumption in the United States must submit information (identity of the food, manufacturer and shipper, grower, country of origin, country from which the food is shipped, and anticipated port of arrival) to FDA about the facility and emergency contacts.
- FDA shall receive prior notice of imported food shipments before the food arrives at any U.S. port, which must include the article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of arrival, and conduct a bioterrorism risk assessment.
- FDA is charged with providing for research on tests and sampling methodologies designed to test food to detect adulteration rapidly, particularly methodologies that detect intentional adulteration and tests that are suitable for inspections of food at ports of entry to the United States.
- FDA is authorized to conduct examinations and investigations through the officers and employees of another Federal Department or Agency, pursuant to a MOU, at facilities or other locations that are jointly regulated by FDA and such department or agency. FDA is required to notify States when there is credible evidence or information indicating that a shipment, or portions of a shipment, of imported food presents a threat of serious adverse health consequences or death to humans or animals.
- Another Federal Department's or Agency's officers and employees are authorized to conduct examinations and investigations on FDA's behalf, pursuant to the signing of a MOU between FDA and the head of the other Federal Agency.
- FDA, in direct coordination with the CDC and USDA, is charged with coordinating the surveillance of zoonotic diseases.

G.1.5 Stafford Act

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, P.L. 93-288 (1938), as amended, codified at 42 U.S.C. §§ 68 (2007), describes the programs and processes by which the Federal Government provides disaster and emergency assistance to State and local governments, tribal nations, eligible private nonprofit organizations, and individuals affected by a declared emergency or major disaster. The Stafford Act covers all hazards, including natural disasters and terrorist events.
www.fema.gov/pdf/about/stafford_act.pdf

G.1.6 Public Readiness and Emergency Preparedness Act

The PREP Act of 2005, "PREP Act," (P.L. 109-148), PHSA § 319F-4, authorizes the Secretary to issue a declaration to provide immunity from tort liability for certain claims that are causally related to development, distribution, administration, or use of "covered countermeasures" and authorizes an emergency fund in the U.S. Treasury for compensation for injuries from covered countermeasures.
www.hrsa.gov/countermeasurescomp/prep_act.htm

G.1.7 Title 21, Code of Federal Regulations

Title 21, Chapter I, is the portion of the CFR that governs FDA-regulated products within the United States for FDA. The regulations described within Chapter I of 21 CFR are enforced by FDA, based on the FFDCA and other applicable laws.
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

G.2 HOMELAND SECURITY PRESIDENTIAL DIRECTIVES

The following HSPDs mandate action from all Federal Departments and Agencies, to include FDA as a HHS OPDIV:

G.2.1 Homeland Security Presidential Directive 3, Homeland Security Advisory System

This HSPD establishes the Homeland Security Advisory System to provide a comprehensive and effective means to disseminate information regarding the risk of terrorist acts to Federal, State, and local authorities and to the American people. www.dhs.gov/xabout/laws/gc_1214508631313.shtm

G.2.2 Homeland Security Presidential Directive 5, Management of Domestic Incidents

This HSPD requires the Secretary of Homeland Security to develop and administer a *NIMS* that will provide a consistent nationwide approach for Federal, State, and local governments to work effectively and efficiently together to prepare for, respond to, and recover from domestic incidents, regardless of cause, size, or complexity. HSPD-5 also requires the Secretary of Homeland Security, after consultation with appropriate Federal officials, to develop and administer a National Response Plan (NRP). The Directive orders the heads of all Federal Agencies to adopt the NIMS and NRP, and provide assistance to the Secretary in their development and maintenance. www.dhs.gov/xabout/laws/gc_1214592333605.shtm

G.2.3 Homeland Security Presidential Directive 7, Critical Infrastructure Identification, Prioritization, and Protection

This HSPD establishes a national policy for Federal Agencies to identify and prioritize U.S. critical infrastructure and key resources and to protect them from terrorist attacks.
www.dhs.gov/xabout/laws/gc_1214597989952.shtm

G.2.4 Homeland Security Presidential Directive 8, National Preparedness

This HSPD establishes policies to strengthen the preparedness of the United States to prevent and respond to threatened or actual domestic terrorist attacks, major disasters, and other emergencies. HSPD-8 requires the development of a National Preparedness Goal that establishes measurable readiness priorities, targets, and standards that appropriately balance the potential threat and magnitude of terrorist attacks, major disasters, and other emergencies with the resources required to prevent, respond to, and recover from them. HSPD-8 also outlines the actions required to strengthen preparedness capabilities of Federal, State, and local entities. www.dhs.gov/xabout/laws/gc_1215444247124.shtm

G.2.5 Homeland Security Presidential Directive 9, Defense of United States Agriculture and Food

This HSPD establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. www.dhs.gov/xabout/laws/gc_1217449547663.shtm

G.2.6 Homeland Security Presidential Directive 10, Biodefense for the 21st Century

This HSPD establishes strategies for preventing, protecting against, and mitigating biological weapons attacks perpetrated against homeland and global interests.
www.dhs.gov/xabout/laws/gc_1217605824325.shtm

G.2.7 Homeland Security Presidential Directive 18, Medical Countermeasures Against Weapons of Mass Destruction

This HSPD establishes an approach for the development and acquisition of medical countermeasures for attacks involving chemical, biological, radiological, or nuclear agents.
www.dhs.gov/xabout/laws/gc_1219175362551.shtm

G.2.8 National Security Presidential Directive 51/Homeland Security Presidential Directive 20, National Continuity Policy

This directive, also known as National Security Presidential Directive 51, establishes a comprehensive national policy on the continuity of Federal Government structures and operations and a single National Continuity Coordinator responsible for coordinating the development and implementation of Federal continuity policies. www.dhs.gov/xabout/laws/gc_1219245380392.shtm

G.2.9 Homeland Security Presidential Directive 21, Public Health and Medical Preparedness

This HSPD establishes a national strategy that will enable a level of public health and medical preparedness sufficient to address a range of possible disasters.
www.dhs.gov/xabout/laws/gc_1219263961449.shtm

G.2.10 Homeland Security Presidential Directive 22, Domestic Chemical Defense

HSPD-22 establishes a national policy and directs actions to strengthen the ability of the U.S. to prevent, protect, respond to, and recover from terrorist attacks employing toxic chemicals and other chemical incidents. (This directive is classified and thus, not publicly available.)

G.3 NATIONAL STRATEGIES

G.3.1 National Strategy for the Physical Protection of Critical Infrastructures and Key Assets

This establishes a foundation for building and fostering the cooperative environment in which government, industry, and private citizens can carry out their respective protection responsibilities more effectively and efficiently. Moreover, this Strategy identifies a clear set of national goals and objectives and outlines the guiding principles that underpin the efforts to secure the infrastructures and assets vital to national security, governance, public health and safety, economy, and public confidence.
www.dhs.gov/xprevprot/publications/publication_0017.shtm

G.3.2 National Strategy for Homeland Security

The National Strategy for Homeland Security guides, organizes, and unifies the Nation's homeland security efforts. Homeland security is a responsibility shared across the entire Nation, and the Strategy provides a common framework to prevent and disrupt terrorist attacks; protect the American people, critical infrastructure, and key resources; respond to and recover from incidents that do occur; and continue to strengthen the foundation to ensure long-term success. It builds upon the 2002 version, reflects an increased understanding of th(Page 96 of 299)ıting the United States today, incorporates lessons learned from exercises and real-world catastrophes, including Hurricane Katrina, and proposes new initiatives and approaches that will enable the Nation to achieve its homeland security objectives. www.dhs.gov/xabout/history/gc_1193938363680.shtm

G.3.3 National Security Strategy

The National Security Strategy guides, organizes, and unifies our Nation's homeland security efforts and lays out a strategic approach for advancing American interests, including the security of the American people, a growing U.S. economy, support for our values, and an international order that can address 21st century challenges. www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf

G.4 FEDERAL PLANS AND GUIDANCE

G.4.1 Comprehensive Preparedness Guide 101

The Comprehensive Preparedness Guide (CPG) 101 expands on FEMA's efforts to provide guidance about response and recovery planning to State, territorial, tribal, and local governments. It also extends those planning concepts into the prevention and protection mission areas. CPG 101 integrates concepts from the *National Preparedness Guidelines, NIMS, NRF, National Strategy for Information Sharing (*NSIS), and *National Infrastructure Protection Plan* (NIPP), and it incorporates recommendations from the 2005 Nationwide Plan Review. CPG 101 also serves as a companion document to the IPS mandated by Annex I of HSPD-8. www.fema.gov/about/divisions/cpg.shtm

G.4.2 Integrated Planning System

The IPS, mandated by Annex I of HSPD-8, provides common processes for developing plans. The purpose of the IPS is to further enhance the preparedness of the United States by formally establishing a standard and comprehensive approach to national planning. It is meant to provide guidance for conducting planning in accordance with the Homeland Security Management System, described in the *National Strategy for Homeland Security of 2007*.
www.hlswatch.com/wp-content/uploads/2009/01/dhs-integrated-planning-system-january-2009.pdf

G.4.3 National Incident Management System

NIMS provides a systematic, proactive approach to guide departments and agencies at all levels of government, nongovernmental organizations, and the private sector to work seamlessly to prevent, protect against, respond to, recover from, and mitigate the effects of incidents, regardless of cause, size, location, or complexity, in order to reduce the loss of life and property and harm to the environment. NIMS works hand in hand with the *NRF*. It provides the template for the management of incidents, while the *NRF* provides the structure and mechanisms for national-level policy for incident management.

NIMS is not an operational incident management or resource allocation plan. It represents a core set of doctrines, concepts, principles, terminology, and organizational processes that enable effective, efficient, and collaborative incident management. www.fema.gov/emergency/nims

NIMS has established ICS as the standardized incident organizational structure for the management of all incidents.

G.4.4 National Infrastructure Protection Plan

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NIPP, and its supporting Sector-Specific Plans (SSPs), provide a coordinated approach to critical infrastructure and key resources (CIKR) protection roles and responsibilities for Federal, State, territorial, tribal, and local government and private sector security partners. NIPP sets national priorities, goals, and requirements for effective distribution of funding and resources, which help ensure that the Nation's government, economy, and public services continue in the event of a terrorist attack or other disaster.
www.dhs.gov/xprevprot/programs/editorial_0827.shtm

The SSPs provide the means by which the NIPP is implemented across all 18 CIKR sectors, as well as a national framework for each sector to address its unique characteristics and risk landscape. FDA is

responsible for the food sector (except meat, poultry, and frozen, dried, and liquid eggs, which are under the authority of the USDA/FSIS). Agency food sector protection efforts are detailed in the Agriculture and Food CIKR SSP to the NIPP, (www.dhs.gov/xlibrary/assets/nipp-ssp-ag-food.pdf). FDA also supports HHS, which is responsible for the SSP for the public health and medical sector.

G.4.5 National Preparedness Guidelines

The National Preparedness Guidelines organizes and synchronizes national (including Federal, State, territorial, tribal, and local) efforts to strengthen preparedness. The Guidelines guide national investments in national preparedness, incorporate lessons learned from past emergencies and disasters into national preparedness priorities, facilitate a capability- and risk-based investment planning process, and establish readiness metrics to measure progress and a system for assessing the Nation's overall preparedness capability to respond to major events, especially those involving acts of terrorism. There are four critical elements to the Guidelines: the national preparedness vision, the 15 National Planning Scenarios, the Universal Task List, and the Target Capabilities List.
www.dhs.gov/xprepresp/publications/gc_1189788256647.shtm

G.4.6 National Response Framework

The *NRF* presents the guiding principles that enable first responders, decisionmakers, and supporting entities to prepare for and provide a unified national response to emergencies and major disasters—from the smallest incident to the largest catastrophe. It establishes a comprehensive, national, all-hazards approach to domestic incident management and defines the key principles, roles, and structures that organize the way the Nation responds.

The *NRF*, an update to the 2004 NRP, describes how communities, tribes, territories, States, the Federal Government, and private-sector and nongovernmental partners apply these principles for a coordinated, effective national response. This document also identifies special circumstances where the Federal Government exercises a larger role, including incidents where Federal interests are involved and catastrophic incidents where a State would require significant support. The *NRF* enables first responders, decisionmakers, and supporting entities to provide a unified national response.
www.fema.gov/emergency/nrf

G.5 U.S. Department of Health and Human Services Plans

HHS plan(s) that guide FDA emergency operations:

- HHS ESF-8 Aerosolized Anthrax Playbook
- HHS ESF-8 Pandemic Influenza Playbook
- HHS ESF-8 Hurricane Response (Page 98 of 299)
- HHS ESF-8 Radiological Dispersal Device Playbook

G.6 FDA Supporting Documentation

G.6.1 Center/Office Emergency Plans and Procedures

Each FDA organizational component has developed individual emergency plans and operating procedures that define the scope of incident management activities necessary for that Center or Office. These EOPs and subordinate procedural documents present specific details on Center/Office response to emergencies

and disasters, such as assigning staff roles, responsibilities, and lines of authority; detailing projected times, places, and coordination mechanisms for carrying out emergency actions; describing how staffs and facilities are protected; and identifying the personnel, equipment, facilities, supplies, and other resources necessary for use during response and recovery operations.

The following represent the compendium of existing FDA emergency/disaster plans and procedures. Each supports implementation of the *FDA EOP* and is available to assist FDA personnel during prevention, preparedness, protection, response, and recovery activities.

- *Regulatory Procedures Manual*. Chapter 8, "Emergency Procedures (March 2009). www.fda.gov/ora/compliance_ref/rpm/chapter8/ch8.html
- *Investigations Operations Manual* 2008. Chapter 8, Section 8.5, "Disaster Procedures." www.fda.gov/ora/inspect_ref/iom

Copies of individual Center and Office Emergency Plans and Procedures may be found on the C/O Intranet Web pages on Inside.FDA.

G.6.2 Standard Operating Procedure for FDA Headquarters Building Closures and Dismissal of Employees

The document, *Office of Real Property Services Standard Operating Procedures for the Operational Status of FDA Headquarters Buildings and Dismissal of Employees for Administrative Situations,* outlines FDA policies and procedures for determining the operational status of FDA headquarters' buildings and dismissal of employees related to administrative situations as defined in the document. This policy covers all FDA locations in the Washington, DC, metropolitan area, including the White Oak Campus.

G.6.3 Center/Office Continuity of Operations Plans

FDA has designed COOP plans for each of its headquarters and field organizational components, including OC, ORA, CBER, CDER, CDRH, CFSAN, CVM, and the Regional and District Offices. These plans ensure that agency essential functions can continue to be performed from alternate locations during all hazards, including localized acts of nature, accidents, and technological or attack-related situations.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Food and Drug Administration

FDA EMERGENCY OPERATIONS PLAN
Appendices

August 2010

OFFICE OF CRISIS MANAGEMENT

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Appendix A: FDA Support for the Emergency Support Function Annexes to the National Response Framework

The ESFs Annexes to the NRF provide the structure for coordinating Federal interagency support for a Federal response to an incident. They are mechanisms for grouping functions most frequently used to provide Federal support to States and Federal-to-Federal support, both for declared disasters and emergencies under the Stafford Act and for non-Stafford Act incidents.

Used by the Federal Government and many State governments as the primary mechanism at the operational level to organize and provide assistance, ESFs align categories of resources and provide strategic objectives for their use. ESFs use standardized resource management concepts such as typing, inventorying, and tracking to facilitate the dispatch, deployment, and recovery of resources before, during, and after an incident.

Depending on the nature of the emergency, FDA's emergency response roles and responsibilities may fall under one or more of the following ESFs:

EMERGENCY SUPPORT FUNCTION #8 "PUBLIC HEALTH AND MEDICAL SERVICES"

ESF #8 – Public Health and Medical Services[46] provides the mechanism for coordinated Federal assistance to supplement State, tribal, and local resources in response to a public health and medical disaster, potential or actual incidents requiring a coordinated Federal response, and/or during a developing potential health and medical emergency.

Primary Agency:

- HHS

ESF Coordinator:

- HHS

The Secretary of HHS leads the ESF #8 response. ESF #8, when activated, is coordinated by the HHS ASPR. Once activated, ESF #8 functions are coordinated by the Emergency Management Group (EMG) through the HHS SOC. HHS notifies and requests all supporting departments and agencies to participate in headquarters coordination activities.

Scope/Functional Areas

When activated by the National Response Coordination Center (NRCC), HHS consults with the appropriate ESF #8 supporting organizations to determine the need for assistance according to the functional areas listed below.

- Assessment of public health/medical needs
- Health surveillance
- Medical care personnel
- All-hazards public health and medical consultation, technical assistance, and support
- Behavioral healthcare
- Public health and medical information

[46] For more information on ESF # 8, refer to: www.fema.gov/pdf/emergency/nrf/nrf-esf-08.pdf

- Health/Medical/Veterinary Equipment and Supplies
- Patient Evacuation
- Patient Care
- Safety and Security of Drugs, Biologics, and Medical Devices
- Blood and Blood Products
- Food Safety and Security
- Agriculture Safety and Security
- Vector Control
- Potable Water/Wastewater and Solid Waste Disposal
- Mass Fatality Management, Victim Identification, and Decontaminating Remains
- Veterinary Medical Support

U.S. Department of Health and Human Services Emergency Support Function #8 Responsibilities

FDA will provide support, personnel, or expertise to HHS for many of the HHS responsibilities listed below. FDA will also:

- Lead the Federal effort to provide public health and medical assistance to the affected area
- Coordinate staffing of the HHS EMG to support the response operation
- Request appropriate ESF #8 organizations to activate and deploy public health, medical, and veterinary medical personnel, equipment, and supplies in response to requests for Federal public health and medical assistance, as appropriate
- Use HHS personnel (U.S. Public Health Service Commissioned Corps, the National Disaster Medical System [NDMS], Federal Civil Service, and civilian volunteers) to address public health, medical, and veterinary medical needs
- Assist and support State, tribal, and local officials in performing monitoring for internal patient contamination and administering pharmaceuticals for internal decontamination
- Assist State, tribal, and local officials in establishing a registry of potentially exposed individuals, performing dose reconstruction, and conducting long-term monitoring of this population for potential long-term health effects
- Confidentially monitor blood and blood product supplies throughout the year using the Blood Availability and Safety Information System as baseline data for ESF #8 activation
- Liaison with the American Association of Blood Banks (AABB) Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (i.e., AABB TF) to assist in logistical requirements and to coordinate a national public blood announcement message for the need to donate
- Monitor blood and blood product shortages and reserves, including the safety and availability of the blood supply
- Activate NDMS as necessary to support response operations
- Evaluate requests for deployment or redeployment of the SNS and Federal Medical Stations based upon relevant threat information
- Coordinate public health and medical support, patient evacuation, and movement requirements with other primary and supporting departments, agencies, and governments throughout the incident
- Ensure the safety and security of food in coordination with other responsible Federal Agencies (e.g., USDA); in cooperation with State, tribal, and local officials, assess whether food manufacturing, food processing, food distribution, food service, and food retail establishments in the affected area are able to provide safe and secure food

- In cooperation with State, tribal, and local officials as well as the food industry, conduct tracebacks or recalls of adulterated products
- In cooperation with Federal, State, tribal, and local officials, ensure the proper disposal of contaminated products and the decontamination of affected food facilities in order to protect public health
- Provide support for public health matters for radiological incidents as a member of the Advisory Team for Environment, Food, and Health

Additional FDA Responsibilities:

- Responsible for maintaining administrative control over their respective response resources after receiving coordinating instructions from HHS
- If requested by the HHS ASPR:

– Provide liaison personnel to the HHS headquarters command locations
– Participate in HHS coordinated audio and video conference calls to discuss the situation and determine the appropriate initial response actions
– Provide a representative to the EMG to provide liaison support
– Provide public health and medical SMEs

EMERGENCY SUPPORT FUNCTION #10 "OIL AND HAZARDOUS MATERIALS RESPONSE"

The ESF #10 – Oil and Hazardous Materials Response Annex[47] provides Federal support in response to an actual or potential discharge and/or uncontrolled release of oil or hazardous materials when activated. Hazardous materials include chemical, biological, and radiological substances, whether accidentally or intentionally released.

The scope of ESF #10 includes the appropriate actions to prepare for, respond to, and recover from a threat to public health, welfare, or the environment caused by actual or potential oil and hazardous materials incidents. The *National Oil and Hazardous Substances Pollution Contingency Plan (NCP)*[48]*, 40 CFR Part 300*, is an operational supplement to the NRF. It provides more detailed information regarding the roles and responsibilities, organizational structures, and procedures described in ESF #10.

Primary Agency:

- EPA, Department of Homeland Security/U.S. Coast Guard

ESF Coordinator:

- EPA

Relationship to Terrorism Incident Law Enforcement and Investigation Annex Scope/Functional Areas

For a terrorist incident involving oil or hazardous materials (such as a weapons of mass destruction [WMD] incident), ESF #10 provides assistance, investigative support, and intelligence analysis for the oil/hazardous materials response in coordination with the activities addressed in the *Terrorism Incident Law Enforcement and Investigation Annex.* For an incident involving oil or hazardous materials and ESF #10 activation that is determined to be an intentional criminal act but not an act of terrorism, the Federal

[47] For more information on ESF #10, refer to: www.fema.gov/pdf/emergency/nrf/nrf-esf-10.pdf
[48] For more information on the *National Oil and Hazardous Substances Pollution Contingency Plan,* refer to www.epa.gov/OEM/content/lawsregs/ncpover.htm.

Agency with jurisdiction (EPA or DHS/USCG) assumes primary Federal responsibility for the Federal criminal investigation.

Relationship to Biological and Nuclear/Radiological Incident Annexes

Hazardous materials addressed under the NCP include certain biological and radiological substances. The *NRF Biological and Nuclear/Radiological Incident Annexes* may therefore be activated simultaneously with ESF #10. The *Biological and Nuclear/Radiological Incident Annexes* describe additional procedures and Federal Agency responsibilities for biological and radiological/nuclear incidents that are not addressed in ESF #10, and are used in conjunction with ESF #10 when applicable.

FDA Responsibilities:

- Work in cooperation with EPA and USDA to ensure the proper disposal of contaminated food or animal feed
- The NCP requires that oil and hazardous materials releases be reported to the National Response Center at 1-800-424-8802. (See 40 CFR 300.125.)
- Provide assistance to States and local agencies with product sampling and analysis upon request

EMERGENCY SUPPORT FUNCTION # 11 "AGRICULTURE AND NATURAL RESOURCES"

ESF #11 – Agriculture and Natural Resources[49] supports State, tribal, and local authorities and other Federal Agency efforts to provide nutrition assistance; control and eradicate, as appropriate, any outbreak of a highly contagious or economically devastating animal/zoonotic (i.e., transmitted between animals and people) disease, or any outbreak of an economically devastating plant pest or disease; ensure the safety and security of the commercial food supply; protect natural and cultural resources and historic properties (NCH) resources; and provide for the safety and well-being of household pets during an emergency response or evacuation situation. ESF #11 is activated by the Secretary of Homeland Security for incidents requiring a coordinated Federal response and the availability of support for one or more of these roles/functions.

Primary Agencies:

- U.S. Department of Agriculture/U.S. Department of the Interior (DOI)

ESF Coordinator:

- U.S. Department of Agriculture

HHS Responsibilities:

FDA will provide support, personnel, or expertise to HHS for many of the HHS responsibilities listed below.

- Determine which foods are fit for human consumption and identifies potential problems associated with contaminated foods
- Provide health education in the areas of food preparation and storage

[49] For more information of ESF #11, refer to: www.fema.gov/pdf/emergency/nrf/nrf-esf-11.pdf

- Provide laboratory and diagnostic support, subject matter expertise, and technical assistance as well as field investigators to assist in product tracing, inspection and monitoring, and interdiction activities
- Provide human health-related information, including surveillance for foodborne disease and occupational safety and health issues
- Provide veterinary public health and clinical subject matter expertise support through the U.S. Public Health Service Commissioned Corps veterinary teams and epidemiologists to address environmental public health, toxicology, bite/scratch injuries from animals, and zoonotic disease hazards; conducts veterinary/animal emergency needs assessments; respond to occupational safety and health issues associated with animal response; and helps implement rabies quarantines, etc.
- Assist in delivering animal healthcare to injured or abandoned animals and performing veterinary preventive medicine activities, including the conducting of field investigations and the provision of technical assistance and consultation as required

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Appendix B: FDA Support for the Incident Annexes to the National Response Framework

The Incident Annexes to the NRF describe the concept of operations to address specific contingency or hazard situations or an element of an incident requiring specialized application of the NRF.

Depending on the nature of the emergency, FDA's response efforts support the following NRF Incident Annexes:

BIOLOGICAL INCIDENT ANNEX

Coordinating Agencies

HHS

Purpose/Scope

The Biological Incident Annex[50] outlines the actions, roles, and responsibilities associated with a response to a human disease outbreak of known or unknown origin requiring Federal assistance. In this annex, a biological incident includes naturally occurring biological diseases (communicable and noncommunicable) in humans as well as terrorist events. This definition also includes those biological agents found in the environment, or diagnosed in animals, that have the potential for transmission to humans (zoonosis). The annex outlines biological incident response actions, including threat assessment notification procedures, laboratory testing, joint investigative/response procedures, and activities related to recovery.

The annex supports policies and procedures outlined in ESF #8, ESF #10, ESF #11, ESF #15 External Affairs, the Terrorism Incident Law Enforcement and Investigation Annex, and the International Coordination Support Annex.

HHS serves as the Federal Government's primary agency for the public health and medical preparation and planning for and response to a biological terrorism attack or naturally occurring outbreak that results from either a known or novel pathogen, including an emerging infectious disease.

The USDA serves as the Government's primary agency for outbreaks and/or attacks that may occur in animals used in the commercial production of food. USDA may also serve as the Government's primary agency for attacks on food processing/slaughtering facilities under its regulatory purview. In the event of a food or animal event, HHS may provide additional public health and veterinary epidemiological assistance to USDA. Wildlife events will be placed under the purview of the DOI, while those involving marine animals will be managed and monitored by the Department of Commerce.

HHS Responsibilities (See ESF #8 for additional information.)

[50] For more information on the NRF Biological Incident Annex, refer to: www.fema.gov/pdf/emergency/nrf/nrf_BiologicalIncidentAnnex.pdf

CATASTROPHIC INCIDENT ANNEX

Coordinating Agency:

- DHS/FEMA

Purpose/Scope

The Catastrophic Incident Annex to the *NRF* (*NRF*-CIA)[51] establishes the context and overarching strategy for implementing and coordinating an accelerated, proactive national response to a catastrophic incident. A catastrophic incident, as defined by the *NRF,* is any natural or manmade incident, including terrorism, which results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population, infrastructure, environment, economy, national morale, and/or government functions.

During a catastrophic incident, normal procedures for certain ESFs may be expedited or streamlined to address the magnitude of urgent requirements of the incident. All ESFs must explore economies of scale to maximize utilization and efficiency of limited resources.

A more detailed and operationally specific *National Response Framework Catastrophic Incident Supplement (NRF-CIS)* is published independently of the *NRF* and annexes.

FDA Responsibilities

Upon notification from the National Operations Center (NOC) that the NRF-CIA has been implemented, Federal Departments and Agencies immediately:

- Take actions to activate, mobilize, and deploy incident-specific resources in accordance with the NRF-CIS
- Take actions to protect life, property, and critical infrastructure under their jurisdiction, and provide assistance within the affected area
- Commence those hazard-specific activities established under the appropriate and applicable NRF Incident Annex(es), including the NRF-CIA
- Commence functional activities and responsibilities established under the NRF ESF Annexes
- All Federal Departments and Agencies and organizations assigned primary or supporting ESF responsibilities immediately begin implementation of those responsibilities, as appropriate or when directed by the President

[51] For more information on the NRF Catastrophic Incident Annex, refer to: www.fema.gov/pdf/emergency/nrf/nrf_CatastrophicIncidentAnnex.pdf

FOOD AND AGRICULTURE INCIDENT ANNEX

Coordinating Agencies:

- U.S. Department of Agriculture
- HHS

Purpose/Scope

The NRF Food and Agriculture Incident Annex[52] describes the roles and responsibilities associated with all incidents involving the Nation's agriculture and food systems that require a coordinated Federal response. The objectives of a coordinated national response to an incident impacting food and agriculture are to:

- Detect the event through the reporting of illness, disease/pest surveillance, routine testing, consumer complaints, and/or environmental monitoring
- Determine the primary coordinating agency
- Determine the source of the incident or outbreak
- Control and contain the distribution of the affected source
- Identify and protect the population at risk
- Assess public health, food, agriculture, and law enforcement implications
- Assess the extent of residual biological, chemical, or radiological contamination, then decontaminate and dispose as necessary

The NRF Food and Agriculture Incident Annex supports policies and procedures outlined in the NRF, ESF #8 – Public Health and Medical Services Annex, the ESF #10 – Oil and Hazardous Materials Response Annex, the ESF #11 – Agriculture and Natural Resources Annex, the Terrorism Incident Law Enforcement and Investigation Annex, and the Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities document.

HHS Responsibilities

(Specific responsibilities are described in greater detail in ESF #8, #10, and #11.)

HHS provides leadership by ensuring the safety and security of food, animal feed, food-producing animals, and animal therapeutics. HHS, through the CDC and in coordination with the States, develops and implements surveillance systems to monitor the health of the human population.

HHS, through FDA, has statutory authority for all domestic and imported food except meat, poultry, and egg products, which are under the authority of the USDA/FSIS. FDA also has statutory authority for animal feed and for the approval of animal drugs intended for both therapeutic and nontherapeutic use in food animals as well as household pets and service animals.)

[52] For more information on the NRF Food and Agriculture Incident Annex, refer to www.fema.gov/pdf/emergency/nrf/nrf_FoodAgricultureIncidentAnnex.pdf.

FDA Responsibilities

- If FDA suspects a threat involving biological, chemical, or radiological agents or indications that instances of disease may not be the result of natural causes, the DOJ must be notified through the DOJ/FBI, WMD Operations Unit.
- Any potential or actual incidents requiring a coordinated Federal response involving contaminated food, infected animals or plants, or economically devastating plant pest infestation should be reported to the Secretary of Homeland Security through NOC at 202-282-8101 and brought to the attention of designated officials according to ESF #8 and ESF #11.
- If terrorist activity is suspected in connection with the incident, procedures outlined in the Terrorism Incident Law Enforcement and Investigation Annex will be followed.

NUCLEAR/RADIOLOGICAL INCIDENT ANNEX

Coordinating Agencies

- DoD
- U.S. Department of Energy
- DHS
- EPA
- National Aeronautics and Space Administration
- Nuclear Regulatory Commission

Purpose/Scope

The Nuclear/Radiological Incident Annex (NRIA) to the NRF describes the policies, situations, concepts of operations, and responsibilities of the Federal Departments and Agencies governing the immediate response and short-term recovery activities for incidents involving release of radioactive materials to address the consequences of the event. These incidents may occur on Federal-owned or -licensed facilities, privately owned property, urban centers, or other areas and may vary in severity from the small to the catastrophic. The incidents may result from inadvertent or deliberate acts. The NRIA applies to incidents where the nature and scope of the incident requires a Federal response to supplement the State, tribal, or local incident response.

This annex applies to two categories of nuclear and radiological incidents: 1) inadvertent or otherwise accidental releases and 2) releases related to deliberate acts. These incidents may also include potential release of radioactive material that poses an actual or perceived hazard to public health, safety, national security, and/or the environment. The category covering inadvertent releases includes: two categories of nuclear facilities (commercial or weapons production facilities), lost radioactive material sources, transportation accidents involving nuclear/radioactive material, domestic nuclear weapons accidents, and foreign accidents involving nuclear or radioactive material that impact the United States or its territories, possessions, or territorial waters. The second category includes, but is not limited to, response to the effects of deliberate attacks perpetrated with radiological dispersal devices (RDDs), nuclear weapons, or INDs.

This annex applies whenever a Federal response is undertaken unilaterally pursuant to Federal authorities, or when an incident exceeds or is anticipated to exceed State, tribal, or local resources. The level of Federal response to a specific incident is based on numerous factors, including the ability of State, tribal, and local officials to respond; the type, amount, and custody of (or authority over) radioactive material involved; the extent of the impact or potential impact on the public and environment; and the size of the affected area.

FDA Responsibilities

- Provide a representative to the Advisory Team for Environment, Food, and Health to develop coordinated advice and recommendations on environmental, food, health, and animal health matters for the Incident Command/Unified Command (IC/UC), DHS, the JFO Unified Coordination Group, the coordinating agency, and/or State, tribal, and local government as appropriate.
- Provide laboratory capabilities for food and agriculture analysis

TERRORISM INCIDENT LAW ENFORCEMENT AND INVESTIGATION ANNEX

Coordinating Agencies

- DOJ/FBI

Purpose/Scope

The purpose of this annex is to facilitate an effective Federal law enforcement and investigative response to all threats or acts of terrorism within the United States, regardless of whether they are deemed credible and/or whether they escalate to an Incident of National Significance. To accomplish this, the annex establishes a structure for a systematic, coordinated, unified, timely, and effective national law enforcement and investigative response to threats or acts of terrorism within the United States.

This annex is a strategic document that:

- Provides planning guidance and outlines operational concepts for the Federal law enforcement and investigative response to a threatened or actual terrorist incident within the United States
- Acknowledges and outlines the unique nature of each threat or incident, the capabilities and responsibilities of the local jurisdictions, and the law enforcement and investigative activities necessary to prevent or mitigate a specific threat or incident

FDA Responsibilities

- Provide support to Federal law enforcement and investigative response efforts related to threats or acts of terrorism involving or impacting FDA-regulated products
- If terrorist activity is suspected in connection with any incident involving FDA-regulated product, the Terrorism Incident Law Enforcement and Investigation Annex will be followed and OCI should be notified of such. OCI will coordinate the Terrorism Incident Law enforcement response with the FBI.

Appendix C: FDA Pre-Scripted Mission Assignments

Requests for support from State and local agencies can be made directly to the agency or, in the case of a declaration of a major disaster or emergency, through FEMA. In order to assist States and local agencies with such requests, FDA has developed PSMAs, which can be used to expedite the submission of such requests.

- FDA investigators (consumer safety officers) or other FDA staff with food safety expertise to provide training in food safety preparation, handling, and storage to volunteers and/or other appropriate disaster response personnel
- FDA analysts (including microbiologists, chemists, biologists, and other disciplines as appropriate) and laboratory facilities to analyze samples of foods, drugs, cosmetics, and/or medical devices for attributes, as necessary, to assist in providing assistance that these commodities are fit for use
- FDA investigators (consumer safety officers) to perform inspections of establishments serving food at retail in <location> for conformance to appropriate food safety standards. Such establishments may include restaurants, school and hospital cafeterias, day care center food service establishments, and temporary shelters, among others
- FDA investigators (consumer safety officers) to perform inspections of pharmacies and other establishments offering human and/or animal drugs and biologics and medical devices at retail to assist in assuring such drugs, biologics and medical devices have been stored under appropriate conditions and are fit for use
- FDA investigators (consumer safety officers) to perform sample collections of human and/or animal foods, human and/or animal drugs, biologics and medical devices subsequent analyses
- FDA SMEs to address issues that impact whether human and/or animal drugs, biologics, human and/or animal foods, and medical devices are appropriate for use; and/or to provide guidance on what steps, if any, may be employed to restore human and/or animal drugs, biologics, human and/or animal foods, and medical devices to a condition whereby they would be fit for use
- FDA investigators (consumer safety officers) with expertise in this area to conduct assessments (field tests) of facilities where diagnostic x-ray and mammography equipment are installed, to help assure the equipment is operating within acceptable radiation emission limits

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Appendix D: Characteristics of Potential Foodborne Agents

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Material was removed from this page in accordance with information rules under 21 CFR 20.66.

Appendix E: Chemical Agents – Background Information[53]

Items in this section are as follows:

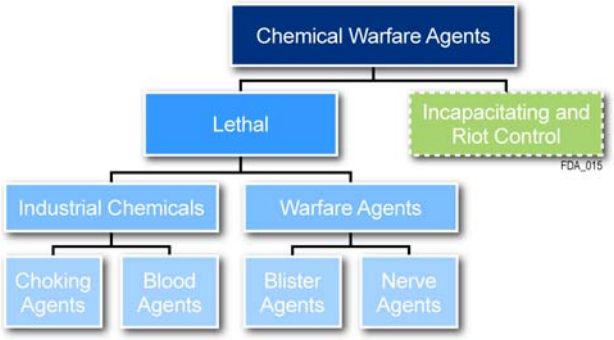
A. General Information
B. Classes of Chemical Warfare Agents
C. Nerve Agent Exposure versus Nerve Agent Intoxication
D. Chemical Agent Characteristics
E. List of Additional Chemical Agents

Additional information on chemical agents may be found at: http://emergency.cdc.gov/chemical/

A. General Information

- Generally liquid (when containerized)
- Normally disseminated as aerosol or gas
- Present a respiratory, dermal, ocular, and mucus membrane hazard
- May be detectable by smell or other senses, but not consistent for all agents
- Dispersal or lack thereof by weather conditions impacts hazard of agent

B. Classes of Chemical Warfare Agents



Lethal

- **Choking Agents (Pulmonary Agents).** Choking agents primarily attack lung tissue, causing pulmonary edema. However, there may also be mild irritation of the eyes and upper respiratory tract.
- **Cyanides (Blood Agents).** Blood agents enter the body following ingestion, skin contact, or inhalation. Once in the body, blood agents inactivate a critical enzyme (cytochrome oxidase); this prevents the cell from using oxygen. Symptoms of blood agent poisoning include respiratory changes, convulsions, and death.
- **Vesicants (Blister Agents).** Blister agents include the mustards, arsenicals (primarily Lewisite), and phosgene oxime. They cause pain and tissue damage. Mustards can have delayed effects (hours), but Lewisite and phosgene oxime cause immediate effects. Vesicants cause either fluid-filled blisters ("blister agents"—mustard and arsenicals) or red, elevated skin lesions (phosgene oxime).
- **Nerve Agents.** Nerve agents cause the greatest concern because of their toxicity, rate of action, and ability to enter the body by multiple routes of entry. Nerve agents are extremely fast acting

[53] Access additional training in this area via the online courses offered by ORA University at http://intranet.ora.fda.gov/dhrd/default.htm.

and classically categorized as colorless and odorless. The symptoms of nerve agents include dimness of vision, runny nose, drooling, difficulty breathing/tightness of chest, nausea, vomiting and diarrhea, muscle jerking or twitching, involuntary urination, defecation, coma, and death.

Incapacitating and Riot Control

Incapacitating and riot control agents are not primary terrorist threats, due to their relatively short duration of effects and minimal toxicity.

C. Nerve Agent Exposure versus Nerve Agent Intoxication

"SLUDGE," bracketed in the box below, is an acronym often used by medical personnel for identifying the symptoms of organophosphate poisoning.

			Vapor Exposure	Liquid Exposure
Mild	P	Pinpointing pupils	X	
	S	Salivation	X	
	L	Lacrimation (tearing)	X	
Severe	U	Urination	X	X
	D	Defecation	X	X
	G	Gastrointestinal; pain and gas	X	X
	E	Emesis (vomiting)	X	X
	M	Muscle twitching	X	X
	C	Convulsions, coma	X	X

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D. Chemical Agent Characteristics

Material was removed from this page in accordance with information rules under 21 CFR 20.66.

E. List of Additional Chemical Agents

Available at: www.bt.cdc.gov/agent/agentlistchem.asp with links for agent description

Chemical Agents	
Abrin	Mustard Gas (H) (Sulfur Mustard)
Adamsite (DM)	Mustard/Lewisite (HL)
Ammonia	Mustard/T
Arsenic	Nitrogen Mustard (HN-1, HN-2, HN-3)
Arsine (SA)	Paraquat
Benzene	Phosgene (CG)
Bromobenzylcyanide (CA)	Phosgene Oxime (CX)
BZ	Phosphine
Chlorine (CL)	Phosphorus, elemental, white or yellow
Chloroacetophenone (CN)	Potassium Cyanide (KCN)
Chlorobenzylidenemalononitrile (CS)	Ricin*
Chloropicrin (PS)	Sarin (GB)
Cyanide	Sesqui Mustard
Cyanogen Chloride (CK)	Sodium Azide
Dibenzoxazepine (CR)	Sodium Cyanide (NaCN)
Diphosgene (DP)	Soman (GD)
Distilled Mustard (HD)	Stibine
Ethylene glycol	Strychnine
Fentanyls and Other Opioids	Sulfur Mustard (H) (Mustard Gas)
Hydrofluoric acid (hydrogen fluoride)	Super warfarin
Hydrogen Chloride	Tabun (GA)
Hydrogen Cyanide (AC)	Thallium
Hydrogen fluoride (hydrofluoric acid)	Unidentified Chemical PDF (20 KB/10 pages)
Lewisite (L, L-1, L-2, L-3)	VX
LSD	White Phosphorus
Mercury	

* May also be considered a biological agent

- For more information on chemical emergencies, including specific chemical agents, information for the public, and information for first responders, refer to the Center for Disease Control and Prevention's Emergency Preparedness and Response Web site at: www.bt.cdc.gov/chemical/.
- For response information for thousands of hazardous materials, including fire and explosion hazards, health hazards, firefighting techniques, cleanup procedures, protective clothing, and chemical properties, refer to: www.cameochemicals.noaa.gov/search/simple

Appendix F: Biological Agents – Background Information[54]

Items in this section are as follows:

A. General Information
B. Classes of Biological Warfare Agents

Additional information on bioterrorism may be found at: www.bt.cdc.gov/bioterrorism/

A. General Information

- Produce delayed effects
- Do not penetrate unbroken skin
- Do not evaporate
- Undetectable by senses
- Difficult to detect in the field
- Range of effects
- Usually obtained from nature
- Can now be produced synthetically starting with coding sequence
- May be engineered for increased virulence
- Have multiple routes of entry
- Potentially destroyed by environment
- Some are contagious
- Virtually impossible to limit spread or deliberate delivery
- Environmental detection systems, for example, BioWatch, for some are now operational
- Countermeasures are available for some agents
- Quarantine strategies may be implemented in an effort to control a biological contagion

B. Classes of Biological Warfare Agents

- **Bacteria.** Bacteria are living unicellular organisms and are predominantly self-sufficient (with the exception of several intracellular species that require a host cell to survive). Bacteria require varying conditions of light, moisture, pH, and temperature to survive. Bacteria cause disease in humans by invading host tissues, by producing toxins, or both. The diseases they produce often respond to specific antibiotic therapies.
- **Viruses.** Viruses need a "host" cell to live and multiply. However, viruses are technically considered living organisms because they contain genetic material. Although environmental detection units utilizing Polymerase Chain Reaction (PCR) technology can detect viruses, they generally would not be able to assess whether or not the virus is viable.
- **Toxins.** Toxins are harmful substances produced by bacteria, plants, and animals. These range from animal venoms (e.g., snake or spider bite), to plant toxins (e.g., ricin), to bacteria toxins (e.g., botulinum toxin). Since they are biochemical moieties (e.g., proteins), they do not replicate and (unlike chemical agents) are nonvolatile and unlikely to cause secondary exposures.

[54] Access additional training in this area via the online courses offered by ORA University at http://intranet.ora.fda.gov/dhrd/default.htm.

C. Epidemiologic Clues that May Signal a Covert Bioterrorism Attack

Adapted below is a CDC list of epidemiologic clues that may signal a biological incident. In addition, FDA may receive information through its adverse event reporting systems, which indicate a possible biological agent contamination. This list provides the opportunity to recognize and respond to the early clues, important for minimizing the harmful impacts of a biological incident.

- A preliminary positive signal from BioWatch Systems
- A signal from the Biosense System
- Intelligence
- Containers of powders or liquids that are in inappropriate places
- Large numbers of ill persons with similar disease or syndrome
- Large numbers of unexplained disease, syndrome, or deaths
- Unusual illness in a population
- Higher morbidity and mortality than expected with a common disease or syndrome
- Failure of a common disease to respond to usual therapy
- Single case of disease caused by an uncommon agent
- Multiple unusual or unexplained disease entities coexisting in the same patient without other explanation
- Disease with an unusual geographic or seasonal distribution
- Multiple atypical presentations of disease agents
- Similar genetic type among agents isolated from temporally or spatially distinct sources
- Unusual, atypical, genetically engineered, or antiquated strain of agent
- Endemic disease with unexplained increase in incidence
- Simultaneous clusters of similar illness in non-contiguous areas, domestic or foreign
- Atypical aerosol, food, or water transmission
- Ill people presenting near the same time
- Deaths or illness among animals that precedes or accompanies illness or death in humans
- No illness in people not exposed to common ventilation systems, but illness among those people in proximity to the systems

D. Bioterrorism Agents/Diseases by Category

This table was created from information from CDC Select Agents Category List (available at: www.bt.cdc.gov/agent/agentlist-category.asp).

For more information on specific biological agents/diseases, including agent lists; fact sheets; questions and answers; references; treatment; laboratory information; and more, refer to the CDC's Emergency Preparedness and Response Web site: www.bt.cdc.gov/agent/agentlist.asp.

Biological Diseases/Agents
Category A
Definition: The U.S. public health system and primary healthcare providers must be prepared to address various biological agents, including pathogens that are rarely seen in the United States. High-priority agents include organisms that pose a risk to national security because they: • Can be easily disseminated or transmitted from person to person • Result in high mortality rates and have the potential for major public health impact • Might cause public panic and social disruption • Require special action for public health preparedness
CATEGORY A AGENTS/DISEASES:
• Anthrax (Bacillus anthracis)
• Botulism (Clostridium botulinum toxin)

Biological Diseases/Agents
• Plague (Yersinia pestis)
• Smallpox (Variola major)
• Tularemia (Francisella tularensis)
• Viral hemorrhagic fevers (filoviruses [e.g., Ebola, Marburg] and arenaviruses [e.g., Lassa, Machupo])
Category B
Definition: Second highest priority agents include those that: • Are moderately easy to disseminate • Result in moderate morbidity rates and low mortality rates • Require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance
CATEGORY B AGENTS/DISEASES:
• Brucellosis (Brucella species)
• Epsilon toxin of Clostridium perfringens
• Food safety threats (e.g., Salmonella species, Escherichia coli O157:H7, Shigella)
• Glanders (Burkholderia mallei)
• Melioidosis (Burkholderia pseudomallei)
• Psittacosis (Chlamydia psittaci)
• Q fever (Coxiella burnetii)
• Ricin toxin from Ricinus communis (castor beans)
• Staphylococcal enterotoxin B
• Typhus fever (Rickettsia prowazekii)
• Viral encephalitis (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis])
• Water safety threats (e.g., Vibrio cholerae, Cryptosporidium parvum)
Category C:
Definition: Third highest priority agents include emerging pathogens that could be engineered for mass dissemination in the future because of: • Availability • Ease of production and dissemination • Potential for high morbidity and mortality rates and major health impact
CATEGORY C AGENTS:
Emerging infectious disease threats such as Nipah virus and hantavirus

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Appendix G: Oversight of Select Agents and Toxins by the U.S. Department of Health and Human Services/Centers for Disease Control and Prevention, and U.S. Department of Agriculture/Animal and Plant Health Inspection Service

(7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73)

HHS SELECT AGENTS AND TOXINS

Abrin
Botulinum neurotoxins
Botulinum neurotoxin producing species of Clostridium
Cercopithecine herpes virus 1 (Herpes B virus)
Clostridium perfringens epsilon toxin
Coccidioides posadasii/Coccidioides immitis
Conotoxins
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus
Francisella tularensis
Lassa fever virus
Marburg virus
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin Lumpy skin disease virus
South American Haemorrhagic Fever viruses
- Flexal
- Guanarito
- Junin
- Machupo
- Sabia

Staphylococcal enterotoxins
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses
- Central European Tick-borne encephalitis
- Far Eastern Tick-borne encephalitis
- Kyasanur Forest disease
- Omsk Hemorrhagic Fever
- Russian Spring and Summer encephalitis

Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)
Yersinia pestis

Overlap Select Agents and Toxins

Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly Pseudomonas *mallei*)
Burkholderia pseudomallei (formerly *Pseudomonas*)
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan Equine Encephalitis virus

USDA Select Agents and Toxins

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Ehrlichia ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus
Menangle virus
Mycoplasma capricolum subspecies *capripneumoniae* (contagious caprine pleuropneumonia)
Mycoplasma mycoides subspecies *mycoides* small colony (*Mmm*SC) (contagious bovine pleuropneumonia)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
Virulent Newcastle disease virus[55]

USDA Plant Protection and Quarantine Select Agents and Toxins

Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly *Pyrenochaeta glycines*)
Ralstonia solanacearum race 3, biovar 2
Rathayibacter toxicus
Sclerophthora rayssiae var zeae
Synchytrium endobioticum
Xanthomonas oryzae
Xylella fastidiosa (citrus variegated chlorosis strain)

11/17/2008

[55] A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

Appendix H: Domestic and International Traceback/Traceforward

H.1 DOMESTIC

When there is an FDA-regulated product potentially affected by an emergency, it is necessary to determine all distribution of the affected product. After appropriate consultation with others (State and local officials, Centers, and CDC), the FDA EOC, in coordination with ORO, initiates a traceback/ traceforward investigation.[56] The FDA EOC coordinates the tracing (forward and backward) of the distribution of any potentially contaminated FDA-regulated products and initiates seizures or recalls, as appropriate. CDC and local or State agencies may provide assistance on the traceback/traceforward.

H.2 INTERNATIONAL

If FDA determines international distribution of the product occurred, OIP notifies foreign governments of the situation, as appropriate. OIP is also FDA's lead office for communicating with various international stakeholders, including the DOS, foreign and U.S. embassies, foreign governments (including counterpart foreign agencies), and international organizations. When FDA learns of suspect or actual incidents involving FDA-regulated products received from or sent to foreign countries, the FDA EOC promptly notifies the Deputy Commissioner for International Programs and the Assistant Director for Communications in OIP, who then coordinates with recall personnel and/or other appropriate staff for the notification and exchange of information with the affected countries.

In addition, OIP coordinates with the FDA EOC to provide timely notification with the appropriate degree of urgency to the following offices as necessary, and appropriate:

- FDA Center international offices or liaisons
- Embassies of the country or countries involved
- Office of Global Health Affairs/HHS
- Desk officers at the DOS
- Other relevant U.S. Agency international components
- Appropriate international organizations

Epidemiological traceback data provide the basis for enforcement strategies. At the border, this includes procedures to facilitate movement of similar products that are in compliance with the FFDCA (as mandated in Section 302 of the Bioterrorism Act) or otherwise not considered a serious threat to public health and safety. Epidemiological traceback data provide intelligence that allows FDA to identify historical shipments through the same or similar streams of commerce of implicated products for appropriate follow-up. Follow-up activities include visiting importers and consignees of previous shipments to identify disposition of imported goods and identifying individuals and firms responsible for the sale, purchase, and receipt of implicated products.

[56] For more information on how the FDA conducts traceback investigations, refer to www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075005.htm and the FDA's "*Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations*," April, 2001.

The agency will use the Operational and Administrative System for Input Support or the Mission Activity Reporting and Compliance System, and may work with the CBP, located at the Commercial Trade Analytical Center, to analyze entry data in order to support decisions for dispatching human resources through assignments or other methods established for rapid response to support operations. The Director of DIOP will advise CBP of the situation and the information needed to use CBP's Automated Targeting System (ATS) to detect and detain future shipments of potentially tainted products before their introduction into U.S. commerce.

Appendix I: FDA/CDC Memorandum of Understanding

A MOU is a critical component of any formal arrangement for cooperation between two or more entities. A MOU usually describes, in broad general terms, an area of mutual interest or concern that two or more agencies or organizations may cooperatively address. MOUs generally do not include specific information regarding detailed scope of work or the exchange of funds or human resources.

MOU 225-09-0002

U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Home > About FDA > Partnerships & Collaborations > Memoranda of Understanding (MOUs)

About FDA

MOU 225-09-0002

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
FOOD AND DRUG ADMINISTRATION
AND THE
CENTERS FOR DISEASE CONTROL AND PREVENTION

1. PURPOSE

This Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) provides a framework for coordination and collaborative efforts between these two agencies which are both components of the Department of Health and Human Services. This MOU also provides the principles and procedures by which information exchanges between FDA and CDC shall take place.

This memorandum supersedes the Memorandum of Understanding Between the Centers for Disease Control and the Food and Drug Administration, dated June 14, 2006, regarding the exchange of information and coordination of actions.

II. BACKGROUND

FDA and CDC are sister agencies within the Department of Health and Human Services. Both FDA and CDC exist and work to protect the public health but have different statuary mandates and responsibilities.

FDA is a regulatory agency responsible for protecting the public health through the regulation of food, cosmetics, and medical products, including drugs, biological products, animal drugs, and medical devices. FDA administers the Federal Food, Drug, and Cosmetic Act and relevant sections of the Public Health Service Act, among other statutes. Among its duties, FDA approves pre-market applications, conducts inspections of manufacturing facilities, and monitors post-marketing adverse events. FDA also initiates civil and criminal litigation to enforce applicable laws and regulations.

CDC's mission is collaborating to create the expertise, information, and tools that people and communities need to protect their health -through health promotion, prevention of disease, injury and disability, and preparedness for new health threats. CDC seeks to accomplish its mission by working with partners throughout the nation and the world to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies, promote healthy behaviors, foster safe and healthful environments, provide leadership and training. CDC conducts its activities under the authority of the Public Health Service Act and several other federal statutes.

CDC's and FDA's respective missions to protect the public health may overlap in a variety of ways depending upon the subject matter. Each agency has a responsibility to work collaboratively to protect and improve public health. It may sometimes be the case that FDA or CDC will be in possession of information that could be useful to the other agency in that agency's performance of its responsibilities. Timely sharing of information between CDC and FDA is therefore critical to protecting the public health.

III. SUBSTANCE OF AGREEMENT AND RESPONSIBILITIES OF EACH AGENCY

A. Coordination and Collaboration Relative to Public Health Activities

It is mutually agreed that:

1. Each agency will coordinate and collaborate with the other agency to protect and improve the public health. To achieve this, each agency will utilize the expertise, resources, and relationships of the other agency in order to increase its own capability and readiness to respond to emergency situations. In addition, each agency will designate central contact points where communications from the other agency, dealing with matters covered by this agreement, should be referred.

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2. Each agency will participate in periodic joint meetings to promote better communication and understanding of regulations, policies, and statutory responsibilities, and to serve as a forum for questions and problems that may arise.

3. Each agency will notify the other agency as soon as possible when issues of mutual concern become evident.

4. Each agency will collaborate with the other agency in all investigations of mutual concern. Such collaboration may include providing alerts to the other agency when issues are identified; providing technical advice in areas of recognized expertise; providing results of analysis; coordinating health protection information and recommendations provided to the public; making available expert witnesses; and exchanging information as described in section III B.

5. Each agency will consult with the other before issuing press or scientific releases or publications that may have a significant impact on the other agency.

6. Each agency will refer its proposed regulations, guidances, or recommendations that may have a significant impact on the other agency for review and comment by that agency before publication.

7. This agreement does not preclude CDC or FDA from entering into other agreements which may set forth procedures for special programs which can be handled more efficiently and expertly by other agreements.

B. Principles and Procedures for the Exchange of Information That is Not Publicly Available

FDA and CDC agree that the following principles and procedures will govern the exchange of nonpublic information between the two agencies.

Although there is no legal requirement that FDA and CDC exchange information in all cases, FDA and CDC agree that there should be a presumption in favor of full and free sharing of information between FDA and CDC. As sister public health agencies within the Department of Health and Human Services, there are no legal prohibitions that preclude FDA or CDC from sharing with each other most agency records in the possession of either agency. Both agencies recognize and acknowledge, however, that it is essential that any confidential information that is shared between FDA and CDC must be protected from unauthorized public disclosure. See e.g., 21 U.S.c. sec. 3310); 18 U.S.C. section 1905; 21 C.F.R. Parts 20 and 21; 45 C.F.R. Parts 5 and 5b, and 42 U.S.c. section 241 (d). Safeguards are important to protect the interests of, among others, owners and submitters of trade secrets and confidential commercial information; patient identities and other personal privacy information; privileged and/or pre-decisional agency records: and information protected for national security reasons. Such safeguards also help ensure FDA's and CDC's compliance with applicable laws and regulations.

To facilitate the sharing of information with each other, it is necessary that FDA and CDC implement procedures to ensure, at a minimum, that such sharing of information is indeed appropriate and that the recipient agency appropriately guards the confidentiality of all non-public information received. There] are separate procedures, as described below, for routine requests for information and for emergency requests. It is incumbent upon both agencies to respond to requests for information in a timely manner. Any unauthorized disclosure of shared confidential information by the agency receiving the information shall be the responsibility of that agency, so long as the agency providing such information conveys the confidential nature of the information to the receiving agency, in accordance with the terms of this MOU, or the receiving agency otherwise has knowledge that such information is confidential.

1. Routine Requests for Non-public Information

a. The requesting agency must demonstrate, in writing, why it is necessary for it to obtain the requested information. This demonstration should consist of a summary that describes in detail the information requested (to facilitate identification of relevant records) and a brief statement of the purpose for which the information is needed. This request shall state which internal agency offices and/or individuals requested the information. A model request
letter is attached.

It is assumed that each agency has implemented or will implement all data and information security requirements and has implemented or will implement, to the extent necessary and practicable all data and information security recommendations.

b. The agency receiving the request for information shall, based upon the sufficiency of the need-to-know demonstration described in section III B 1 above, determine whether it is appropriate to share the requested information with the requesting agency. The need-to-know threshold is a low one. As stated above, there is a presumption in favor of information exchange between FDA and CDC. An agency should only decide not to share information in response to a request if it has credible information and a reasonable belief that the requesting agency may not be able to comply with applicable laws or regulations governing the protection of non-public information or with principles or procedures set forth in the MOD. If an agency decides that it is not appropriate to share information with the requesting agency, it shall describe to the requesting agency the reasons for such decision.

MOU 225-09-0002

c. The requesting agency agrees that it shall comply with the following conditions:

--The requesting agency shall limit the dissemination of shared information it receives to internal agency offices and/or individuals that have been identified in its written request and/or have a need-to-know. The agency official who signs the request letter will be responsible for ensuring that there are no other recipients of the information.

--The requesting agency shall agree in writing not to publicly disclose any shared information in any manner including publications and public meetings. If the requesting agency wishes to disclose shared information, including information that it believes is publicly releasable, it shall first request and obtain the written permission of the agency that has shared the information. If the requesting agency receives a Freedom of Information Act (FOIA) request for the shared information, it will refer the request to the information-sharing agency for it to respond directly to the requestor regarding the releasability of the information. In such cases, the agency making the referral will notify the requestor that a referral has been made and that a response will issue directly from the other agency.

--The agency that shares information with the requesting agency shall include a transmittal letter, along with any agency records exchanged. The transmittal letter shall indicate the type of information being shared (e.g. confidential commercial information, personal privacy, or pre-decisional). A model transmittal letter is attached.

--The requesting agency shall promptly notify the appropriate office of the information-sharing agency when there is any attempt to obtain shared information by compulsory process, including but not limited to, a FOIA request, subpoena, discovery request, or litigation complaint or motion.

--The requesting agency shall notify the information-sharing agency before complying with any judicial order that compels the release of such information so that the agencies may determine the appropriate measures to take, including where appropriate the filing of a motion or an appeal with the court.

2. Emergency Requests for Non-public Information

In cases in which the requesting agency has a need to obtain certain information as soon as possible due to emergency circumstances, such as an outbreak of illness, FDA and CDC may utilize the following procedures. These procedures are intended for use only in the case of an actual emergency situation and are not appropriate for routine requests for information.

a. The requesting agency shall indicate orally or in writing to the agency in possession of the relevant information that it has the need to obtain certain identifiable information as soon as possible due to the existence of emergency circumstances. The requesting agency shall also describe what the emergency circumstances are.

b. The requesting agency shall verbally agree to protect from unauthorized public disclosure any and all information that is shared, according to all applicable laws and regulations.

c. The existence of an actual emergency situation shall warrant, as determined by the agency in possession of the requested records, the waiver of the need to-know demonstration and determination described above in section III B I a and B I b. However, once the requesting agency has obtained the information it seeks, it shall comply with those procedures set forth in section III B 1 c above.

IV. NAME AND ADDRESS OF PARTICIPATING PARTIES

A. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

B. Centers for Disease Control and Prevention
Department of Health and Human Services
1600 Clifton Road, NE
Atlanta, Georgia 30333

MOU 225-09-0002

IV. LIAISON OFFICERS

A. Contact for FDA:
Ellen F. Morrison, Director
Office of Crisis Management
Food and Drug Administration
Rockville, MD 20857
(301) 827-5660

B. Contact for CDC
Tanja Popovic, M.D, PhD.
Chief Science Officer
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30333
(404) 639-7000

V. PERIOD OF AGREEMENT

This agreement becomes effective upon signature of both parties and will continue for five years. It may be modified by mutual consent or terminated by either party upon 120 days written notice.

Attachments
Model Request Letter
Model Transmittal Letter

Approved and Accepted
for the Centers of Disease Control and Prevention
Signed by: Thomas R. Frieden, M.D., M.P.H.
Director, Centers for Disease Control and Prevention
Date: June 25, 2009

Approved and Accepted
for the Food and Drug Administration
Signed by: Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Date: June 18, 2009

Reference: Formerly 225-03-8001; 225-00-8000 and 225-06-8401

http://wcms.fda.gov/FDAgov/AboutFDA/PartnershipsCollaborations/MemorandaofUnders... 5/21/2010

MOU 225-09-0002

[Model Transmittal letter from CDC to FDA]

This letter accompanies agency records that the Centers for Disease Control and Prevention (CDC) is sharing with the Food and Drug Administration (FDA) in response to FDA's request, dated_____. These agency records contain one or more of the following categories of non-public information, including information the public disclosure of which may be prohibited by law:

[CDC checks applicable items below]

_trade secrets;
_confidential commercial or financial information;
_information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
_ information subject to the Privacy Act;
_intra-agency records;
_ records or information compiled for law enforcement purposes;
_information protected for national security reasons; or
__other.

FDA shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain shared information by compulsory process, including but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

FDA shall notify the information-sharing agency before complying with any judicial order that compels the release of such information so that FDA and/or CDC may take appropriate measures, including filing a motion with the court or an appeal.

FDA has agreed, by this letter or e-mail and by a signed request letter dated _____ not to publicly disclose the above-described information without prior written permission of CDC. FDA acknowledges that applicable laws and regulations may prohibit the disclosure of such information. See, e.g., 21 U.S.c. §331(j); 18 U.S.C. §1905,21 C.F.R. Parts 20 and 21,45 C.F.R. Parts 5 and 5b and 42 U.S.C. §241(d). FDA also agrees to comply with the principles and procedures set forth in the 2009 Memorandum of Understanding between FDA and CDC.

http://wcms.fda.gov/FDAgov/AboutFDA/PartnershipsCollaborations/MemorandaofUnders... 5/21/2010

MOU 225-09-0002

[Model Transmittal letter from FDA to CDC]

This letter accompanies agency records that the Food and Drug Administration (FDA) is sharing with the Centers for Disease Control and Prevention (CDC) in response to CDC's request, dated_____. These agency records contain one or more of the following categories of non-public information, including information the public disclosure of which may be prohibited by law:

[FDA checks applicable items below]

_trade secrets;

_confidential commercial or financial information;

_information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

_ information subject to the Privacy Act;

_intra-agency records;

_ records or information compiled for law enforcement purposes or

_information protected for national security reasons

CDC shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain shared information by compulsory process, including but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

CDC shall notify the information-sharing agency before complying with any judicial order that compels the release of such information so that FDA and/or CDC may take appropriate measures, including filing a motion with the court or an appeal.

CDC has agreed, by this letter or e-mail and by a signed request letter dated _____, not to publicly disclose the above-described information without prior written permission of FDA. CDC acknowledges that applicable laws and regulations may prohibit the disclosure of such information. See e.g., 21U.S.C.§331G); 18U.S.C.§1905, 21 C.F.R. Parts 20 and 21, 45 C.F.R. Parts 5 and 5b and 42 U.S.C. §241(d). CDC also agrees to comply with the principles and procedures set forth in the 2009 Memorandum of Understanding between FDA and CDC.

Links on this page:

http://wcms.fda.gov/FDAgov/AboutFDA/PartnershipsCollaborations/MemorandaofUnders... 5/21/2010

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Appendix J: FDA/USDA Memoranda of Understanding

A MOU is a critical component of any formal arrangement for cooperation between two or more entities. A MOU usuall describes, in broad general terms, an area of mutual interest or concern that two or more agencies or organizations may cooperatively address. MOUs generally do not include specific information regarding detailed scope of work or the exchange of funds or human resources.

U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Home > About FDA > Partnerships & Collaborations > Memoranda of Understanding (MOUs)

About FDA

MOU 225-99-2001

Memorandum of Understanding

Between
The Food Safety and Inspection Service
United States Department of Agriculture

and

The Food and Drug Administration
United States Department of Health and Human Services

I. PURPOSE

This agreement between the Food and Drug Administration, Department of Health and Human Services (FDA) and the Food Safety and Inspection Service, United States Department of Agriculture (FSIS), is intended to facilitate an exchange of information between the agencies about establishments and operations that are subject to the jurisdiction of both agencies. This exchange of information will permit more efficient use of both agencies' resources and will contribute to improved public health protection.

II. BACKGROUND

In May 1997 Report to the President entitled "Food Safety From Farm to Table – A National Food-Safety Initiative," the agencies primarily responsible for food safety made several recommendations to improve public health protection from foodborne illeness. Several recommendations addressed the issues of increasing cooperation among agencies and, more specifically, of ensuring that the resources and experience of FDA and FSIS are used as efficiently as possible to avoid duplication of efforts.

To advance the purposes of the President's Food Safety Initiative, FDA and FSIS have re-evaluated a previous Memorandum of Understanding on coordination of inspectional efforts signed by FSIS on July 14, 1983 and by FDA on July 25, 1983. The agencies have determined that changes in inspectional activities, available resources, and food safety hazards necessitate updating that agreement. Therefore, FDA and FSIS have entered into this Memorandum of Understanding to address today's public health needs.

III. STATUTORY AUTHORITIES

FSIS is responsible for implementing and enforcing the Federal Meat Inspection Act (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451, *et seq.*), and parts of the Egg Products Inspection Act (21 U.S.C. 1031, *et seq.*). In carrying out its responsibilities under these acts, FSIS places inspectors in meat and poultry slaughterhouses and in meat, poultry, and egg processing plants. FSIS also conducts inspections of warehouses, transporters, retail stores, restaurants, and other places where meat, poultry, and egg products are handled and stored. In addition, FSIS conducts voluntary inspections under the Agriculture Marketing Act (7 U.S.C. 1621, *et seq.*).

FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq.*), the Public Health Service Act (42 U.S.C. 201, *et seq.*), the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), and parts of the Egg Products Inspection Act. In carrying out its responsibilities under these acts, FDA conducts inspections of establishments that manufacture, process, pack, or hold foods, with the exception of certain establishments that are regulated exclusively by FSIS. FDA also inspects vehicles and other conveyances, such as boats, trains, and airplanes, in which foods are transported or held in interstate commerce.

Nothing in this agreement shall lessen the responsibilities or authorities of FSIS and FDA under their statutory authorities.

IV. SUBSTANCE OF AGREEMENT

1. List of District Level Contacts

The agencies agree to develop, maintain, and annually update a list of their districts and of persons to contact at the district management level. In addition to the annual updates to these lists, each district aggrees to promptly inform its counterpart district of any change in the contact person for that district. The agencies also agree to develop and maintain a list of the district offices responsible for each state and territory. Each agency agrees to promptly inform the other agency of any changes in the jurisdiction of district offices or in the field organization of the agency. These lists are to be distributed to the district managers of both FSIS and FDA.

2. List of Dual Jurisdiction Establishments

The agencies agree to develop, maintain, and annually update a list of dual jurisdiction establishments (hereinafter "DJEs"), that is, establishments that prepare, pack, hold, or otherwise handle both foods regulated by FSIS and foods regulated by FDA. This list is to be organized by state and territory and will be distributed to the district managers of both FSIS and FDA. When updating this list, each agency agrees to identify all DJEs that have discontinued operations that are under it jurisdiction.

3. System of Communication

The district offices of each agency agree to promptly report to their counterparts district offices certain findings, as set forth in paragraphs 5, 6, and 7, relating to DJEs. The district office receiving the report agrees to respond with information regarding any planned or completed follow-up action relating to the reported information. District management of both agencies are encouraged to initiate contact and to meet annually, or as frequently as necessary, to facilitate the exchange of information about establishments and foods prepared, packed, held, or otherwise handled by these establishments. The agencies agree to work together to develop, put in place, and maintain a system of electronic communication at the district level to facilitate the exchange of information about the DJEs.

4. Notification of Periodic Inspection

Each agency agrees to attempt to notify the appropriate contact identified in paragraph 1 of this section prior to conducting an inspection of a DJE that is not under continuous FSIS inspection. In addition, FDA agrees to attempt to notify the FSIS inspector prior to inspecting a DJE that is under continuous inspection and to invite the FSIS inspector to accompany the FDA investigator on the inspection.

5. Findings Involving DJEs That Are To Be Reported By Both Agencies

The district office of each agency is to notify its counterpart district office of the following findings in a DJE:

a. Foods implicated in outbreaks of foodborne illness, injuries, or adverse reactions.

b. Foods found to be contaminated or mislabeled such that there is a reasonable probability that the use of or exposure to such products will cause serious adverse health consequences. Hazards that constitute contamination or mislabeling covered under this paragraph are attached as Appendix A.

c. A processing condition or failure that is likely to result in food contamination leading to outbreaks of foodborne illness, injuries, or adverse reactions.

d. Foods that have been recalled.

e. Reports of tampering or threats of tampering.

f. A food handler diagnosed as having a communicable disease that is likely to result in food contamination or outbreaks of foodborne illness (e.g., hepatitis).

g. Convictions of a DJE, or any officer or key employee of a DJE, for any felony or more than one misdemeanor involving the DJE or any food prepared, packed, held, or otherwise handled in the DJE.

h. Convictions of an establishment preparing, packing, holding, or otherwise handling meat, poultry or egg products solely under state regulation and foods regulated by FDA, or any office or key employee of such an establishment, for any felony or more than one misdemeanor involving the establishment or any food prepared, packed, held, or otherwise handled in the establishment.

6. Additional Findings Involving DJEs That Are To Be Reported By FSIS to FDA

In addition to the findings in paragraph 5, the FSIS district office is to notify its counterpart district office of FDA of the following finding in a DJE:

a. FSIS action to withhold the mark of inspection or to suspend or withdraw the grant of inspection.

7. Additional Findings Involving DJEs That Are To Be Reported By FDA to FSIS

In addition to the findings in paragraph 5, the FDA district office is to notify its counterpart district office of FSIS of the following findings:

a. Any other processing condition in a DJE that could render foods bearing a USDA mark of mandatory or voluntary inspection adulterated or mislabeled.

b. Reason to believe that an FDA-regulated ingredient that would adulterate a meat, poultry, or egg product if used in it has been sent to or received by an FSIS-regulated establishment.

8. Follow-Up Action

a. The agency receiving the notification of a finding listed in paragraphs 5, 6, or 7 agrees to evaluate it and take appropriate action.

b. For all reported findings listed in paragraphs 5, 6, or 7, the agency receiving the notification agrees to track and use the information in program evaluation, work planning, and consideration of whether action against the establishment is warranted.

c. The agency receiving the notification of a finding listed in paragraph 5, 6, or 7 agrees to respond to the notification within 30 days by communicating the disposition of the notification to the notifying agency at the district management level, including, if appropriate, any and all actions planned and taken by the agency receiving notification. In addition, the agencies agree to explore the feasibility of granting each other access to appropriate computer monitoring system to permit interagency tracking of findings listed in paragraphs 5, 6, or 7.

9. Information Sharing and Confidentiality

To promote increased cooperation and efficient use of enforcement resources, each agency agrees to share information for enforcement purposes

upon request by the other agency, to the extent permitted by applicable law. All non-public information shared between the two agencies pursuant to this agreement is subject to all applicable limitations established by statute or regulation on interagency sharing of information. The current policies and procedures for sharing such information are attached as Appendix B.

10. Training

The agencies agree to develop and provide appropriate training in the inspectional techniques and processes of each agency as the agencies determine is necessary to ensure that the contacts for each agency have an appropriate understanding of the workings of the other agency. This understanding will help ensure the successful implementation of this agreement. The agencies agree to develop and initiate the training as quickly as possible. The district managers of both agencies are encouraged to evaluate training needs during annual meetings, or as frequently as necessary, to determine whether additional training is warranted.

11. Joint Enforcement Activities

The agencies agree to establish a group to explore the feasibility of joint enforcement activities. This group is to report its findings and recommendations by March 1, 1999 to the Commissioner of FDA and the Administrator of FSIS.

12. Re-evaluation of the Agreement

The agencies agree to re-evaluate the effectiveness of this agreement after it has been in effect for one year. The agencies also agree to explore the feasibility of expanding their cooperative activities after one year, or sooner if the agencies agree that it is appropriate to do so.

V. PERIOD OF AGREEMENT

The agencies agree to begin implementing this agreement within 30 days from execution by both parties. This agreement will be effectively indefinitely. It may be modified by mutual consent or terminated by either party upon 30 days' written notice to the other.

VI. PREVIOUS AGREEMENTS

This agreement supersedes the Memorandum of Understanding on coordination of inspectional efforts signed by FSIS on July 14, 1983 and by FDA on July 25, 1983. This MOU does not modify any other existing agreements between USDA and FDA.

VII. NAME AND ADDRESSES OF PARTICIPATING AGENCIES

Food Safety and Inspection Service
1400 Independence Ave., S.W.
Washington, D.C. 20250-3700

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

VIII. LIAISON OFFICERS

For FSIS:
John McCutcheon
Associate Deputy Administrator,
Office of Field Operations
Food Safety Inspection Service
1400 Independence Ave. S.W.
Washington, DC 20250-3700
202-720-5190

For FDA:
Gary Pierce
Director, Division of Emergency and Investigational Operations
Food and Drug Administration
5600 Fishers Lane (HFC-130)
Rockville, MD 20857
301-827-5655

Appendix A
Findings That Constitute Contamination or Mislabeling Under Section IV, 5, b.

The following findings of contamination or mislabeling should be reported by FSIS to FDA under section IV, 5, b:

1. pathogenic organisms

2. undeclared allergens (e.g., peanuts, peanut butter, peanut flour, hydrolyzed peanut protein, pecans, walnuts, hazelnuts, filberts, cashews, Brazil nuts, eggs, egg whites, egg yolk, egg albumen, powered eggs, shrimp, crab, crayfish, lobster, oysters, clams, scallops, mussels, almonds, pistachios, cow milk, cream, dry milk, whey, other proteins from cow's milk, soy, soybeans, soy protein, soy flour, corn, corn flour, corn meal, fish, oats, wheat):

3. undeclared color additives FD&C Yellow No. 5 and FD&C Yellow No. 6; and

4. undeclared sulfites.

Appendix B
Policies and Procedures for Information Sharing

Under this MOU, neither FDA nor FSIS will disclose to each other confidential commercial or trade secret information. The information FDA and FSIS disclose to each other under this MOU may include other information exempt from public disclosure, such as information compiled for law enforcement purposes and predecisional information.

To promote the sharing of information for enforcement purposes, while ensuring that both agencies protect information exempt from public disclosure, FDA and FSIS agree to comply with the following conditions:

1. The agency that shares information ("the information-sharing agency") shall include a transmittal letter along with any non-electronic agency records exchanged that are exempt from public disclosure. A model transmittal letter is attached. The first page of each document provided shall be stamped "CONFIDENTIAL [name of information-sharing agency] DOCUMENTS: DO NOT DISCLOSE WITHOUT WRITTEN PERMISSION OF [name of information-sharing agency]." Electronic records, such as e-mails, that are exchanged and that contain information exempt from public disclosure shall include the following statement: "This e-mail contains information exempt from public disclosure that is being shared in accordance with the Memorandum of Understanding dated January 22, 1999, between FDA and FSIS regarding dual-jurisdiction establishments. This information may not be further disclosed without prior written permission from the agency that provided it."

2. The agency that receives the information ("the recipient agency") shall not disclose any shared information designated by the information-sharing agency as exempt from public disclosure to any person or entity outside the recipient agency, including the Department of Justice or a court, without first requesting and obtaining written permission of the information-sharing agency. The information-sharing agency will not withhold permission to disclose information pursuant to a court order, provided that the recipient agency notifies the information-sharing agency upon receipt of the order provided in paragraph 4.

3. The recipient agency shall notify the information-sharing agency upon receipt of any request from a third party for shared information designated by the information sharing agency as exempt from public disclosure. In addition to its ordinary English meaning, the term "request" includes Freedom of Information Act requests, Congressional inquiries, and attempts to obtain information by compulsory process, including, but not limited to, subpoenas and discovery requests.

4. The recipient agency shall notify the information-sharing agency upon receipt of any judicial order that compels the release of shared information designated by the information-sharing agency as exempt from public disclosure so that the information-sharing agency may take appropriate measures, such as filing a motion with the court that issued the order or filing an appeal.

Model Transmittal letter

This letter accompanies agency records that are being shared in accordance with the Memorandum of Understanding dated January 22, 1999, between FDA and FSIS regarding dual-jurisdiction establishments. These agency records contain information exempt from public disclosure and may not be further disclosed without written permission from the agency that provided them.

Approved and Accepted
for the Food Safety Inspection Service

Signed by: Thomas J. Billy
Administrator, FSIS

Date: February 23, 1999

Approved and Accepted
for the Food and Drug Administration

Signed by: Michael A. Friedman, M.D.
Deputy Commissioner for Operations, FDA

Date: February 23, 1999

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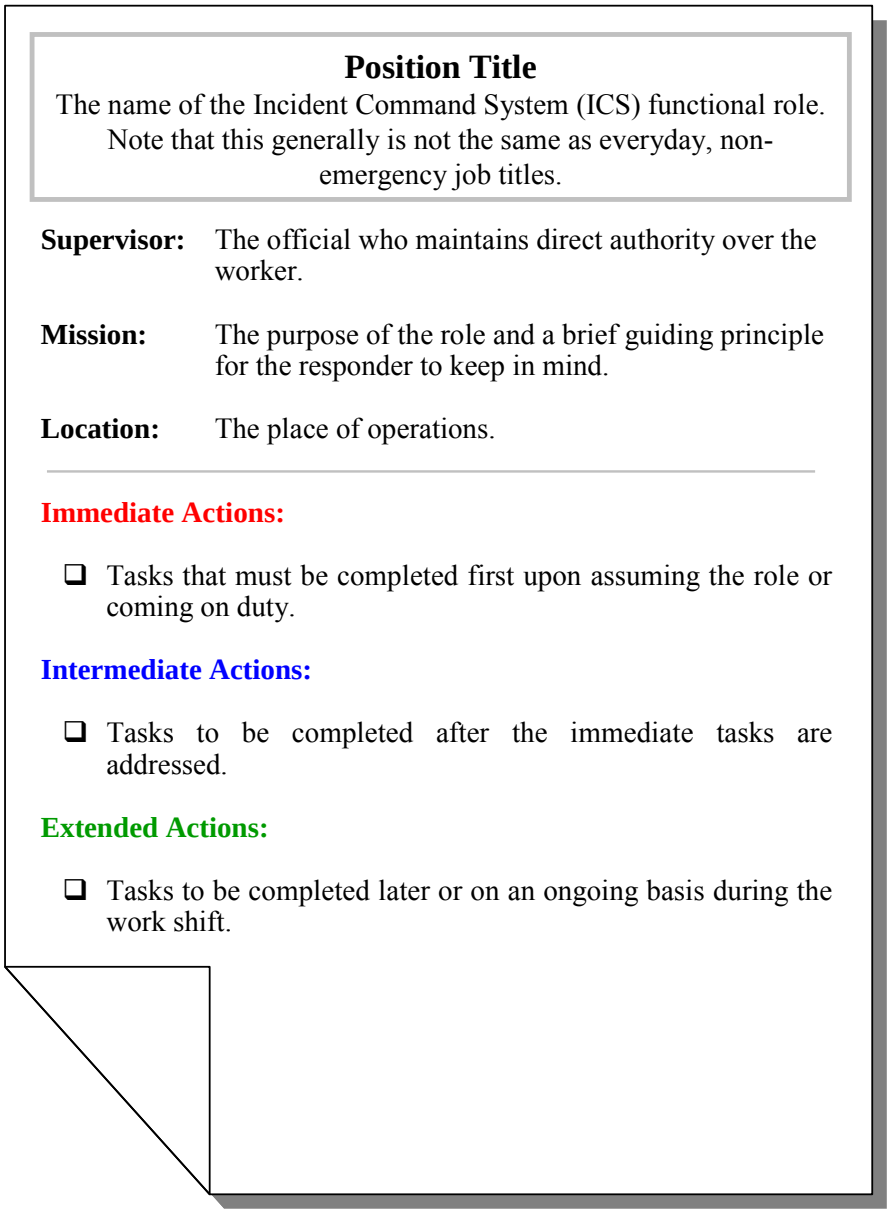
Appendix K: Job Action Sheets

Job Action Sheets are tools for defining and performing specific emergency response functional roles. The Job Action Sheets contained within this Appendix are designed to assist FDA Command and General Staffs during all hazards. They can be easily amended to fit the specific requirements of the situation at-hand. The key elements are as follows:



The following Job Action Sheets contain recommended actions that are reminders of activities to take into consideration when fulfilling the assigned role.

K.1 Agency Incident Coordinator (IMG)

Supervisor: Commissioner or AEG

Mission: Organize and manage Command and General Staffs. Coordinate and report on agency organizational components responsible for performing emergency response operations.

Location: FDA EOC

Immediate Actions:

- ❑ Read this entire Job Action Sheet.
- ❑ Identify all Command Staff and Section Chiefs who are required for this response. Construct an agency ICS organizational chart.
- ❑ Develop and provide an initial incident briefing to all personnel staffing the ICS.
- ❑ Distribute section packets to each position, which contain: Job Action Sheets and any other relevant guides, forms, or templates. Refer all assigned personnel to the EON IMS for additional materials.
- ❑ Confer with OCM.
- ❑ Director regarding activation of the FDA EOC. Notify all relevant FDA and external Federal Agency personnel of activation level and reporting requirements.
- ❑ Confer with Command Staff and Section Chiefs to develop an IAP for a defined period of time, establishing priorities (Section Chiefs will communicate IAP to responsible Center/Office emergency personnel).
- ❑ Consider and assign responsibilities for communicating with agency organizational components and external Federal Agencies, as appropriate.
- ❑ Assure that contact has been established and resource information shared with relevant Federal Agencies.

Intermediate Actions:

- ❑ Schedule routine briefings with Section Chiefs and update the IAP regarding the continuance and/or termination of agency emergency operations.
- ❑ Participate in regularly scheduled agency situation/status briefings and teleconferences.
- ❑ Maintain contact with AEG.
- ❑ Maintain contact with relevant Federal Agencies.

Extended Actions:

- ❑ Observe all staff for status and signs of stress and provide regular rest periods.
- ❑ At shift change, provide a briefing on past and ongoing agency emergency response activities to incoming staff. Provide additional detailed information to your replacement, as required.
- ❑ Plan for the possibility of extended operations.

K.2 PUBLIC INFORMATION OFFICER (IMG)

Supervisor: AIC

Mission: Serve as a conduit of information between, and maintain regular communications with, AIC, OEA, and Center/Office External Affairs and communications staffs. Inform Command and General Staffs of any associated activities, concerns, and requests related to incident information.

Location: FDA EOC or OEA Office

Immediate Actions:

- ❑ Upon notification, report to the FDA EOC. Notify appropriate OEA staff of activation status and close out performance of all day-to-day activities.
- ❑ Read this entire Job Action Sheet and review the agency ICS organizational chart.
- ❑ Obtain briefing from the AIC. Report this information to appropriate OEA, Center/Office, and field public affairs/communications staffs.
- ❑ Assist the Planning Section Chief with formulation of an IAP.

Intermediate Actions:

- ❑ Report on OEA, Center/Office, and field public affairs and communications activities, RFIs, concerns, and scheduled agency press conferences to the AIC.
- ❑ Evaluate agency External Affairs strategy in support of the IAP and overall response efforts.
- ❑ Assist OEA, headquarters Centers/Offices, and field offices in drafting press reports and media releases. Ensure that the AIC and Section Chiefs, as appropriate, review and approve of all public information releases.
- ❑ Assist OEA in developing and posting public and industry messaging and guidance to the FDA Web site.
- ❑ Participate in regularly scheduled agency situation/status briefings and teleconferences. Provide spot reports to appropriate OEA staff, as necessary.
- ❑ If the incident warrants establishment of a JIC, monitor its activities to ensure agency adherence to Federal, State, and local External Affairs strategies.

Extended Actions:

- ❑ At shift change, provide a briefing on past and ongoing External Affairs activities to incoming staffs. Provide additional detailed information to your replacement, as required.
- ❑ Plan for the possibility of extended operations.

K.3 LIAISON OFFICER (IMG)

Supervisor: AIC

Mission: Represent the Department/Agency at the FDA EOC. Serve as the direct link between the AIC and the Federal Agency's headquarters element. Work as a member of FDA's EOC and provide input on the Federal Agency's policies, emergency response activities, concerns, resource availability, and other incident-related matters.

Location: External Federal Agency EOC or as otherwise directed

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Immediate Actions:

- ❑ Upon request for liaison, report to the FDA EOC.
- ❑ Read this entire Job Action Sheet and review the agency ICS organizational chart.
- ❑ Obtain briefing from the AIC.
- ❑ Establish contact with external Federal Agency EOC.
- ❑ Coordinate with the Logistics Officer to transmit visit request/security clearance information to FDA security office, if necessary.
- ❑ Set up desk/workstation in FDA's EOC and report contact information to the AIC.
- ❑ Obtain an appropriate FDA identification badge, if needed.

Intermediate Actions:

- ❑ Respond to RFIs from the external Federal Agency regarding FDA policies, emergency response activities, and resource availability.
- ❑ Keep the external Federal Agency aware of FDA actions and concerns related to the incident.
- ❑ Advise the External Federal Agency of any requests for FDA resource assistance from the external Federal Agency.
- ❑ Monitor the incident to identify current or potential agency implications.
- ❑ Participate in regularly scheduled FDA situation/status briefings and teleconferences.
- ❑ Participate in external Federal Agency situation/status briefings, as appropriate.
- ❑ Maintain a written record of your actions (to include voice and data message traffic). Provide a copy of this report to the AIC and external Federal Agency, as appropriate, upon shift change.

Extended Actions:

- ❑ At shift change, provide a briefing on past and ongoing FDA and external Federal Agency activities to your replacement. Also, provide a written record of your actions (to include voice and data message traffic) to the AIC and external Federal Agency, as appropriate.
- ❑ Plan for the possibility of extended operations.

K.4 LEGAL ADVISOR (IMG)

Supervisor: AIC

Mission: Provides advice to the AIC on issues that involve application or interpretation of relevant statutes and regulations.

Location: FDA EOC or OCC Office

Immediate Actions:

- ❑ Upon notification, report to the FDA EOC. Notify appropriate OCC staff of activation status and close out performance of all day-to-day activities.
- ❑ Read this entire Job Action Sheet and review the agency ICS organizational chart.
- ❑ Obtain briefing from the AIC. Report this information to appropriate OCC staff.
- ❑ Assist the Planning Section Chief with formulation of an IAP.

General Staff (IMG)

K.5 Operations Section Chief[57]

Supervisor: AIC

Mission: Coordinate and report on all agency headquarters and field activities. Establish an agency-wide common operating picture.

Location: FDA EOC

Immediate Actions:

- ❑ Upon notification, report to the FDA EOC. Obtain packet containing Operations Section Job Action Sheets.
- ❑ Read this entire Job Action Sheet and review the agency ICS organizational chart.
- ❑ Obtain briefing from the AIC.
- ❑ Notify geographical Divisions and/or functional Groups of activation, as appropriate. Appoint Division/Group Supervisors and distribute Job Action Sheets.
- ❑ Establish communications with responding C/O ECs, Field Emergency Coordinators, and/or Incident Management Team, as appropriate.
- ❑ Assist the Planning Section Chief with formulation of an IAP.

Intermediate Actions:

- ❑ Monitor RFIs and assistance from external Federal Agencies to ensure appropriate assignment, processing, and tracking, as well as those from HHS SOC and internal FDA.
- ❑ Routinely brief the AIC and Planning Section Chief on the status of agency headquarters and field emergency response operations.
- ❑ Participate in regularly scheduled agency situation/status briefings and teleconferences.

Extended Actions:

- ❑ At shift change, provide a briefing on past and ongoing agency and Operations Section activities to your replacement, as required.
- ❑ Plan for the possibility of extended operations.

[57] This section, dependent on the scope of the event, could become the Information and Intelligence Gathering Section.

General Staff (IMG)

K.6 Division/Group Supervisor

Supervisor: Operations Section Chief

Mission: Organize and direct the activities of personnel assigned to a designated geographic Division or functional Group. This may include headquarters and/or field staffs.

Location: Normal work location or FDA EOC

Immediate Actions:

- ❑ Upon notification, report to the FDA EOC for an initial briefing or contact the Operations Section Chief at 301-443-1240 if not located in the same physical location as the FDA EOC. Notify appropriate Center/Office staff of activation status and close out performance of all day-to-day activities.
- ❑ Read this entire Job Action Sheet.
- ❑ Review the IAP. Provide information on the incident and agency objectives to supporting branch personnel, as appropriate.
- ❑ Establish and maintain communications with responding field offices, as appropriate.
- ❑ If operating from your normal work location, provide contact information to the Operations Section Chief.

Intermediate Actions:

- ❑ Issue mission assignments to and monitor the activities of Division/Group personnel, to include all responding Center/Office staff. Maintain a log of all agency objectives and the Division/Group personnel assigned to associated tasks.
- ❑ Ascertain information or resources needed by Division/Group personnel and arrange for appropriate support.
- ❑ Monitor the progress and status of responding Division/Group personnel and immediately report any changes or issues that cannot be resolved to the Operations Section Chief.
- ❑ Participate in regularly scheduled agency situation/status briefings and teleconferences. Provide spot reports to Division/Group personnel, as necessary.

Extended Actions:

- ❑ At shift change, provide a briefing on past and ongoing Division/Group activities to your replacement, as required.
- ❑ Plan for the possibility of extended operations.

General Staff (IMG)

K.7 Center/Office Emergency Coordinator

Supervisor: Center Director

Mission: Organize and direct the activities of the Center emergency management team. Maintain communications with the FDA EOC.

Location: Center

Immediate Actions:

- ❑ Notify the FDA EOC at 301-443-1240 of any alerts, presumptive information, or confirmed reports received from FDA field offices, external government agencies, consumers, or industry regarding a potential or ongoing incident.
- ❑ Upon notification of FDA EOC activation, contact the Operations Section Chief to receive an incident briefing and additional instructions, as appropriate. Notify appropriate Center staff of activation status and close out performance of all day-to-day activities.
- ❑ Read this entire Job Action Sheet.
- ❑ Review the IAP. Provide information on the incident and agency objectives to the Center Director and Center emergency management team, as appropriate.
- ❑ Initiate contact with Center product-associated trade and industry groups.
- ❑ Provide Center emergency management team contact information to the Operations Section Chief.

Intermediate Actions:

- ❑ Ensure implementation of Center emergency plans and procedures, as applicable.
- ❑ Receive, process, and distribute information between the Center and the FDA EOC.
- ❑ Provide input on situation reports submitted by responding field offices to the Operations Section Chief.
- ❑ Participate in regularly scheduled agency situation/status briefings and teleconferences. Provide spot reports to the Center Director and Center emergency management team, as necessary.

Extended Actions:

- ❑ At shift change, provide a briefing on past and ongoing Center activities to your replacement, as required.
- ❑ Plan for the possibility of extended operations.

General Staff (IMG)

K.8 Planning Section Chief

Supervisor: AIC

Mission: Collect, evaluate, and disseminate incident information to Command and General Staffs. Coordinate agency status reporting, monitor and display situational information, and formulate and update the IAP.

Location: FDA EOC

Immediate Actions:

- ❑ Upon notification, report to the FDA EOC.
- ❑ Read this entire Job Action Sheet and review the Agency ICS organizational chart.
- ❑ Obtain briefing from the AIC.
- ❑ Notify all supporting Unit personnel and necessary technical specialists of activation, as appropriate.
- ❑ Confer with the AIC and Operations Section Chief to formulate an IAP.

Intermediate Actions:

- ❑ Ensure implementation of the *FDA EOP*.
- ❑ Issue mission assignments to Unit personnel and technical specialists.
- ❑ Collect, interpret, and synthesize information regarding the status of agency resources and response activities. Update the IAP to reflect this information and distribute to the AIC and Command and General Staffs.
- ❑ Coordinate regularly scheduled agency situation/status briefings and teleconferences. Send invitations, agendas, and other meeting materials to the AEG, the AIC, and Command and General Staffs.
- ❑ Maintain documentation of all agency actions and decisions on a continual basis. Use archived data to begin construction of an incident AAR/Improvement Plan (IP).

Extended Actions:

- ❑ At shift change, provide a briefing on past and ongoing agency and Planning Section activities to your replacement, as required.
- ❑ Plan for the possibility of extended operations.

General Staff (IMG)

K.9 Logistics Section Chief

Supervisor: AIC

Mission: Organize, direct, and coordinate those operations associated with maintenance of the physical environment (facilities), security, and personnel deployment. Provide for adequate levels of equipment and supplies to support headquarters (IMG) Command and General Staffs.

Location: FDA EOC

Immediate Actions:

- ❑ Upon notification, report to the FDA EOC. Notify appropriate OM staff of activation status and close out performance of all day-to-day activities.
- ❑ Read this entire Job Action Sheet and review the agency ICS organizational chart.
- ❑ Obtain briefing from the AIC.
- ❑ Notify all supporting Unit personnel of activation, as appropriate.
- ❑ Assist the Planning Section Chief with formulation of an IAP.
- ❑ Receive direction from the AIC regarding current agency logistical services and support needs.

Intermediate Actions:

- ❑ Monitor deployment of agency resources (personnel, equipment, and supplies) in support of headquarters and field response operations.
- ❑ Provide facility management and security services support to headquarters personnel.
- ❑ Coordinate provision of headquarters IT assistance, as necessary. Ensure headquarters voice and data communications systems and equipment are functioning properly.
- ❑ Inventory equipment and supplies and project needs based upon requests from the AIC, Operations Section, and/or Planning Section.
- ❑ Participate in regularly scheduled agency situation/status briefings and teleconferences, as appropriate. Provide spot reports to appropriate OM staff, as necessary.

Extended Actions:

- ❑ At shift change, provide a briefing on past and ongoing agency and Logistics Section activities to your replacement, as required.
- ❑ Plan for the possibility of extended operations.

General Staff (IMG)

K.10 Finance/Administration Section Chief

Supervisor: AIC

Mission: Serve as a conduit of information between the AIC, ORA, and responsible Centers on all financial and HR matters related to the incident. Monitor and report on agency resource costs, procurement issues, and employee compensation/claims.

Location: FDA EOC

Immediate Actions:

- ❑ Upon notification, report to the FDA EOC. Notify appropriate ORA staff of activation status and close out performance of all day-to-day activities.
- ❑ Read this entire Job Action Sheet and review the agency ICS organizational chart.
- ❑ Obtain briefing from the AIC. Report this information to appropriate Center/Office staffs.
- ❑ Assist the Planning Section Chief with formulation of an IAP.

Intermediate Actions:

- ❑ Report on the anticipated or requested costs of ORA field activities.
- ❑ Advise the AIC of agency financial systems and HR policies and procedures as they apply to headquarters and field response efforts.
- ❑ Assist ORA in accounting, payment processing, financial reporting, foreign and domestic travel, employee relocation, payroll liaison, and financial systems related to the incident.
- ❑ Participate in regularly scheduled agency situation/status briefings and teleconferences. Provide spot reports to appropriate staff, as necessary.

Extended Actions:

- ❑ At shift change, provide a briefing on past and ongoing financial/HR activities to incoming staffs. Provide additional detailed information to your replacement, as required.
- ❑ Plan for the possibility of extended operations.

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Appendix L: Forms and Templates

Listed below are some common forms and templates to be used by FDA personnel during the course of an incident. Hyperlinks attached to each title link directly to the appropriate form/template included within this Appendix. Electronic copies can be found on the EON IMS.

INCIDENT BRIEFING, FDA ICS FORM 201

INCIDENT BRIEFING	1. Incident Name	2. Date Prepared	3. Time Prepared
4. Map Sketch			
ICS 201 Page 1 of 4	**5. Prepared by (Name and Position)**		

5/2010

6. Summary of Current Actions

ICS 201	Page 2

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7. Current Organization	
ICS 201	Page 3

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8. Resources Summary				
Resource Ordered	**Ordered By**	**ETA**	**Report To**	**Location/Assignment**
ICS 201	Page 4			

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Incident Objectives, FDA ICS Form 202

INCIDENT OBJECTIVES	1. INCIDENT NAME	2. DATE	3. TIME
4. OPERATIONAL PERIOD (DATE/TIME)			
5. GENERAL CONTROL OBJECTIVES FOR THE INCIDENT (INCLUDE ALTERNATIVES)			
6. WEATHER FORECAST FOR OPERATIONAL PERIOD			
7. GENERAL SAFETY MESSAGE			

8. Attachments (☑ if attached)

☐ Organization List (ICS 203)	☐ Medical Plan (ICS 206)	☐ Weather Forecast
☐ Assignment List (ICS 204)	☐ Incident Map	☐
☐ Communications Plan (ICS 205)	☐ Traffic Plan	☐

9. PREPARED BY (PLANNING SECTION CHIEF)	10. APPROVED BY

05/2010

Incident Management Group Organization Assignment List, FDA ICS Form 203

IMG ORGANIZATION ASSIGMENT LIST	1. INCIDENT NAME	2. DATE PREPARED	3. TIME PREPARED

POSITION	NAME
5. INCIDENT COORDINATION STAFF	
AGENCY INCIDENT COORDINATOR	
DEPUTY	
SAFETY OFFICER	
INFORMATION OFFICER	
LIAISON OFFICER	
6. AGENCY EXECUTIVE GROUP	
POSITION	**NAME**
7. AGENCY REPRESENTATIVES	
AGENCY	**NAME**
8. PLANNING SECTION	
CHIEF	
DEPUTY	
RESOURCES UNIT	
SITUATION UNIT	
DOCUMENTATION UNIT	
DEMOBILIZATION UNIT	
TECHNICAL SPECIALISTS	
9. LOGISTICS SECTION	
CHIEF	
DEPUTY	
COMMUNICATIONS UNIT	
SUPPLY UNIT	

4. OPERATIONAL PERIOD (DATE/TIME)

10. OPERATIONS SECTION		
CHIEF		
DEPUTY		
a. BRANCH I-DIVISION/GROUPS		
BRANCH DIRECTOR		
DEPUTY		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
b. BRANCH II- DIVISION/GROUPS		
BRANCH DIRECTOR		
DEPUTY		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
c. BRANCH III- DIVISIONS/GROUPS		
BRANCH DIRECTOR		
DEPUTY		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
11. FINANCE/ADMINISTRATION SECTION		
CHIEF		
DEPUTY		

PREPARED BY (RESOURCES UNIT)

5/2010

Incident Management Team Organization Assignment List, FDA ICS Form 203

IMT ORGANIZATION ASSIGMENT LIST		1. INCIDENT NAME	2. DATE PREPARED	3. TIME PREPARED
		4. OPERATIONAL PERIOD (DATE/TIME)		

POSITION	NAME
5. INCIDENT COMMAND AND STAFF	
INCIDENT COMMANDER	
DEPUTY	
SAFETY OFFICER	
INFORMATION OFFICER	
LIAISON OFFICER	
6. AGENCY REPRESENTATIVES	
AGENCY	**NAME**
7. PLANNING SECTION	
CHIEF	
DEPUTY	
RESOURCES UNIT	
SITUATION UNIT	
DOCUMENTATION UNIT	
DEMOBILIZATION UNIT	
TECHNICAL SPECIALISTS	
8. LOGISTICS SECTION	
CHIEF	
DEPUTY	
COMMUNICATIONS UNIT	
SUPPLY UNIT	

9. OPERATIONS SECTION		
CHIEF		
DEPUTY		
a. BRANCH I-DIVISION/GROUPS		
BRANCH DIRECTOR		
DEPUTY		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
b. BRANCH II- DIVISION/GROUPS		
BRANCH DIRECTOR		
DEPUTY		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
c. BRANCH III- DIVISIONS/GROUPS		
BRANCH DIRECTOR		
DEPUTY		
DIVISION/GROUP		
DIVISION/GROUP		
DIVISION/GROUP		
10. FINANCE/ADMINISTRATION SECTION		
CHIEF		
DEPUTY		

PREPARED BY (RESOURCES UNIT)

5/2010

Assignment List, FDA ICS Form 204

1. BRANCH	2. DIVISION/GROUP	ASSIGNMENT LIST
3. INCIDENT NAME	4. OPERATIONAL PERIOD DATE _____ TIME _____	

5. OPERATIONAL PERSONNEL

OPERATIONS CHIEF _____ DIVISION/GROUP SUPERVISOR _____

BRANCH DIRECTOR _____ _____

6. RESOURCES ASSIGNED TO THIS PERIOD

Group/ Division		LEADER	NUMBER PERSONS	Report Location/	Estimated Time of Departure	Estimated Time of Return

7. CONTROL OPERATIONS/TACTICAL DIRECTIONS

8. SPECIAL INSTRUCTIONS

9. COMMUNICATIONS SUMMARY : Contact Phone #s

GRP SUP #	OSC #	ICP #	
PREPARED BY (RESOURCE UNIT LEADER)	APPROVED BY (PLANNING SECT. CH.)	DATE	TIME

5/2010

Incident Communications Plan, FDA ICS Form 205

INCIDENT COMMUNICATIONS PLAN	1. Incident Name	2. Date/Time Prepared	3. Operational Period Date/Time

4. Incident Communications Plan

Name	Primary Number	Secondary Number	E-mail	Section	Remarks

5. Prepared by (Communications Unit)

5/2010

SITUATION REPORT

Template for creation of Situation Reports by FDA Incident Management Groups

FDA SITUATION REPORT

Page Header:

- Distributing Office (EOC)
- Title of Incident
- FDA Situation Report Number #
- Date (Day of the Week, Month Day, Year)
- Timeframe report covers (Military time, Month/Date/Year to Military time, Month/Date/Year)

A. Executive Summary:

- A brief description of the incident
- Initial and long-term response operations
- The resources that were deployed, including whether specific resources were requested through the SOC, FEMA, mutual aid, or another mechanism
- A description of key events and the timeframes of occurrence
- Decisions that were made in response to events and the results
- Issues that arose during the course of operations. Include those between or among MAC System entities, between the Incident Command and the EOC, and within the EOC.

B. New Information:

C. Investigations-Related Information and Other Data: (Data sources may include State, local, and other Federal departments/agencies. The following are examples of what data to report in this section.)

- Outbreak Data
- Epidemiological Data
- Lab Testing Data
- Analytical Data
  - Traceback Data
  - Traceforward Data
  - Assignments
- Sampling Data

D. Documentation Unit:

E. Communications:

- Internal (within FDA)
- External (with other agencies, including HHS and CDC)
- Public Information (issuance of press releases; Consumer Health Information posted to FDA Web site; Call Center; outreach to patient, health professional and industry groups)

F. Strategic Objectives:

G. Additional Incident Response Information:

H. Prepared by:

I. Reviewed/Approved by:

Operational Planning Worksheet, FDA ICS Form 215

OPERATIONAL PLANNING WORKSHEET	1. Incident Name	2. Date Prepared Time Prepared	3. Operational Period (Date/Time)

4. Division/Group or Other Location	5. Work Assignments		Resource by Category																6. Reporting Location	7. Requested Arrival Time
		Req																		
		Have																		
		Need																		
		Req																		
		Have																		
		Need																		
		Req																		
		Have																		
		Need																		
		Req																		
		Have																		
		Need																		
		Req																		
		Have																		
		Need																		
		Req																		
		Have																		
		Need																		
8. Total Resources		Req																		
		Have																	Prepared by (Name and Position)	
		Need																		

5/2010

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Appendix M: Glossary of Terms

This Appendix contains definitions of key terms as they are applied within the *FDA EOP*. All supporting agency emergency plans and procedural documentation shall be compliant with the terminology contained herein.

Term	Definition
Abbreviated New Drug Application (ANDA)	An Abbreviated New Drug Application (ANDA) contains data which, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provide for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low-cost alternative to the American public. A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use. Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug). One way scientists demonstrate bioequivalence is to measure the time it takes the generic drug to reach the bloodstream in 24 to 36 healthy volunteers. This gives them the rate of absorption, or bioavailability, of the generic drug, which they can then compare to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug. The ANDA regulations can be found in Title 21 of the Code of Federal Regulations (CFR) part 314, subpart C [21 CFR].
Activation	Implementation of an emergency plan, in whole or in part, in response to a confirmed report of an incident
Agency	The U.S. Food and Drug Administration (FDA)
Agency Emergency Coordinator	Employees who serve as FDA's central emergency coordination point with FDA Field Offices, Headquarters, and Centers, and Federal, State, and local entities, including the Centers for Disease Control and Prevention (CDC). They provide interagency coordination and response during adverse events, foodborne illnesses, injuries, product tampering, and man-made and natural disasters. In addition, they provide essential support and lead the agency proportional response to bioterrorism, shortage, and recall emergencies. They serve as a subject matter expert in the Incident Command System and the National Incident Management System.
Agency Executive Group (AEG)	The AEG is established when an emergency calls for the involvement of senior FDA officials with the knowledge and authority to address a wide range of issues that may arise. The AEG, whether convened as a collective unit or acting as individual members, serves primarily to provide strategic policy direction and guidance for major agency emergency response activities and to approve important policy decisions in consultation with the Commissioner and Agency Incident Coordinator when necessary.
Agency Incident Coordinator (AIC)	The individual responsible for the overall coordination of agency emergency management teams assigned. The AIC ensures that conflicts are resolved, incident objectives are established, and strategies are selected for the use of critical agency resources. He/she is also responsible for communicating with FDA headquarters and field organizational components and external Federal Agencies. The AIC reports directly to the AEG. Until an AIC is appointed by the Commissioner, Deputy Commissioner, or other designated senior agency official, the Director, Office of Emergency Operations (OEO), within the Office of Crisis Management (OCM), may serve as the AIC.
Alert	Incident information without support. An alert is issued to agency emergency personnel when the following is received:

	• An unconfirmed report of a product-related illness/injury or unanticipated adverse reaction • An unconfirmed report of the presence of a toxic (nuclear/radiological, biological, or chemical) substance • A report of a natural (hurricane, flood, tornado) or manmade (oil spill, radiological accident) disaster
All-Hazards	Describing an incident, natural or manmade, that warrants action to protect life, property, environment, and public health or safety, and to minimize disruptions of government, social, or economic activities
Alpha Particle	The nucleus of a helium atom composed of two neutrons and two protons with a charge of +2. Certain radioactive nuclei emit alpha particles. Alpha particles generally carry more energy than gamma or beta particles and deposit that energy over very short distances while passing through tissue. A thin layer of light material, such as a sheet of paper, can stop alpha particles. Alpha particles cannot penetrate the outer, dead layer of skin; therefore, they do not damage living tissue when outside the body. However, alpha-emitting atoms are especially damaging when inhaled or swallowed because they transfer relatively large amounts of ionizing energy to living cells. See also Beta Particle, Gamma Ray, Neutron, and X-ray.
Antiviral	Drug that is used to prevent or cure a disease caused by a virus, by interfering with the ability of the virus to multiply in number or spread from cell to cell
Avian influenza (AI)	An infection caused by type A influenza viruses. These viruses occur naturally among birds worldwide, particularly waterfowl and shore birds. Wild birds are the natural reservoir of AI viruses and carry the viruses in their intestines; they usually do not become ill from them. Infected birds shed influenza virus in their saliva, nasal secretions, and feces. Susceptible birds become infected when they have contact with contaminated excretions or with surfaces that are contaminated with excretions or secretions. Domesticated poultry may become infected with AI virus through direct contact with infected waterfowl or other infected poultry or through contact with surfaces (such as dirt or cages) or materials (such as water or feed) that have been contaminated with the virus.
Becquerel (Bq)	A unit of radioactivity equivalent to one decay (disintegration) per second.
Catastrophic Incident	Any natural or manmade incident, including terrorism, that results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population, infrastructure, environment, economy, national morale, and/or government functions
Center/Office Emergency Coordinator (CEC)	The staff member who has responsibility for Center/Office emergency management programs and activities. The role is one of coordinating all aspects of the Center's mitigation, preparedness, response, and recovery capabilities, and serving in a liaison capacity between the Center/Office emergency management team and the Operations Section Chief. The CEC may serve as the AIC for all emergencies and disasters involving or affecting his/her product Center, unless otherwise directed.
Centers	FDA Product Centers: • Center for Biologics Evaluation and Research (CBER) • Center for Drug Evaluation and Research (CDER) • Center for Devices and Radiological Health (CDRH) • Center for Food Safety and Applied Nutrition (CFSAN) • Center for Veterinary Medicine (CVM) • Center for Tobacco Products FDA Research Center: • National Center for Toxicological Research
Centers for Disease Control and Prevention (CDC)	The USG agency at the forefront of public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental health threats. CDC is one of 13 major operating components of HHS.

Chief	The Incident Command System (ICS) title for individuals responsible for management of functional sections: Operations, Planning, Logistics, and Finance/Administration
Command Staff	The staff who report directly to the Incident Commander/AIC, including the Public Information Officer, Safety Officer, Liaison Officer, and other positions as required. They may have an assistant or assistants, as needed.
Commissioner	The Commissioner of Food and Drugs
Committed Dose	The cumulative dose to an individual's whole body or a specific organ resulting from continuous exposure to radioactive materials deposited inside the body, projected to either 50 or 70 years for an occupational worker or member of the general public, respectively.
Common Operating Picture	A continuously updated overview of an incident compiled throughout an incident's lifecycle from data shared between integrated systems for communication, information management, and intelligence and information sharing. The common operating picture allows agency headquarters and field personnel to make effective, consistent, and timely decisions.
Confirmed Report	Report that a problem has been confirmed through laboratory analyses, field investigations, analysis of epidemiological data, or a combination of these. Information received from another governmental agency or other source known to be reliable may be accepted for confirmation purposes.
Contamination (Radioactive)	The unexpected or undesired presence of radioactive material in or on the surfaces of structures, areas, objects, or people. See also Decontamination.
Cooperating Agency	Cooperating agencies include Federal Agencies that provide additional technical and resource support specific to nuclear/radiological incidents to DHS and the coordinating agencies.
Coordinating Agency	Coordinating agencies provide the leadership, expertise, and authorities to implement critical and specific nuclear/radiological aspects of the response, and facilitate nuclear/radiological aspects of the response in accordance with those authorities and capabilities. The coordinating agencies are those Federal Agencies that own, have custody of, authorize, regulate, or are otherwise assigned responsibility for the nuclear/radioactive material, facility, or activity involved in the incident. These Federal Agencies have nuclear/radiological authorities, technical expertise, and/or assets for responding to the unique characteristics of nuclear/radiological incidents that are not otherwise described in the NRF.
Corrective Action	Implementing procedures that are based on lessons learned from actual incidents or from training and exercises.
Crisis Management Team (CMT)	The CMT is established when an emergency calls for the Commissioner and senior-level officials to resolve unprecedented legal, regulatory, policy, and resource problems and impasses brought about by the emergency and which impact the ageny's ability to respond effectively.
Decay (Radioactive)	Disintegration of the nucleus of an unstable atom by the release of radiation.
Demobilization	The orderly, safe, and efficient return of agency resources to their original location and operating status. Demobilization signals the transition from the response phase of operations to recovery.
Deployment	The relocation of agency resources to desired operational areas. Deployment encompasses all activities from departing normal locations through arrival at destinations.
Division	The organizational level having responsibility for operations within a defined geographic area. Divisions are established within the Operations Section, at the headquarters-level, to coordinate and monitor the operations of responding FDA Regions/Districts within a particular location and/or when a foreign country is involved.
Dose Coefficient	A factor used to convert radionuclide intake or content to radiation dose. One usually expresses it as dose per unit intake (e.g., sieverts [Svs] per becquerel).
Dose Equivalent	A quantity used in radiation protection to place all radiation on a common scale for calculating tissue damage. Dose equivalent is the absorbed dose in grays times a quality factor. The quality factor accounts for differences in radiation effects caused by different

	types of ionizing radiation. Some radiation, including alpha particles, causes a greater amount of damage per unit of absorbed dose than other radiation. The Sv is the unit that measures dose equivalent.
Dosimeter	A small portable instrument (e.g., a film badge, thermoluminescent dosimeter [TLD], or pocket dosimeter) for measuring and recording the total accumulated dose of ionizing radiation a person receives.
Effective Dose	A dosimetric quantity useful for comparing the overall health effects of irradiation of the whole body. It takes into account the absorbed doses received by various organs and tissues and weighs them according to present knowledge of the sensitivity of each organ to radiation. It also accounts for the type of radiation and the potential for each type to inflict biologic damage. Use the effective dose, for example, to compare the overall health detriments of different radionuclides in a given mix. The unit of effective dose is the Sv; 1 Sv = 1 J/kg.
Emergency	Any incident, whether natural or manmade, that requires responsive action to protect life or property. Under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, an emergency means any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States.
Emergency Management	The coordination and integration of all activities necessary to build, sustain, and improve the capability to prepare for, protect against, respond to, recover from, or mitigate against threatened or actual natural disasters, acts of terrorism, or other manmade emergencies.
Emergency Operations Plan (EOP)	The ongoing plan maintained by an FDA organizational component for response to a wide variety of potential hazards.
Emergency Support Function (ESF)	Used by the Federal Government and many State governments as the primary mechanism at the operational level to organize and provide assistance. ESFs align categories of resources and provide strategic objectives for their use. ESFs utilize standardized resource management concepts such as typing, inventorying, and tracking to facilitate the dispatch, deployment, and recovery of resources before, during, and after an incident.
Emergency Support Function (ESF) Annexes	Annexes to the *FDA EOP* that present the missions, policies, structures, and responsibilities of FDA organizational components for coordinating resource and programmatic support to other Federal Agencies, States, territories, tribes, and local jurisdictions when *National Response Framework (NRF)* ESFs are activated during an incident.
Emergency Use Authorization (EUA)	Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3) permits the Commissioner of Food and Drugs to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces. The EUA authority allows FDA to strengthen the public health protections against biological, chemical, radiological, and nuclear agents that may be used to attack the American people or U.S. Armed Forces. Under Section 564 of the Act, the FDA Commissioner may allow medical countermeasures to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives. Before FDA can issue an EUA, the HHS Secretary must declare an emergency justifying the authorization to use the product, based on one of three determinations: a determination by the Secretary of Homeland Security of a domestic emergency; or the significant potential for a domestic emergency, a determination by the Secretary of Defense of a military emergency, or the significant potential for a military emergency, or a determination by the HHS Secretary of a public health emergency under the Public Health Service Act.
Epidemic	A disease occurring suddenly in humans in a community, region, or country in numbers clearly in excess of normal. (See Epizootic and Pandemic.)
Exposure (Radiation)	A measure of ionization in air caused by x-rays or gamma rays only. The unit of exposure most often used is the Roentgen (R).

Exposure Pathway	A route by which a radionuclide or other toxic material can enter the body. The main exposure routes are inhalation, ingestion, absorption through the skin, and entry through a cut or wound in the skin.
Good Manufacturing Practices (GMP)	Manufacturers establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food, drugs, biological products, and devices) are known as current good manufacturing practices (GMP), also seen as cGMP or as CGMP. The GMP regulations for food are at 21 CFR, part 110. For human drugs and most biological products, the CGMP regulations are at 21 CFR parts 210 and 211. For devices, the CGMP regulations are at 21 CFR, part 820 (quality system regulation).
Group	An organizational subdivision established to divide the incident management structure into functional areas of operation. Groups within the Operations Section, composed of headquarters personnel, are created to address similar emergency response activities.
Hazard	Something that is potentially dangerous or harmful, often the root cause of an unwanted outcome
Headquarters	Includes all Offices within the Office of the Commissioner (OC), Office of Regulatory Affairs (ORA), the product Centers, and any divisions or branches therein
Homeland Security Advisory System	Tool used by the Department of Homeland Security to inform all levels of government and local authority, as well as the public, of the current risk of terrorism. The System involves a five-level, color-coded threat condition indicator to correspond to the current situation. Agency-specific protective measures associated with each threat condition allow a flexible, graduated, and appropriate response to a change in the Nation's level of risk.
Improvised Nuclear Device (IND)	An IND is an illicit nuclear weapon bought, stolen, or otherwise originating from a nuclear State, or a weapon fabricated by a terrorist group from illegally obtained fissile nuclear weapons material that produces a nuclear explosion. The nuclear yield achieved by an IND produces extreme heat, powerful shockwaves, and prompt radiation that would be acutely lethal for a significant distance. It also produces radioactive fallout, which may spread and deposit over very large areas. If a nuclear yield is not achieved, the result would likely resemble a Radiological Dispersal Device (RDD) in which fissile weapons material was utilized.
Incident	An occurrence, natural or manmade, that requires a response to protect life or property. Incidents can, for example, include major disasters, emergencies, terrorist attacks, terrorist threats, civil unrest, wildland and urban fires, floods, hazardous materials spills, nuclear accidents, aircraft accidents, earthquakes, hurricanes, tornadoes, tropical storms, tsunamis, war-related disasters, public health and medical emergencies, and other occurrences requiring an emergency response.
Incident Action Plan (IAP)	An oral or written plan containing general objectives reflecting the overall agency strategy for managing an incident. It may include the identification of operational resources and assignments and/or attachments that provide direction and important information for management of the incident throughout its lifecycle. The Planning Section Chief, in coordination with other Incident Command and General Staff members, is responsible for developing the IAP.
Incident Annexes	Describe the concepts of operations to address specific hazards requiring specialized application of the *FDA EOP*.
Incident Command Post (ICP)	The field location where the primary functions are performed. The ICP may be co-located with the Incident Base or other incident facilities.
Incident Command System (ICS)	A standardized on-scene emergency management construct designed to provide for the adoption of an integrated organizational structure that reflects the complexity and demands of single or multiple incidents, without being hindered by jurisdictional boundaries. ICS is designed to enable effective incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure. It is used for all kinds of emergencies and is applicable to small as well as large and complex incidents. ICS is used by various jurisdictions and functional

	agencies, both public and private, to organize incident management operations.
Incident Commander (IC)	The individual responsible for all incident activities at field level, including the development of strategies and tactics and the ordering and release of resources. The IC has overall authority and responsibility for conducting incident operations and is responsible for the management of all incident operations.
Influenza	A serious disease caused by viruses that infect the respiratory tract
Investigational New Drug (IND) Application	The IND regulations are at 21 CFR, part 312. Current Federal law requires that a new drug be the subject of an approved marketing application before it is transported or distributed across State lines unless the drug is shipped for investigational uses under an IND. During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. FDA's role in the development of a new drug begins when the drug's sponsor (usually the manufacturer or potential marketer), having screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system. The IND application must contain information in three broad areas: • Animal Pharmacology and Toxicology Studies. Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included is any previous experience with the drug in humans (often foreign use). • Manufacturing Information. Information pertaining to the composition, manufacture, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug. • Clinical Protocols and Investigator Information. Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks and whether later stage trials are designed in a way to provide reliable evidence concerning effectiveness. Also, information on the qualifications of clinical investigators—professionals (generally physicians) who oversee the administration of the experimental compound—to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board (IRB), and to adhere to the investigational new drug regulations. Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials unless FDA grants a waiver. During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk. There are two general categories of INDs: • Commercial. An IND for which the sponsor intends for the product to be commercialized at some point. The sponsor for a commercial IND is generally a corporate entity or, in some cases, the NIH or an academic institution. • Research (Noncommercial). An IND for which a study is being conducted for research purposes rather than commercial development. These INDs are generally sponsored by an individual investigator or an academic institution. Within the two IND categories, there are several IND types. • "Standard IND," while not a regulatory term, refers to an IND submitted as described under 21 CFR 312.23. Such an IND may be either a commercial or research IND. • Emergency IND, emergency use of an investigational drug is permitted by FDA based on

	telephone or other rapid communication request in some circumstances in which there is not time for submission of an IND under the regulations. See 21 CFR 312.36. The term emergency IND is also, however, sometimes used to describe an IND that is specific to a particular patient and as to which use of the investigational drug is justified because alternative treatments are not available. • Treatment INDs, described under 21 CFR 312.34, are used to make promising new drugs available to desperately ill patients as early in the drug development process as possible. FDA will permit an investigational drug to be used under a treatment IND if there is preliminary evidence of drug efficacy and the drug is intended to treat a serious or life-threatening disease, or if there is no comparable alternative drug or therapy available to treat that stage of the disease in the intended patient population. In addition, these patients are not eligible to be in the definitive clinical trials, which must be well underway, if not almost finished. (www.fda.gov/oashi/patrep/treat.html)
Isolation	A state of separation between persons or groups to prevent the spread of disease. The first published recommendations for isolation precautions in U.S. hospitals appeared as early as 1877, when a handbook recommended placing patients with infectious diseases in separate facilities. Isolation measures can be undertaken in hospitals or homes, as well as in alternative facilities.
Joint Field Office (JFO)	The primary Federal incident management field structure. The JFO is a temporary Federal facility that provides a central location for the coordination of Federal, State, territorial, tribal, and local governments and private-sector and nongovernmental organizations with primary responsibility for response and recovery. The JFO structure is organized, staffed, and managed in a manner consistent with NIMS principles and is led by a Unified Coordination Group. Although the JFO uses an ICS structure, the JFO does not manage on-scene operations. Instead, the JFO focuses on providing support to on-scene efforts and conducting broader support operations that may extend beyond the incident site.
Joint Information Center (JIC)	An interagency entity established to coordinate and disseminate information for the public and media concerning an incident. JICs may be established locally, regionally, or nationally depending on the size and magnitude of the incident.
Lead District	The FDA District Office with primary responsibility for addressing an incident. For the majority of incidents involving FDA-regulated products, the District in which the event is occurring (e.g., the physical location where people have been affected), will generally assume the lead District role.
Liaison Officer (LNO)	A member of the Command Staff responsible for coordinating with external Federal Agencies (i.e., HHS, CDC, USDA, DHS, FBI, or the Department of State). LNOs serve as direct links between the Agency Incident Coordinator and their assigned agencies, and they work as members of the external agencies' EOCs providing input on FDA policies, activities, concerns, resource availability, and other incident-related matters.
Logistics Section	Section responsible for providing facilities, services, and material support for the incident
Major Disaster	Under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, any natural catastrophe (including any hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought) or, regardless of cause, any fire, flood, or explosion in any part of the United States that, in the determination of the President, causes damage of sufficient severity and magnitude to warrant major disaster assistance under the Stafford Act to supplement the efforts and available resources of States, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby.
Memorandum of Understanding (MOU)	A formal agreement between FDA and another government agency (Federal, State, or local) or private institution, or an informal agreement with foreign governments or other foreign institutions
Mission Assignment	A task given to an agency component to perform within a given operational period that is based on operational objectives defined in the Incident Action Plan.
National Disaster	A federally coordinated system that augments the Nation's medical response capability. The

Medical System (NDMS)	overall purpose of the NDMS is to supplement an integrated National medical response capability for assisting State and local authorities in dealing with the medical impacts of major peacetime disasters and to provide support to the military and the Department of Veterans Affairs medical systems in caring for casualties evacuated back to the United States from overseas armed conventional conflicts. The National Response Framework uses the NDMS, as part of HHS, Office of Preparedness and Response, under ESF #8, Health and Medical Services, to support Federal Agencies in the management and coordination of the Federal medical response to major emergencies and federally declared disasters including: • Natural Disasters • Major Transportation Accidents • Technological Disasters • Acts of Terrorism including Weapons of Mass Destruction Events
National Incident Management System (NIMS)	Provides a systematic, proactive approach to guide departments and agencies at all levels of government, nongovernmental organizations, and the private sector to work seamlessly to prevent, protect against, respond to, recover from, and mitigate the effects of incidents, regardless of cause, size, location, or complexity, in order to reduce the loss of life and property and harm to the environment. The NIMS works hand-in-hand with the NRF. It provides the template for the management of incidents, while the NRF provides the structure and mechanisms for national-level policy for incident management.
National Infrastructure Protection Plan (NIPP)	Plan that provides a coordinated approach to critical infrastructure and key resources (CIKR) protection for Federal, State, tribal, local, and private-sector security partners. It sets national priorities, goals, and requirements for effective distribution of funding and resources that will help ensure that our government, economy, and public services continue in the event of a terrorist attack or other disaster.
National Operations Center (NOC)	Serves as the primary national hub for situational awareness and operations coordination across the Federal Government for incident management. The NOC provides the Secretary of Homeland Security and other principals with information necessary to make critical national-level incident management decisions.
National Preparedness Guidelines	Guidance that establishes a vision for national preparedness and provides a systematic approach for prioritizing preparedness efforts across the Nation. These guidelines focus policy, planning, and investments at all levels of government and the private sector.
National Response Framework (NRF)	Guides how the Nation conducts all-hazards response. The NRF documents the key response principles, roles, and structures that organize national response. It describes how communities, States, the Federal Government, and private-sector and nongovernmental partners apply these principles for a coordinated, effective national response. Also, it details special circumstances where the Federal Government exercises a larger role, including incidents where Federal interests are involved and catastrophic incidents where a State would require significant support. The NRF allows first responders, decisionmakers, and supporting entities to provide a unified national response.
New Drug Application (NDA)	The NDA is the vehicle through which drug sponsors formally propose that FDA approve a new pharmaceutical for sale and marketing in the United States. The data gathered during the animal studies and human clinical trials of an IND become part of the NDA. The goals of the NDA are to provide enough information to permit the FDA reviewer to reach the following key decisions: • Whether the drug is safe and effective in its proposed use(s) and whether the benefits of the drug outweigh the risks • Whether the drug's proposed labeling (package insert) is appropriate and what it should contain • Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical trials, what are the ingredients of the drug, the results of

	the animal studies, how the drug behaves in the body, and how it is manufactured, processed, and packaged. The NDA regulations are at 21 CFR, part 314.
Nuclide	A general term applicable to all atomic forms of an element. The number of protons and neutrons in the nucleus and the amount of energy contained within the atom characterize nuclides.
Offices	Refers to the collective headquarters and field offices, including those of the Office of the Commissioner (OC) and Office of Regulatory Affairs (ORA).
Operating Divisions (OPDIVs)	Agencies within the Department of Health and Human Services (HHS). HHS OPDIVs include FDA and the following: • Administration for Children and Families (ACF) • Administration on Aging (AoA) • Agency for Healthcare Research and Quality (AHRQ) • Agency for Toxic Substances and Disease Registry (ATSDR) • Centers for Disease Control and Prevention (CDC) • Centers for Medicare & Medicaid Services (CMS) • Health Resources and Services Administration (HRSA) • Indian Health Service (HIS) • National Institutes of Health (NIH) • Substance Abuse and Mental Health Services Administration (SAMHSA)
Operations Section	The ICS Section responsible for all tactical incident operations and implementation of the Incident Action Plan. In ICS, the Operations Section normally includes subordinate Branches, Divisions, and/or Groups.
Organizational Component	As defined by FDA Staff Manual Guide (SMG) 1005.1, "Policy and Procedures Regarding Organizational Changes," any part of the FDA organization that is separately established as an organizational entity by law, regulation, the Secretary, or an official who has been delegated authority and that has formally assigned functions and an approved Standard Administrative Code and title. FDA organizational components include all Centers, Offices, Divisions, Branches, and Resident Posts at the headquarters and field levels.
Pandemic	The worldwide outbreak of a disease in humans in numbers clearly in excess of normal. (See Panzootic and Epidemic.)
Planning Section	The ICS Section responsible for the collection, evaluation, and dissemination of operational information related to the incident and for the preparation and documentation of the IAP. This Section also maintains information on the current and forecasted situation and on the status of resources assigned to the incident.
Plume	The material spreading from a particular source and traveling through environmental media, such as air or ground water. For example, a plume could describe the dispersal of particles, gases, vapors, and aerosols in the atmosphere, or the movement of contamination through an aquifer (e.g., dilution, mixing, or adsorption onto soil).
Preparedness	Actions that involve a combination of planning, resources, training, exercising, and organizing to build, sustain, and improve operational capabilities. Preparedness is the process of identifying the personnel, training, and equipment needed for a wide range of potential incidents and developing specific plans for the delivery of agency capabilities. While not part of the phases of FDA emergency operations, preparedness ensures that agency resources are available and effectively implemented when needed.
Presumptive	Used to describe information that strongly suggests a problem exists. Presumptive information consists of: • Epidemiological data that provides a significant association between an illness, injury, or unanticipated adverse reaction and a product • An original analysis by a reliable laboratory revealing a significant level of a toxic substance in a regulated product, but confirmation is not complete

	• Natural or manmade incident reporting, the extent of which is unknown at the present time
Prevention	Actions to avoid an incident or to intervene to stop an incident from occurring. It involves applying intelligence and other information to a range of activities that may include such countermeasures as deterrence operations; heightened inspections; investigations to determine the full nature and source of the threat; public health and agricultural surveillance and testing processes; and, as appropriate, specific law enforcement operations aimed at deterring, preempting, interdicting, or disrupting illegal activity and apprehending potential perpetrators and bringing them to justice.
Protection	Actions to mitigate the overall risk to FDA-regulated products resulting from accidental or intentional contamination/ adulteration. Protection includes actions to deter the threat, mitigate vulnerabilities, or minimize consequences associated with a terrorist attack or other potential incident.
Public Health	The science and practice of protecting and improving the overall health of the community through disease prevention and early diagnosis, control of communicable diseases, health education, injury prevention, sanitation, and protection from environmental hazards
Public Health Emergency	Pursuant to Section 319 of the Public Health Service Act, a determination by the Secretary of Health and Human Services that a disease or disorder presents a public health risk, including significant outbreaks of infectious diseases or bioterrorist attacks. Existence of a public health emergency authorizes the Secretary to take certain actions appropriate to respond to the incident or potential incident, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder.
Public Information Officer (PIO)	A member of the Command Staff responsible for managing incident-related information requirements. The PIO coordinates development and release of agency public health and consumer protection messages for use with the public, media, and/or other agencies with approval from FDA headquarters and HHS.
Quarantine	The period of isolation decreed to control the spread of disease. Before the era of antibiotics, quarantine was one of the few available means of halting the spread of infectious disease. It is still employed today as needed. The list of quarantinable diseases in the United States is established by Executive Order of the President, on recommendation of the Secretary of the HHS, and includes cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, and viral hemorrhagic fevers (such as Marburg, Ebola, and Congo-Crimean disease). In 2003, severe acute respiratory syndrome (SARS) was added as a quarantinable disease. In 2005 another disease was added to the list, influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.
Radiation	Energy moving in the form of particles or waves. Familiar radiations are heat, light, radio waves, and microwaves. Ionizing radiation is a very high-energy form of electromagnetic radiation.
Radioactive Contamination	The deposition of unwanted radioactive material on the surfaces of structures, areas, objects, or people. It can be airborne, external, or internal. See also Contamination, Decontamination.
Radioisotope (Radioactive Isotope)	Isotopes of an element that have an unstable nucleus. Science, industry, and medicine commonly use radioactive isotopes. The nucleus eventually reaches a stable number of protons and neutrons through one or more radioactive decays. Roughly 3,700 natural and artificial radioisotopes have been identified.
Radiological Dispersal Device (RDD)	A device that disperses radioactive material by conventional explosive or other mechanical means, such as a spray.
Radionuclide	An unstable and therefore radioactive form of a nuclide.
Recovery (Short-Term)	The transition from emergency response back to normal operations. During the short-term recovery phase, FDA analyzes the cause of the incident to minimize the chance of the incident, emergency, or crisis reoccurring and repairs any strained relationships with stakeholders. The agency also assesses the actions taken to resolve the incident and

	addresses any short- or long-term effects. As a result, agency policies, plans, and procedures are updated, incorporating lessons learned from the event.
Resources	Personnel and major items of agency equipment, supplies, and facilities available or potentially available for assignment to incident operations and for which status is maintained.
Response	Immediate actions to protect consumers and ensure the safety of FDA-regulated products. Response also includes the execution of agency emergency plans and procedures and actions to support and mitigation of short-term recovery. Response activities may include applying intelligence and other information to lessen the effects or consequences of an incident; investigations into nature and source of the threat; ongoing public health and product surveillance and testing processes; and law enforcement operations aimed at preempting, interdicting, or disrupting illegal activity, and apprehending actual perpetrators and bringing them to justice.
Secretary	Secretary of Health and Human Services
Shelf Life Extension Program	The Department of Defense (DoD), the CDC, and Department of Veterans' Affairs (VA) maintain significant reserves of critical medical supplies. CDC maintains its reserves in the SNS. These supplies include drug products that have expiration dates. Constantly replacing drug products as they reach their expiration dates can be quite costly. To reduce overall costs to the Federal Government and to the taxpayer, DoD, CDC, and VA work with FDA to determine whether a drug product's useful life can be extended beyond the expiration date. FDA tests samples of specified lots of stored drug products submitted by participating Federal entities and analyzes the data to determine whether the data are adequate to allow for the use of product beyond the expiration date on the product labeling. The stored drug products are to be maintained under each product's labeled storage conditions.
Shielding	The use of material placed between a radiation source and an individual to reduce exposure.
Sievert (Sv)	A unit of dose equivalent. This relates the absorbed dose in human tissue to the effective biological damage of the radiation. Not all radiation has the same biological effect, even for the same amount of absorbed dose. Dose equivalent is often expressed as millionths of a Sv, or micro-sieverts (μSv). One Sv is equivalent to 100 rem.
Situation Report (SITREP)	Contains confirmed reports and explicit details (who, what, when, where, and how) of an incident. SITREPs are produced by FDA field offices and Centers and consolidated by the Planning Section Chief for dissemination across the agency.
Situational Awareness	The ability to identify, process, and comprehend the critical elements of information about an incident.
Stakeholder	Any person or entity involved in or affected by an FDA course of action. Stakeholders include consumers, FDA employees, vendors, and external government agencies.
Standard Operating Procedure (SOP)	A complete reference document or an operations manual that provides the purpose, authorities, duration, and details for the preferred method of performing a single function or a number of interrelated functions in a uniform manner.
Status Report	Information specifically related to the availability or assignment of agency resources. Status reports are used by Center, Regional, and/or District emergency coordinators to provide FDA senior officials with real-time information on the status of agency resources (personnel, facilities, equipment, and other materials) impacted by an incident and/or those deployed in support of emergency response operations. FDA status reports generally come in the form of daily teleconferences, or more frequently depending on situation requirements, sponsored by the Planning Section Chief.
Strategic National Stockpile (SNS)	The SNS is a national repository of vaccines, antivirals, antibiotics, chemical antidotes, antitoxins, life-support medications, intravenous administration, airway maintenance supplies, and medical/surgical items. The SNS is designed to supplement and resupply State and local public health agencies in the event of a national emergency anywhere and at anytime within the United States or its territories.
Strontium (Sr)	A silvery, soft metal that rapidly turns yellow in air. Sr-90 is one of the radioactive fission materials created within a nuclear reactor during its operation. Sr-90 emits beta particles

	during radioactive decay.
Surveillance and Detection	The ongoing, systematic collection, analysis, and interpretation of public health data essential to the planning, execution, and evaluation of FDA emergency operations, closely integrated with the timely dissemination of these data to those responsible for prevention and control
Technical Specialists	Person with special skills that can be used anywhere within the ICS organization. No minimum qualifications are prescribed, as technical specialists normally perform the same duties during an incident that they perform in their everyday jobs.
Terrorism	As defined under the Homeland Security Act of 2002, any activity that involves an act dangerous to human life or potentially destructive of critical infrastructure or key resources; is a violation of the criminal laws of the United States or of any State or other subdivision of the United States in which it occurs; and is intended to intimidate or coerce the civilian population or influence or affect the conduct of a government by mass destruction, assassination, or kidnapping
Threat	An indication of possible violence, harm, or danger
Unified Command (UC)	An ICS application used when more than one agency has incident jurisdiction or when incidents cross political jurisdictions. Agencies work together through the designated members of the UC, often the senior persons from agencies and/or disciplines participating in the UC, to establish a common set of objectives and strategies and a single IAP.
Vaccine	A preparation consisting of antigens of a disease-causing organism which, when introduced into the body, stimulates the production of specific antibodies or altered cells. This produces immunity to the disease-causing organism. The antigen in the preparation can be whole disease-causing organisms (killed or weakened) or parts of these organisms.
Virus	Any of various simple submicroscopic parasites of plants, animals, and bacteria that often cause disease and that consist essentially of a core of ribonucleic acid (RNA) or deoxyribonucleic acid (DNA) surrounded by a protein coat. Unable to replicate without a host cell, viruses are typically not considered living organisms.
Warning Letter	A warning letter is a written communication from FDA notifying an individual or firm that the agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act, or other relevant statutes, and that failure of the responsible party to take appropriate and prompt action to correct and prevent any future repeat of the violation may result in administrative and/or regulatory enforcement action without further notice.
World Health Organization (WHO)	An agency of the United Nations established in 1948 to further international cooperation in improving health conditions

Appendix N: List of Acronyms and Abbreviations

This Appendix provides the meaning of acronyms and abbreviations used in the *FDA EOP*.

Acronym/ Abbreviation	Definition
AABB	American Association of Blood Banks
AAR	After Action Report
ACOMS	Advisory Committee Oversight and Management Staff
ACRA	Associate Commissioner for Regulatory Affairs
ADE	Adverse Drug Experiences
AEG	Agency Executive Group
AERS	Adverse Event Reporting System
AIC	Agency Incident Coordinator
ANDA	Abbreviated New Drug Application
ASPA	Assistant Secretary for External Affairs
BARDA	Biomedical Advanced Research and Development Authority
Bq/kg	Becquerel
CBER	Center for Biologics Evaluation and Research
CBP	U.S. Customs and Border Protection
CBRN	Chemical, Biological, Radiological, and Nuclear
CBRNE	Chemical, Biological, Radiological, Nuclear, and High-Yield Explosive
CCMRF	CBRNE Consequence Management Response Forces
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CEC	Center Emergency Coordinator
CERFP	CBRN Enhanced Response Force Package
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CIO	Chief Information Officer
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CIKR	Critical Infrastructure and Key Resources
CIS	Catastrophic Incident Supplement
CMHT	Consequence Management Home Team
CMT	Crisis Management Team
C/O EC	Center/Office Emergency Coordinator
COBOP	Continuity of Business Operations Plan
CONOPS	Concept of Operations
COOP	Continuity of Operations
CPG	Comprehensive Preparedness Guide
CSR	CDER Situation Room
CST	Civil Support Team
CTP	Center for Tobacco Products

CVM	Center for Veterinary Medicine
DEC	District Emergency Coordinator
DFAS	Defense Financial Accounting Center
DFDD	Deputy Food and Drug Director
DFI	Division of Field Investigations
DFS	Division of Field Science
DFSR	Division of Federal-State Relations
DHS	U.S. Department of Homeland Security
DIL	Derived Intervention Level
DIOP	Division of Import Operations and Policy
DNA	Deoxyribonucleic Acid
DNDO	Domestic Nuclear Detection Office
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
DOI	U.S. Department of the Interior
DOJ	U.S. Department of Justice
DOL	U.S. Department of Labor
DOS	U.S. Department of State
DOT	U.S. Department of Transportation
DSCA	Defense Support of Civil Authorities
EEN	Emergency/Event Notification System
eLEXNET	Electronic Laboratory Exchange Network
EMEA	European Medicines Agency
EMG	Emergency Management Group
EOC	Emergency Operations Center
EON IMS	Emergency Operations Network Incident Management System
EOP	Emergency Operations Plan
EPA	U.S. Environmental Protection Agency
Epi-X	Epidemic Information Exchange
ERIC	Employee Resource and Information Center
ERL	Essential Regulatory Laboratory
ESF	Emergency Support Function
EUA	Emergency Use Authorization
FACTS	Field Accomplishments and Compliance Tracking System
FBI	Federal Bureau of Investigation
FCC	Forensic Chemistry Center
FDA	U.S. Food and Drug Administration
FDMS	Federal Dockets Management System
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
FFDCA	Federal Food, Drug, and Cosmetic Act of 1938
FOI	Division of Freedom of Information
FOIA	Freedom of Information Act
FoodNet	Foodborne Diseases Active Surveillance Network
FRMAC	Federal Radiological Monitoring and Assessment Center

FRPCC	Federal Radiological Preparedness Coordinating Committee
FSIS	Food Safety and Inspection Service
GCP	Good Clinical Practice
GETS	Government Emergency Telecommunications Service
GIS	Geographic Information System
GISN	Global Influenza Surveillance Network
GMP	Good Manufacturing Practices
GSA	General Services Administration
HAN	Health Alert Network
HHS	U.S. Department of Health and Human Services
HR	Human Resources
HSIN	Homeland Security Information Network
HSC	Homeland Security Council
HSP	Human Subject Protection
HSPD	Homeland Security Presidential Directive
IAEA	International Atomic Energy Agency
IAG	Interagency Agreement
IAP	Incident Action Plan
IC	Incident Command(er)
ICLN	Integrated Consortium of Laboratory Networks
ICP	Incident Command Post
ICS	Incident Command System
IDE	Investigational Device Exemption
IMAAC	Interagency Modeling and Atmospheric Center
IMG	Incident Management Group
IMS	Incident Management System
IMT	Incident Management Team
IND	Improvised Nuclear Device
IND	Investigational New Drug
IPS	Integrated Planning System
IRB	Institutional Review Board
IT	Information Technology
IVD	In-Vitro Diagnostics
JFO	Joint Field Office
JIC	Joint Information Center
JOC	Joint Operations Center
LAN	Local Area Network
LDO	Late Duty Officer
LNO	Liaison Officer
LRN	Laboratory Response Network
MAC	Multi-Agency Coordination
MAC-FIO	Multi-Agency Coordination Group for Foodborne Illness Outbreaks
MAUDE	Manufacturer and User Facility Device Experience (System)
MedSun	Medical Product Surveillance Network
ML	Mobile Lab

MOU	Memorandum of Understanding
NARAC	National Atmospheric Release Advisory Center
NASA	National Aeronautics and Space Administration
NBIS	National Biosurveillance Integration System
NCH	Natural and Cultural Resources and Historic Properties
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NCS	National Communications System
NCTC	National Counter Terrorism Center
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NDMS	National Disaster Medical System
NJTTF	National Joint Terrorism Task Force
NIH	National Institutes of Health
NIMS	National Incident Management System
NIPP	National Infrastructure Protection Plan
NNSA	National Nuclear Security Agency
NOAA	National Oceanic and Atmospheric Administration
NOC	National Operations Center
NRC	Nuclear Regulatory Commission
NRCC	National Response Coordination Center
NRIA	Nuclear/Radiological Incident Annex
NRF	National Response Framework
NRF-CIA	NRF Catastrophic Incident Annex
NRF-CIS	NRF Catastrophic Incident Supplement
NRP	National Response Plan
NSIS	National Strategy for Information Sharing
NSPD	National Security Presidential Directive
NSSE	National Special Security Event
NVPO	National Vaccine Program Office
OA	Office of Administration
OAGS	Office of Acquisitions and Grants Services
OB	Office of Budget
OC	Office of the Commissioner
OCC	Office of the Chief Counsel
OCET	Office of Counterterrorism and Emerging Threats
OCI	Office of Criminal Investigations
OCM	Office of Crisis Management
OCP	Office of Combination Products
OCS	Office of the Chief Scientist
OCoS	Office of the Chief of Staff
OE	Office of Enforcement
OEA	Office of External Affairs
OEO	Office of Emergency Operations
OER	Office of External Relations
OF	Office of Foods

OFM	Office of Financial Management
OFO	Office of Financial Operations
OGC	Office of General Counsel
OGCP	Office of Good Clinical Practice
OIM	Office of Information Management
OIP	Office of International Programs
OM	Office of Management
OSO	Office of Security Operations
OSP	Office of Special Programs
OIT	Office of Information Technology
OL	Office of Legislation
OM	Office of Management
OMB	Office of Management and Budget
OO	Office of Operations
OPA	Office of Public Affairs
OPDIV	Operating Division
OPM	Office of Personnel Management
OPPB	Office of Policy, Planning, and Budget
OPT	Office of Pediatric Therapeutics
ORA	Office of Regulatory Affairs
ORM	Office of Resource Management
ORO	Office of Regional Operations
OSHA	Occupational Safety and Health Administration
OSHC	Office of Science and Health Coordination
OSHI	Office of Special Health Issues
OSMP	Office of Special Medical Programs
OSO	Office of Security Operations
OSS	Office of Shared Services
OWA	Outlook Web Access
PAG	Protective Action Guide
PAR	Protective Action Recommendation
pCi/kg	Picocuries Per Kilogram
PCR	Polymerase Chain Reaction
PETNet	Pet Event Tracking Network
PHS	Public Health Service
PHSA	Public Health Service Act
PIO	Public Information Officer
PNC	Prior Notice Center
POC	Point of Contact
PPE	Personal Protective Equipment
PREP	Public Readiness and Emergency Preparedness
PSC	Program Support Center
PSMA	Pre-Scripted Mission Assignment
RAP	Radiological Assistance Program
RDD	Radiological Dispersal Device

REC	Regional Emergency Coordinator
RES	Recall Enterprise System
RFI	Request for Information
RNA	Ribonucleic Acid
RRCC	Regional Response Coordination Center
RRHR	Regional Radiological Health Representative
RRT	Rapid Response Team
RSA	Remote Secure Access
RSS	Really Simple Syndication
SAIC	Special Agent in Charge
SARS	Severe Acute Respiratory Syndrome
SEO	Senior Energy Official
SGE	Special Government Employee
SITREP	Situation Report
SLEP	Shelf-Life Extension Program
SME	Subject Matter Expert
SNS	Strategic National Stockpile
SOC	Secretary's Operations Center
SOM	Senior Operations Manager
SOP	Standard Operating Procedure
SRAS	Special Routing Arrangement Service
SSP	Sector-Specific Plan
TLD	Thermoluminescent Dosimeter
UC	Unified Command
U.S.C.	United States Code
USCG	U.S. Coast Guard
USDA	U.S. Department of Agriculture
USG	U.S. Government
VA	U.S. Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VoIP	Voiceover Internet Protocol
WAN	Wide Area Network
WEAC	Winchester Engineering and Analytical Center
WHO	World Health Organization
WMD	Weapons of Mass Destruction

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Food and Drug Administration

FDA NUCLEAR/RADIOLOGICAL ANNEX TO THE FDA EMERGENCY OPERATIONS PLAN

August 2010

OFFICE OF CRISIS MANAGEMENT

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Record of Changes

Change #	Page #	Section	Change Description	Change Made By	Date
1	228	Appendix D: Protective Actions	Deleted: **Table E-1** shows the nine principal radionuclides expected to be major contributors from these types of emergencies and their corresponding DILs.	OCM	2/8/11
2	229	Appendix D: Protective Actions	Changed wording to incorporate information from deleted sentence Change #1.	OCM	2/8/11
3	229	Appendix D: Protective Actions	Deleted: See Annex O – Medical Countermeasures for additional information as therapies, either approved or investigational, are not available for all of the above-mentioned radionuclides.	OCM	2/8/11
4	229	Table E-1	Changed Title Table E-1 to D-1.	OCM	2/8/11
5		Appendix C: Activation/Notification of the Advisory Team for Nuclear/ Radiological Emergencies	Added “agency’s” to title “Lead Radiological Emergency Response Coordinator.”	OCM	3/15/11

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Table of Contents

A INTRODUCTION

Radiological emergencies, whether accidental or intentional, have the potential to cause adverse health and safety effects for large segments of the human and animal populations. In order to mitigate the consequences of such incidents, the U.S. Food and Drug Administration (FDA) must possess the resources and capabilities necessary to prevent, prepare for, protect against, and rapidly and effectively respond to and recover from radiological incidents. A planned and coordinated approach to emergency operations by FDA organizational components in support of Federal, State, tribal, territorial, and local government, international authorities, and responders in the field, can save lives and ensure that critical public health and medical needs are met.

The *FDA Nuclear/Radiological Annex to the FDA Emergency Operations Plan (EOP)* establishes a framework for the agency's management of radiological incidents. It provides the measures, operating structures, roles and responsibilities, and mechanisms for direction and coordination of FDA resources before, during, and after radiological emergencies that pose a risk to human or animal health. The *Nuclear/Radiological Annex* is compatible with the scalable, flexible, and adaptable Federal Government emergency coordinating structures of the *National Response Framework (NRF)*, and is consistent with the concepts, principles, and terminology of the *National Incident Management System (NIMS)*[58] and the *FDA EOP*.[59] The Nuclear/Radiological Annex is to be used, in conjunction with the *FDA EOP*, to assist FDA in conducting response operations for any radiological emergency.

A.1 MISSION

During a radiological emergency, FDA must continue to meet its mission. In addition to the activities listed in the *FDA EOP*, FDA activities may expand to include performance of specific, incident-related functions, such as:

- Activities conducted under the NRF's Nuclear/Radiological Incident and Food and Agriculture Annexes, Emergency Support Functions (ESFs), and the Catastrophic Incident Supplement
- Assistance and recommendations to Coordinating Agencies and State, tribal, and local governments through the Advisory Team for the Environment, Food, and Health (Advisory Team)[60]

A.2 PURPOSE

The Nuclear/Radiological Annex is intended to be used in conjunction with the *FDA EOP* and is not intended to be a "standalone" plan. The purpose of the *Nuclear/Radiological Annex* is to detail FDA responsibilities and operations specific to a radiological emergency and provide radiological specific reference material in order to provide a coordinated and consistent agency approach to preparing for, preventing, protecting against, responding to, and recovering from radiological incidents involving or impacting FDA-regulated products. To accomplish this, the *Nuclear/Radiological Annex*:

- Is compatible with and expands on the *FDA EOP*, the overarching FDA-wide operational plan that addresses the full spectrum of natural and technological hazards and terrorist threats, and the "umbrella plan" under which the *Nuclear/Radiological Annex* fits
- Defines the FDA radiological emergency operations structure and assigns essential tasks to the FDA organizational components involved in prevention, protection, response, and recovery efforts

[58] For more information on the *NRF* and *NIMS*, refer to the "Authorities and References" section of this Plan or visit www.fema.gov/emergency/nrf/ and the *FDA EOP Appendicies* A & B.
[59] For more information on how the FDA responds to emergencies, refer to the FDA EOP.
[60] For more information on the Advisory Team for Environment, Food and Health, refer to the Nuclear/Radiological Annex Appendix A.

A.3 SCOPE AND APPLICABILITY

The *Nuclear/Radiological Annex* covers the requirements in anticipation of or in response to a radiological or nuclear incident that affects or involves an FDA-regulated product. This annex applies to inadvertent and deliberate nuclear/radiological events. According to the Nuclear/Radiological Incident Annex (NRIA) to the NRF, inadvertent releases include: nuclear facility's accidents (commercial or weapons production facilities), lost radioactive material sources, transportation accidents involving nuclear/radioactive material, domestic nuclear weapons accidents, and foreign accidents involving nuclear or radioactive material that impact the United States or its territories, possessions, or territorial waters. In addition, this annex includes, but is not limited to, response to the effects of deliberate attacks perpetrated with radiological dispersal devices (RDDs), nuclear weapons, or improvised nuclear devices (INDs). Refer to *FDA EOP* Appendix "Glossary of Terms" for RDD and IND definitions.

A.4 PLANNING ASSUMPTIONS

The *Nuclear/Radiological Annex* is based on the same planning assumptions as referenced in the *FDA EOP* and in addition:

- The U.S. Department of Homeland Security (DHS) will review the situation and determine whether to assume Federal leadership for the overall response in accordance with the NRF.
- To ensure the capability to implement the *Nuclear/Radiological Annex*, each FDA headquarters and field organizational component tasked with radiological emergency roles and responsibilities, as identified in this *Nuclear/Radiological Annex* or the *FDA EOP*, may develop and maintain individual emergency plans and procedures that identify the critical and time-sensitive missions, functions, assignments, and processes to be performed by their organizational component during a radiological incident. These documents shall be consistent with the *FDA EOP* and this annex and available to all Center/Office personnel.

A.5 ACTIVATION

The Public Health and Medical Services (ESF #8) response to a radiological event will be directed by the U.S. Department of Health and Human Services (HHS) Office of the Secretary, in coordination with the DHS, which is responsible for managing the U.S. Government (USG) response. FDA is a subordinate Operating Division (OPDIV) of HHS and it will align its response activities with those of HHS. FDA will use the full spectrum of its resources to accomplish assigned roles, responsibilities, functions, goals, and missions.

This annex will be consulted and implemented together with the *FDA EOP* when there is a radiological incident. Examples of events that could trigger activation of this Plan include, but are not limited to, any radiological incident, including nuclear power plant accidents, man-made accidents, RDDs, or INDs, that impacts an FDA-regulated product or leads to a response from FDA via the Advisory Team for Environment, Food and Health.

Regional Food and Drug Directors, District Directors, and Center/Office Directors may activate their individual organizational component's EOP without activation of the Nuclear/Radiological Annex.

A.6 SUPERSEDENCE

The *Radiological Annex (2009)* supersedes the *FDA Radiological Emergency Response Plan* (2004).

B CONCEPT OF OPERATIONS

The following concept of operations (CONOPS) describes the principal authorities' governing agency emergency functions and the phases within which FDA conducts radiological incident-related operations.

B.1 EMERGENCY AUTHORITIES

FDA's emergency authorities are prescribed by several statutes and conducted in accordance with applicable regulations established within Title 21, "Food and Drugs," of the Code of Federal Regulations (21 CFR).[61] The emergency authorities relevant to a radiological/nuclear incident are under two primary focus areas:

1) Providing medical countermeasures and FDA scientific resources:
   - Section 564 of the (Federal Food, Drug, and Cosmetic Act of 1938 [FFDCA]), amended by the Project BioShield Act of 2004, prescribes FDA's mission, in part, as ensuring that safe and effective drugs and devices are available for consumer use.
2) Promoting and protecting public health:
   - Title 44, "Emergency Management and Assistance," Part 351 "Radiological Emergency Planning and Preparedness" of the CFR, authorizes FDA to assist State and local government officials in preparing for radiological emergencies and in the development of their radiological plans.

B.2 EMERGENCY OPERATIONS PHASES

The following three phases comprise the entire spectrum of FDA emergency operations: ***Prevention and Protection, Response, and Recovery.*** During a Nuclear/Radiological event FDA employees are expected to follow the activities described in the *FDA EOP*, Section B.2. *Emergency Operation Phases*. Although emergency operations may involve each of these phases over the course of a radiological incident, the nature and severity of an event and FDA organizational component(s) responding will determine the specific order, actions, and responsible parties required for each.[62] The following sections describe additional resources available during FDA's emergency operations for prevention and protection specific to a radiological or nuclear event.

B.2.1 Prevention and Protection

FDA participates in a number of planning subcommittees under the Federal Radiological Preparedness Coordinating Committee (FRPCC), which coordinates all Federal responsibilities for assisting State and local governments in their emergency planning and preparedness for peacetime radiological emergencies, developing protective action recommendations for human and animal feed, providing guidance on radioprotective substances and prophylactic drugs to reduce radiation dose, and providing medical and mental health support through ESF #8. FEMA is the chair of the FRPCC.

The FRPCC performs the following functions:

- Assisting the Director of FEMA in providing policy direction with respect to Federal assistance to State and local governments in their radiological emergency planning and preparedness activities
- Establishing subcommittees to aid in carrying out its functions; current subcommittees include Training, Offsite Instrumentation, Transportation, and Federal Response.

[61] A more detailed summary of the laws, regulations, directives, and policy guiding FDA emergency operations is provided in Section G, "Authorities and References," of this Plan.

[62] Refer to Section C, "Organization and Assignment of Responsibilities," of this Plan for an overview of FDA organizational component roles and responsibilities during a radiological incident.

- Assisting FEMA in resolving issues relating to granting final approval (under 44 Code of Federal Regulations [CFR] 350) of a State radiological emergency preparedness plan
- Coordinating research and study efforts of its member agencies relative to State and local government radiological emergency preparedness to ensure minimum duplication and maximum benefits to State and local governments

The FRPCC works directly with HHS and FDA seeking guidance for State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g., potassium iodide, Radiogardase) to reduce the radiation dose to specific organs, including dosage and projected radiation exposures.

B.2.1.1 Surveillance and Detection

B.2.1.1.1 Winchester Engineering and Analytical Center

Winchester Engineering and Analytical Center (WEAC) is an FDA/Office of Regulatory Affairs (ORA) laboratory that is equipped and staffed to handle the analysis of radioactive materials and the Federal laboratory having the greatest capability in the United States to analyze samples for radioactive contamination. As such, WEAC serves as the lead for the radiological component of the Food Emergency Response Network (FERN).[63] The FDA FERN program is administered by the Division of Field Science/ORA. FDA conducts import and domestic food surveillance programs for radioactive contamination, e.g., imported samples, domestic nuclear reactor, and market basket survey samples.

B.2.1.2 Medical Countermeasures

Information on available medical countermeasures can be provided by Center Emergency Coordinators as needed through their contact and work with Center subject matter experts (SME).

B.2.2 Response

B.2.2.1 Gain and Maintain Situational Awareness

B.2.2.1.1 Alert and Notification

FDA may be alerted to a threat, hazard, or other significant event through a variety of means, including the surveillance systems discussed in the *FDA EOP* Table I-2 and/or directly from external Federal Agencies (e.g., the HHS Secretary's Operations Center [SOC], the Environmental Protection Agency [EPA], DHS, and/or the Federal Bureau of Investigation [FBI]); State, tribal, territorial, local, and international public health agencies; industry; consumers; news media; and internal FDA organizational components.

If FDA becomes aware of a radiological incident, it should notify the coordinating agency and the DHS National Operations Center (NOC) at 202-282-8101 and comply with other appropriate statutory requirements for notification. If FDA becomes aware of an overt threat or act involving nuclear/radiological material/device or indications the event is not inadvertent or otherwise accidental, the U.S. Department of Justice (DOJ) should be notified through the FBI.

B.2.2.1.2 Assessment and Monitoring

During a radiological response, WEAC is the lead laboratory to receive samples and analyze them for radioactive contamination for radiological emergency consequence management, e.g., medical countermeasures.

[63] For more information on the Radiological Food Emergency Response Network and WEAC, refer to the Nuclear/Radiological Annex Appendix B.

B.2.2.2 Activation and Deployment of Resources and Capabilities

FDA is a member of the Advisory Team for the Environment, Food, and Health (Advisory Team), a Federal interagency group of radiation SMEs who provide coordinated, science-based advice and recommendations to the coordinating agency[64] and/or the State, tribal, and local government on protective measures that may be taken following a radiological incident. The Advisory Team comprises representatives from the EPA, the U.S. Department of Agriculture (USDA), and HHS, including the Centers for Disease Control and Prevention (CDC) and FDA. Other departments or agencies may be asked to participate as needed. The Advisory Team works closely with the Federal Radiological Monitoring and Assessment Center (FRMAC), an interagency group led by the U.S. Department of Energy's (DOE's) National Nuclear Security Agency (NNSA).[65]

If Federal assistance is requested for a radiological/nuclear incident and the Advisory Team participation is needed, FDA will send an ORA Regional Radiological Health Representative (RRHR). (See Radiological Annex Appendix C for activation/notification procedures of the Advisory Team.)

B.2.2.3 Coordination of Response Actions

During the response phase, FDA's role is to provide information about countermeasures and facilitate their availability as stated in the *FDA EOP*, Section B.2.2.3.5 Medical Countermeasures: Expanded Access and Emergency Use Authorization.

To assist FDA's Emergency Operations Center (EOC) in responding to a radiological emergency, staff personnel in the medical product Centers maintain the status of medical countermeasure product availability and relevant manufacturing information. Each Center has detailed policies and procedures in place to make critical medical countermeasures available, and the FDA EOC coordinates the sharing of this information during an emergency.

Exposure Determination Information

Based on data provided by FRMAC and other field assessments, the coordinating agency will provide the following information, which may be helpful in guiding decisions about medical countermeasures:

- Identity of the radioisotopes
- Quality of radiation (alpha, beta, gamma, and neutrons)
- Nature of device, e.g., IND or RDD
- Casualty information, including estimates of combined radiation and non-radiation injuries, such as blast and burn
- Plume direction and characteristics (estimated population exposure)
- Amount of external radiation exposure

This information may assist coordinating agencies in predicting who may develop:

- Hematopoietic syndrome (projected needs for cytokines and antimicrobials)
- Gastrointestinal syndrome (possible use of investigational cytokines)
- Cardiac/central nervous system syndrome (following extremely high doses, with death likely)

[64] Coordinating agencies are those Federal Agencies that own, have custody of, authorize, regulate, or are otherwise assigned responsibilities for the nuclear/radioactive material, facility, or activity involved in the incident. A listing of Coordinating agencies can be found in Table 1 of the NRF Nuclear/Radiological Incident Annex. www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf

[65] For additional information, see the Nuclear/Radiological Annex Appendix A.

B.2.3 Recovery

During the recovery phase, some FDA objectives that would support Federal, State, tribal, territorial, or local agencies are:

- To manage a potentially large number of samples of FDA-regulated products associated with nuclear/radiological releases, including long-term sampling, product destructions, and product reconditioning
- To provide technical support (along with the CDC) through the Advisory Team for the Environment, Food, and Health in establishing "clean-up" levels in following a radiological incident

C ORGANIZATION AND ASSIGNMENT OF RESPONSIBILITIES

This section identifies the roles and responsibilities specific to a radiological incident of FDA headquarters and field organizational components in preventing and protecting against, responding to, and recovering from a radiological incident. FDA staffs work closely with one another and with governmental and industry partners to ensure the safety, efficacy, and security of FDA-regulated products that mitigate the public health effects of an emergency or disaster in the United States or worldwide. This is done by using novel and expeditious approaches to product regulation in order to optimize the availability and use of FDA-regulated products in all populations.

Below is a brief description of the radiological emergency functions performed by responsible organizational components.[66] Refer to individual Center/Office emergency plans and procedural documentation, as applicable, for more detailed information on radiological emergency activities. For additional information on general FDA Center/Office emergency roles and responsibilities, refer to *FDA EOP*, Section C, Organization and Responsibilities of the *FDA EOP*.

C.1 OFFICE OF THE COMMISSIONER

C.1.1 Office of the Counselor to the Commissioner

C.1.1.1 Office of Crisis Management

In addition to the activities specified in the *FDA EOP*, the Office of Crisis Management (OCM) and Office of Emergency Operations (OEO) will communicate with external coordinating agencies[67] and share information with internal FDA entities for nuclear/radiological incidents affecting FDA-regulated products. Dependent on the type of incident, some of the agencies with which FDA would communicate are: U.S. Department of Defense (DoD), DOE, National Aeronautics and Space Administration (NASA), DHS, EPA, and Nuclear Regulatory Commission (NRC). For a detailed description of what the NRF provides about the response and coordinating responsibilities, see Appendix A to this annex or the NRF Nuclear/Radiological Incident Annex (www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf).

The external coordinating agencies will share with OCM/OEO (EOC) information about response activities of interest to FDA. The information to be shared with FDA includes but is not limited to:

[66] Those FDA organizational components without defined radiological emergency roles or responsibilities are not described within this Annex.

[67] NRF Nuclear/Radiological Incident Annex, June 2008
NRF Nuclear/Radiological Incident Annex, June 2008 Table 1 provides an overview of the coordinating agencies and the types of nuclear/radiological incidents in which they will be involved. The specific responsibilities of coordinating agencies are further described in Table 2.

Response Activities Information	Responsible Federal Agency
Laboratory Analysis	CDC, EPA, and/or DOE
Atmospheric Plume Modeling Data	Interagency Modeling and Atmospheric Center (IMAAC)/ National Atmospheric Release Advisory Center (NARAC), DHS and/or DOE/Lawrence Livermore National Laboratory
Population Modeling Data	HHS (ESF 8) or DHS
Protective Action Recommendations (PARs)	Advisory Team
Contaminated Animal Management	USDA (ESF #3 & #10)
Contaminated Agricultural Product Management	USDA (ESF #11, #3, & #10)

(Source: NRF Nuclear Radiological Incident Annex, Table 4: Nuclear/Radiological Incident Response Activities. For a description of the responsible Federal Agencies see www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf.)

C.2 OFFICE OF REGULATORY AFFAIRS

ORA, led by the Associate Commissioner for Regulatory Affairs (ACRA), protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products. ORA is the lead office for all agency field activities and is composed of four headquarters offices—Resource Management, Criminal Investigations, Enforcement, and Regional Operations—as well as five Regional and 20 District Offices and WEAC, ORA's radiological field lab. In addition to the *FDA EOP* activities described in *FDA EOP*, ORA is responsible for providing RRHRs and other qualified ORA staff, as needed, to be FDA representatives to the field component of the Advisory Team.

C.2.1 Regional Radiological Health Representatives[68]

The RRHRs represent the agency on committees chaired by the Federal Emergency Management Agency (FEMA) and composed of representatives from the Public Health Service, EPA, USDA, the NRC, Coast Guard, and others. These committees are responsible for evaluating State and local emergency plans for nuclear power plants and radiological emergencies.

In addition to serving as representatives on these committees, the RRHRs represent FDA on the onsite Advisory Team (Section B.2.2.2) during a radiological incident. Other FDA SMEs may also represent FDA on the Advisory Team via phone/e-mail in a reachback status. FDA staff is activated for the Advisory Team as per the Advisory Team Activation Standard Operating Procedure (SOP) (see Appendix C). When an incident has occurred, RRHRs are the agency's onsite liaisons to the Advisory Team. If there is a request for PARs for FDA-regulated products, RRHRs help develop the recommendations in consultation with other FDA scientific and policy experts. For additional information on PARs and Protective Action Guidelines, refer to Annex Appendix D, Protective Action.

C.3 FDA CENTERS

FDA product Centers are responsible for the regulation of a defined set of products. Their professional staff includes both clinical and scientific experts. This expertise (analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is available for critical consultation in the event of a nuclear/radiological incident. In addition, Center for Food Safety and Applied Nutrition (CFSAN) has responsibilities that are specific to a radiological incident.

[68] The duties and responsibilities of the RRHRs were defined in a Compliance Program Guidance Manual (CPG) 7386.009—Emergency Planning and Response Activities.

C.3.1 Center for Food Safety and Applied Nutrition

CFSAN, in conjunction with the agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the Nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and labeled properly. In addition to the activities described in the *FDA EOP*, CFSAN is responsible for, but not limited to, the following activities during radiological emergency:

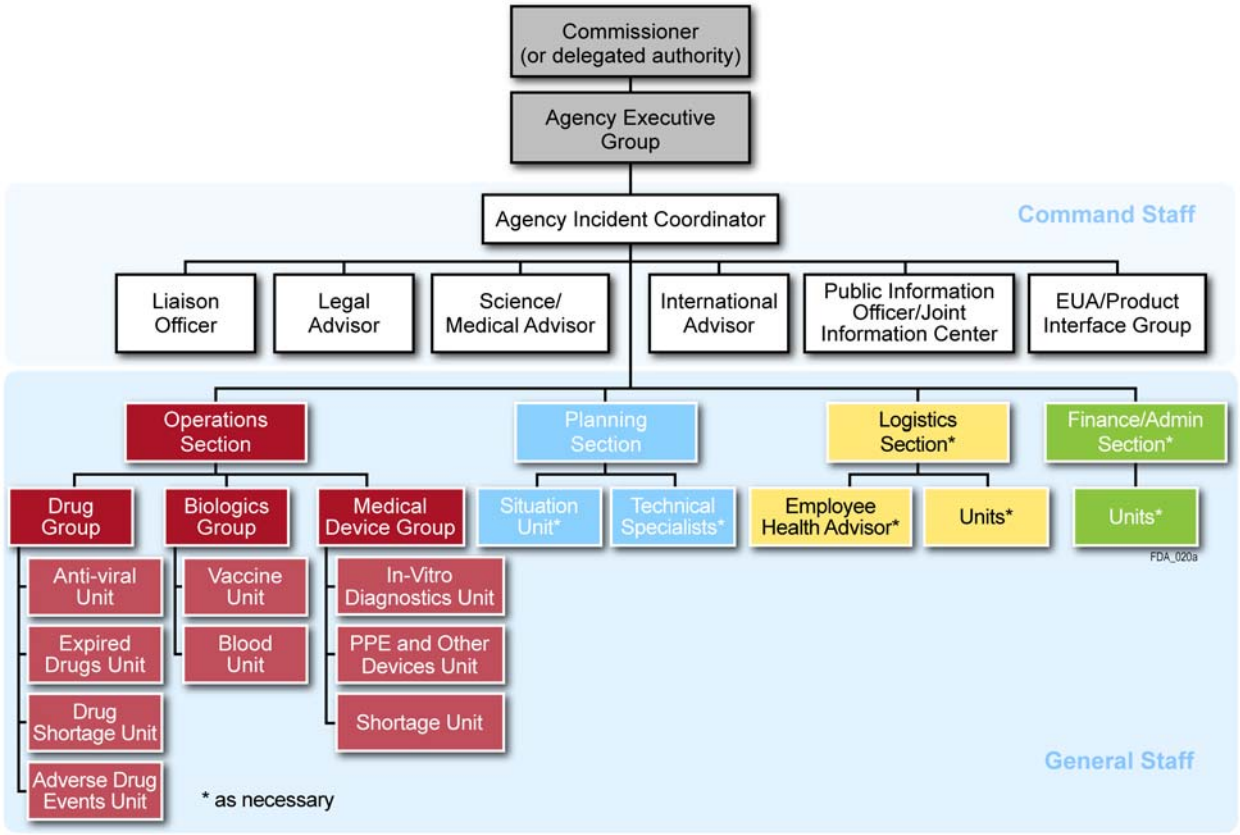
- Oversees the safety of the U.S. food supply following radiological emergencies through its Compliance Program and its participation with the Advisory Team, using the FDA Food Protective Action Guidance as the principal source of doctrine
- Through its involvement with FRMAC, participates in the development of assessment methods and guidance for food protective measures
- Provides scientific, technical, and policy expertise, guidance, and support within FDA and to other Federal and State agency components, the regulated industry, and the public
- Issues recommendations and guidelines on acceptable levels of radioactive contamination of foods, dietary supplements, and cosmetics
- Provides advice regarding health risks from radioactive contamination of food, dietary supplements, and cosmetics; this includes advice on actions that can be taken by FDA, State and local authorities, industry, or consumers to reduce public exposure to contaminated food, dietary supplements, and cosmetics
- Oversees the overall response to verify that the necessary food and cosmetic-related actions are taken
- Provides advice regarding sampling procedures and testing methodology (screening and confirmatory)
- Provides advice regarding product traceback and traceforward investigations
- Develops field programs to meet intermediate to long-range consequence management needs

D DIRECTION, CONTROL, AND COORDINATION

This section provides a description of radiological-specific positions and teams and describes their primary roles and responsibilities. These individuals are expected to have read and be familiar with the NRF Nuclear/Radiological Incident Annex.
www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf.

FDA organizes emergency response operations in accordance with the concepts, principles, and terminology of the ICS, as defined within *NIMS*.[69] Incident Command and subordinate Planning, Operations, Logistics, and Finance/Administration functions lay the foundation for the agency's implementation of ICS during all hazards, at headquarters and field levels, and across geographic divides. The inherent design of this system enables rapid, scalable, and flexible agency-wide emergency management activities. **Figure D-1** depicts FDA's Incident Management Group (IMG) emergency response coordinating structure. For a complete listing of the FDA ICS structure,[70] refer to the *FDA EOP,* Section D, Direction, Control, and Coordination.

Figure D-1. FDA Incident Management Group during a Radiological/Nuclear Event



[69] For more information on the ICS, refer to www.training.fema.gov/EMIWeb/IS/ICSResource/index.htm.
[70] For more information on specific roles and responsibilities of each ICS position, refer to the FDA EOP Appendix K "Job Action Sheets."

D.1 COMMAND STAFF

The FDA Command Staff includes a Public Information Officer (PIO), Liaison Officers (LNOs), and relevant Technical Advisors, such as Science/Medical Advisors, Emergency Use Authorization (EUA), who report directly to the Agency Incident Coordinator: Science/Medical Advisors, EUA/Product Interface Advisor, and Legal Advisor.[71]

D.1.1 Radiological-Specific Liaisons

When activated, the FDA EOC serves as the agency-wide focal point for radiological emergency operations, coordination, and communications for incidents involving regulated products. External liaisons from USDA, NRC or other agencies may be present at the FDA EOC. FDA may also send liaisons to the Coordinating agency for the event or participate in the response coordination if an incident or unified command is set up.

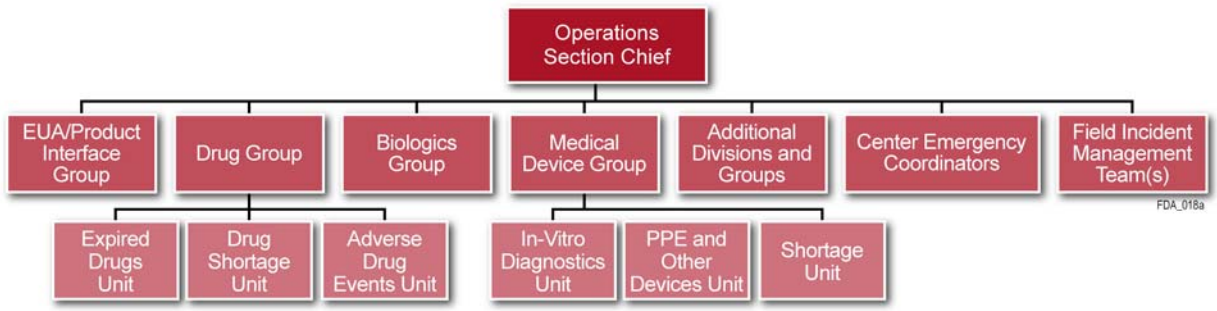
D.2 GENERAL STAFF

The General Staff is responsible for the functional aspects of the FDA ICS. The General Staff consists of Operations, Planning, Logistics, and Finance/Administration Sections composed of designated FDA headquarters and field emergency staffs. Individual position assignments within these Sections are discussed in the *FDA EOP*.

D.2.1 Operations Section

The Operations Section is responsible for coordinating all agency field activities in response to a radiological/nuclear event involving a regulated product. **Figure D-2** depicts FDA's Operations Section during the event. The Groups included in the chart below could possibly be established when the number of resources exceeds the manageable span of control of the Incident Management Group and the Operations Section Chief. Groups are established to divide the incident into functional areas of operation. Additional levels of supervision may also exist below the Group level. Resources may be organized and managed by Task Forces depending on the requirements of the incident. Task Forces are any combination of resources assembled in support of a specific mission or operational need. All resource elements within a Task Force must have common communications and a designated leader. The use of Task Forces is encouraged, when appropriate, to optimize the use of resources, reduce the span of control, and reduce the complexity of incident management coordination and communications.[72]

Figure D-2. Possible Operations Section Organizational Elements



[71] See FDA EOP, Section D.3.4. Technical Advisors, for descriptions of these positions.
[72] DHS NIMS (Dec. 2008)

Expansion or contraction of the Operations Section may vary according to numerous considerations and operational factors associated with an incident. In some cases, a functional approach may be used. In other cases, the organizational structure will be determined by geographical or Center/Office jurisdictional boundaries. In still others, a mix of functional and geographical considerations may be appropriate. The agency Incident Manager/Coordinator will determine the appropriate structural approach based on the specific circumstances of the incident at-hand.

D.2.1.1 Field Incident Command Staff (Incident Management Team)

During a radiological/nuclear event, the IMT may be part of the chain of command under IMG Operations Section Chief as described in the *FDA EOP*. Should FDA-regulated products need to be collected within a (potentially) contaminated site, staff from the FRMAC[73] who have extensive radiological training will collect samples. FDA does not expect its personnel to enter these areas until State and local officials have declared the site safe. However, if it becomes necessary for FDA investigators to enter a (potentially) contaminated site, only trained FDA personnel equipped with appropriate personal protective equipment (PPE) are authorized to enter the site in coordination with the on-scene Incident Commander (see Appendix D for Protective Action Guides). For example, FDA might need to respond to an incident to collect and packag or samples of FDA-regulated products. Samples will be collected, packaged, and shipped in accordance with FDA's Investigations Operations Manual, International Air Transport Association, and U.S. Department of Transportation procedures/regulations.

D.2.1.2 Drug Group

The Drug Group addresses drug issues such as adverse event reporting, labeling changes, whether EUAs for drugs are appropriate, and what restrictions should be placed on uses authorized under EUAs related to a radiological operational response. Some potential Units, led by Center for Drug Evaluation and Research (CDER) staff, which may be needed to manage mitigation and recovery issues include:

D.2.1.2.1 Expired Drugs Unit

The Expired Drugs Unit deals with such issues as use of expired drugs and drugs out of specification, including those in the Strategic National Stockpile (SNS). This Unit would have input in discussing whether an EUA should/can include private sector stockpiles (e.g., hospital associations, large employers) or whether a separate authorization is needed. The Expired Drugs Unit would also monitor labeling and shelf-life extension program (SLEP) issues related to the event.

D.2.1.2.2 Drug Shortage Unit

The Drug Shortage Unit is responsible for reporting on the availability and surge capacity for drugs, monitoring commercial inventory, and working with manufacturers of drug products to prepare for possible increases in demand. The Unit would contact intravenous fluid manufacturers and other critical care drug manufacturers in order to prepare for possible increased needs.

D.2.1.2.3 Adverse Drug Events Unit

The Adverse Drug Events Unit assists with the monitoring of adverse drug events to identify undesired side effects and unexpected adverse effects from a drug product used for treatment.

D.2.1.3 Biologics Group

The Biologics Group addresses blood and other biologics issues as part of a radiological/nuclear operational response.

[73] See Nuclear/Radiological Annex Appendix A for a description of FRMAC

D.2.1.4 Medical Device Group

The Medical Device Group would manage issues related to a radiological/nuclear operational response. Potential Units, with leaders from Center for Devices and Radiological Health (CDRH) staff members, who may be needed to manage mitigation and recovery issues, are:

D.2.1.4.1 In-Vitro Diagnostics Unit

The In-Vitro Diagnostics (IVD) Unit addresses issues related to the following:

- Triage of EUA requests
- Response to inquiries regarding EUA requests from CDC, DoD, and domestic and international commercial sources for IVDs claiming to assess radiation exposure
- Contact with manufacturers regarding assays and instruments to be used in development of IVDs
- Clear or approved tests and instruments that detect and measure in situ radioisotope contamination and absorbed radiation dose in exposed individuals
- Monitor reagent and system shortages on a short-term daily or weekly basis as well as a long-term monthly basis
- Monitor radiation biodosimetry and in situ radioactivity contamination detection device functional claims
- Review data and labeling of cleared or approved devices for which a company is proposing new claims and changes
- Address fraudulent claims by monitoring Web sites and complaints regarding product claims and issue warning letters as appropriate

D.2.1.4.2 Personal Protective Equipment and Other Devices Unit

The PPE and Other Devices Unit oversees or manages the following:

- Exchange of information with the CDC/SNS, States, and manufacturing sector and real-time monitoring of consumption/utilization rates of PPE during emergencies
- Respond to State and private sector inquiries about perceived shortages during public health emergencies
- Anticipate and plan for future surges in demand for devices
- Track/trace status of devices released from SNS
- Meet with manufactures about the development of new PPEs
- Address PPE shortages by working with industry to update current manufacturing capabilities and assist with long-term planning by the manufacturing sector to meet demands for potential surges

D.2.1.4.3 Shortage Unit

This Unit would be created if shortages of IVDs, PPEs, and other devices are too extensive to be managed by the above Units alone.

D.2.2 Planning Section

The Planning Section is responsible for collecting, evaluating, and disseminating operational information pertaining to the incident. This Section maintains information and intelligence on the current and forecasted situation, as well as the status of FDA resources assigned to the incident.

D.2.2.1 Lead Radiological Emergency Response Unit

The Radiological Emergency Response Unit comprises a Lead Radiological Emergency Response Coordinator, identified by OCM, and the Radiological Emergency Response Team. The Lead Radiological Emergency Response Coordinator oversees a cadre of radiological health SMEs called upon to form a Radiological Emergency Response Team during a radiological emergency to provide technical advice to FDA senior management and liaisons to external agencies. The Radiological Emergency Response Team will comprise SMEs from relevant Centers with a variety of backgrounds, including health physics, medical physics, radiology, nuclear medicine, and radiation oncology.

D.2.3 Logistics Section

D.2.3.1 Employee Health Advisor

The Employee Health Advisor is a staff member of the Office of Counterterrorism and Emerging Threats (OCET) or the Office of Management (OM) and addresses the need for appropriate health protection for high-risk FDA employees. The Advisor works with HHS and the U.S. Public Health Service's Federal Occupational Health Services to ensure that adequate medical countermeasures are made available to protect FDA responders.

E COMMUNICATIONS AND INFORMATION MANAGEMENT

Effective emergency management and incident response activities rely upon flexible communications and information systems that provide for a "common operating picture" across all agency components and staffs. Radiological/nuclear incident responders are expected to follow the *FDA EOP,* Section E, Communication and Information Management.

Emergency Alerts

Upon receipt, the Emergency Coordinator or Late Duty Officer (LDO) may use the Notification Listing below Radiological Emergency listed in the OCM/OEO Redbook.

F AUTHORITIES AND REFERENCES

The legal authorities that guide the structure, development, and implementation of the *Nuclear/Radiological Annex* include statutes and regulations, Presidential directives, national strategies, and Federal Government plans and guidance. In addition, internal emergency plans and procedures augment the *Nuclear/Radiological Annex* and provide specific guidance to agency personnel during emergencies and disasters. In addition to the authorities and references listed in the *FDA EOP*, Section G, Authorities and References, the following authorities and references apply.[74]

F.1 CODE OF FEDERAL REGULATIONS

Title 44, "Emergency Management and Assistance"

Title 44, Part 351 of the CFR, "Radiological Emergency Planning and Preparedness" of the CFR, authorizes Federal Agencies, including HHS, to assist State and local government officials in the development of their radiological plans. www.access.gpo.gov/nara/cfr/waisidx_02/44cfrv1_02.html

F.2 FEDERAL PLANS AND GUIDANCE

The following list of Federal plans and Guidance are applicable during a radiological nuclear event. For a more detailed description, please see Appendix A and B or the links provided.

National Response Framework Nuclear/Radiological Incident Annex

www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf

Food and Agriculture Incident Annex

www.fema.gov/pdf/emergency/nrf/nrf_FoodAgricultureIncidentAnnex.pdf

Terrorism Incident Law Enforcement and Investigation Annex

www.learningservices.us/pdf/emergency/nrf/nrp_terrorismincidentlawenforcementannex.pdf

Emergency Support Function #8 "Public Health and Medical Services"

www.fema.gov/pdf/emergency/nrf/nrf-esf-08.pdf

Emergency Support Function #10 "Oil and Hazardous Materials Response"

www.fema.gov/pdf/emergency/nrf/nrf-esf-10.pdf

National Oil and Hazardous Substances Pollution Contingency Plan

www.epa.gov/OEM/content/lawsregs/ncpover.htm

Emergency Support Function # 11 "Agriculture and Natural Resources"

www.fema.gov/pdf/emergency/nrf/nrf-esf-11.pdf

[74] This list is not exhaustive, and the associated summaries should not be used as a substitute for the authorities and references themselves.

F.3 FDA SUPPORTING DOCUMENTATION

F.3.1 Winchester Engineering and Analytical Center, Radiation Safety Manual

Radiation Safety Manual, *Winchester Engineering and Analytical Center Policies and Procedures for Users of Radioactive Material and Radiation Emitting Devices*, issued by the WEAC Radiation Committee.

F.3.2 FDA Food Protective Guidance

FDA has guidance on acceptable levels of radioactive contamination in food (called Derived Intervention Levels [DILs]) entitled, "Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies" (CDRH, 1998). This guidance provides a method for calculating the DIL for a specific radionuclide based on a limiting radiation dose to an individual consuming food contaminated at the level of a DIL for a period of 1 year. This guidance has been adopted by many States for their nuclear power plant safety programs and has been incorporated into EPA's Protective Action Guide (PAG) Manual. FDA's representatives on the Advisory Team for the Environment, Food, and Health, along with CFSAN radiation SMEs, assist with the interpretation of the guidance.

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Appendix A: Other Federal Department and Agency Responsibilities

(EXCERPT FROM NRF NUCLEAR/RADIOLOGICAL INCIDENT ANNEX)

FDA consults with a variety of agencies and organizations in order to respond to a radiological emergency. Consultation occurs with other agencies or organizations prior to any action that may affect them. Consultation may be directly from agency to agency, or within committees or working groups, such as the Federal Radiological Preparedness Coordinating Committee.

As outlined in the NRF Nuclear/Radiological Incident Annex,[75] responsibilities for a radiological incident that requires an interagency response are divided among coordinating agencies and cooperating agencies. For incidents wherein the Secretary of Homeland Security is not fulfilling domestic incident management responsibilities, the coordinating agency will be the responsible agency for domestic incident management as defined by their authorities.

Coordinating Agencies provide the leadership, expertise, and authorities to implement critical and specific nuclear/radiological aspects of the response and facilitate nuclear/radiological aspects of the response in accordance with those authorities and capabilities. The coordinating agencies are those Federal Agencies that own, have custody of, authorize, regulate, or are otherwise assigned responsibility for the nuclear/radioactive material, facility, or activity involved in the incident. These Federal Agencies have nuclear/radiological authorities, technical expertise, and/or assets for responding to the unique characteristics of nuclear/radiological incidents that are not otherwise described in the NRF. Coordinating agencies are listed in **Table 1**.

- DoD or DOE, as appropriate, for incidents involving nuclear/radiological materials or facilities owned or operated by DoD or DOE
- DoD or DOE, as appropriate, for incidents involving a nuclear weapon, special nuclear material, and/or classified components under DoD or DOE custody
- NASA for nuclear material under NASA custody
- The NRC for incidents involving materials or facilities licensed by the NRC or Agreement States
- DHS, generally through Customs and Border Protection (CBP), for incidents involving the inadvertent import of radioactive materials as well as any other incidents where radioactive material is detected at borders
- EPA or DHS/U.S. Coast Guard (USCG), as appropriate, for environmental response and cleanup for incidents not otherwise covered above
- DHS for all deliberate attacks involving nuclear/radiological facilities or materials, including RDDs and INDs

Cooperating Agencies include other Federal Agencies that provide additional technical and resource support specific to nuclear/radiological incidents to DHS and the coordinating agencies. The capabilities provided by cooperating agencies are described in **Table 2**.

Other Federal Agencies may also provide support to DHS and the coordinating agency in accordance with the NRF ESF and Support Annexes.

[75] For more information on the NRF Nuclear/Radiological Incident Annex, refer to www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf

Table 1 provides an overview of the coordinating agencies and the types of nuclear/radiological incidents in which they will be involved.[76]

Table I-1. Coordinating Agencies for Nuclear/Radiological Incidents

Nuclear/Radiological Facilities or Materials Involved in an Incident	Coordinating Agency
Nuclear facilities: (1) Owned or operated by DoD or DOE (2) Licensed by NRC or Agreement State (3) Not licensed, owned, or operated by a Federal Agency or an Agreement State, or currently or formerly licensed facilities for which the owner/operator is not financially viable or is otherwise unable to respond	(1) DoD or DOE (2) NRC (3) EPA
Radioactive materials being transported: (1) Materials shipped by or for DoD or DOE[77] (2) Shipment of NRC or Agreement State-licensed materials (3) Shipment of materials in certain areas of the coastal zone that are not licensed or owned by a Federal Agency or Agreement State (see DHS/USCG list of responsibilities for further explanation of "certain areas") (4) All others	(1) DoD or DOE (2) NRC (3) DHS/USCG (4) EPA
Radioactive materials in space vehicles impacting within the United States: (1) Managed by NASA or DoD (2) Not managed by DoD or NASA and impacting certain areas of the coastal zone (3) All others	(1) NASA or DoD (2) DHS/USCG (3) EPA
Foreign, unknown, or unlicensed material:[78] (1) Incidents involving inadvertent import of radioactive materials (2) Incidents involving foreign or unknown sources of radioactive material in certain areas of the coastal zone (3) All others	(1) DHS/CBP (2) DHS/USCG (3) EPA
Nuclear weapons	DoD or DOE (based on custody at time of incident)
All deliberate attacks involving nuclear/radiological facilities or materials, including RDDs or INDs[79] [80]	DHS

[76] For specific responsibilities of each coordinating agency, as specified by statutory authorities or other mandating doctrine, refer to the NRF Nuclear Radiological Incident Annex.

[77] The coordinating agency is either DoD or DOE, depending on which of these agencies has custody of the material at the time of the incident.

[78] The DHS Domestic Nuclear Detection Office (DNDO) coordinates the adjudication of unresolved radiation detection alarms (see Table 5 for additional information).

[79] For deliberate attacks, DHS assumes its domestic incident management responsibilities under Homeland Security Presidential Directive (HSPD) 5, paragraph 4, and is also the coordinating agency for implementing the activities in this annex with respect to deliberate attacks.

[80] For deliberate attacks, DOJ assumes those law enforcement coordination activities under HSPD-5, paragraph 8.

Table 2. Coordinating Agency-Specific Key Responsibilities for Nuclear/Radiological Incidents

Agency	Description
U.S. Department of Agriculture (USDA)	(See the Emergency Support Function (ESF) #11 Annex[81] and the Food and Agriculture Annex[82] of the NRF for additional USDA responsibilities.) • Assists in the planning and collection of agricultural samples within the Ingestion Exposure Pathway Emergency Planning Zone • Assesses damage to crops, soil, livestock, poultry, and processing facilities and incorporates the findings in a damage assessment report • Assists in the evaluation and assessment of data to determine the impact of the incident on agriculture • Provides support and advice on screening and decontamination of pets and farm animals that may have been exposed to radiation or contaminated with radioactive materials • Assists in the planning and operational aspects of animal carcass disposal • Inspects and assists in the collection of samples of crops, meat and meat products, poultry and poultry products, and egg products to ensure that they are safe for human consumption • Assists, in conjunction with HHS, in monitoring the production, processing, storage, and distribution of food through the wholesale level to eliminate contaminated product and to ensure that the levels of contamination in the product are safe and below the DILs
U.S. Department of Commerce (DOC)	• Provides near or on-scene weather observations upon request • Prepares forecasts tailored to support emergency incident management activities • Participates in the IMAAC by providing atmospheric transport and dispersion (plume) modeling assessment and forecasts, surface weather observations, and weather forecasts to the IMAAC, when activated • When the IMAAC is not activated, provides atmospheric transport and dispersion (plume) modeling assessment and forecasts to the coordinating agency, in accordance with established procedures • Maintains and further develops the Hybrid Single Particle Lagrangian Integrated Trajectory Model transport and dispersion model • Archives, as a special collection, the meteorological data from national observing and numerical weather analysis and prediction systems applicable to the monitoring and assessment of the response • Provides assistance and reference material for calibrating radiological instruments • Provides support in the testing and evaluation of radiation shielding materials • In the event of materials potentially crossing international boundaries, provides atmospheric transport and dispersion products to international hydrometeorological services and associated agencies through the mechanisms afforded by the World Meteorological Organization • Provides radioanalytical measurement support and instrumentation • Provides assistance for collection and monitoring for marine and estuary contamination assessment • Advises and provides assistance on building operations (e.g., heating, ventilation, and air conditioning) for contamination control and decontamination processes • Provides laboratory support for analysis of materials and environmental samples

[81] For more information on ESF #11, refer to: www.fema.gov/pdf/emergency/nrf/nrf-esf-11.pdf

[82] For more information on the Food and Agriculture Annex, refer to: www.fema.gov/pdf/emergency/nrf/nrf_FoodAgricultureIncidentAnnex.pdf

Agency	Description
U.S. Department of Defense (DoD)	• Provides Defense Support of Civil Authorities (DSCA) in response to requests for assistance during domestic incidents. With the exception of support provided under Immediate Response Authority, the obligation of DoD resources to support requests for assistance is subject to the approval of the Secretary of Defense; under certain critical circumstances, the President or Secretary of Defense may direct DSCA activities without a specific request. Details regarding DSCA and immediate response are provided in the NRF Core Document. • May provide DoD and DoD-funded assets for the response to radiological incidents, to include: – Weapons of Mass Destruction (WMD) Civil Support Teams (CSTs) – National Guard teams that assess a suspected WMD attack, advise civilian responders on appropriate actions through onsite testing and expert reachback, and facilitate the arrival of additional State and Federal military forces; each team consists of 22 personnel and is equipped with PPE for operating in unknown hazardous environments, nuclear, biological, and chemical detectors, sampling/analytical systems, a decontamination system, and communications equipment used to reach back to experts via satellite. These are State assets that can be federalized. There is nominally one CST per State, as well as one each in Guam, Puerto Rico, the Virgin Islands, and the District of Columbia. – Chemical, Biological, Radiological, and Nuclear (CBRN) Enhanced Response Force Packages (CERFPs) – National Guard elements that provide an immediate response capability to a Governor; the CERFPs are capable of searching an incident site (including damaged buildings), rescuing any casualties, decontaminating them, and performing medical triage and initial treatment to stabilize them for transport to a medical facility. This includes extracting anyone trapped in the rubble. The CERFP is composed of four elements staffed by personnel from already established National Guard units. The elements are search and extraction, decontamination, medical, and security. The CERFP command and control team directs the overall activities of the CERFP and coordinates with the Joint Task Force – State and the Incident Commander. There is at least one CERFP in each FEMA region. – Chemical, Biological, Radiological, Nuclear, and High-Yield Explosive (CBRNE) Consequence Management Response Forces (CCMRF) – Multiservice (active and reserve component military) follow-on assets designed to augment the CSTs and CERFPs, if necessary; specific CCMRF capabilities include, but are not limited to, robust command and control, technical search and rescue, explosive ordnance disposal, aviation evacuation, specialized medical response teams, and enhanced chemical, biological, and nuclear detection/decontamination. – DoD advisory teams – Various teams that may deploy, either independently or as part of the CCMRFs, that provide guidance and advice to the Incident Commander on potential health hazards, radiation injury treatment, survey data evaluations, population monitoring, etc. These include the Consequence Management Advisory Team, U.S. Air Force Radiation Assessment Team, the U.S. Army's Radiological Advisory Medical Team, and the Armed Forces Radiobiology Research Institute's Medical Radiobiological Advisory Team.

Agency	Description
	• Provides immediate assistance under Immediate Response Authority for any civil emergency that may require immediate action to save lives, prevent human suffering, or mitigate great property damage; when such conditions exist and time does not permit prior approval from higher headquarters, local military commanders and responsible officials from DoD components and agencies are authorized by DoD directive, subject to any supplemental direction that may be provided by their DoD component, to take necessary action to respond to requests of civil authorities. All such necessary action is referred to as "Immediate Response."
U.S. Department of Defense (DoD)/U.S. Army Corps of Engineers	(See the ESF #3 – Public Works and Engineering Annex[83] for additional information.) • For RDD/IND incidents, provides response and cleanup support as a cooperating agency. • Integrates and coordinates with other agencies, as requested, to perform any or all of the following: – Radiological survey functions – Gross decontamination – Site characterization – Contaminated water and debris management – Site remediation
U.S. Department of Energy (DOE)	• Develops and maintains FRMAC policies and procedures, determines FRMAC composition, and maintains FRMAC operational readiness • Coordinates Federal radiological environmental monitoring and assessment activities as lead technical organization in the FRMAC (emergency phase), regardless of who is designated the coordinating agency • Maintains technical liaison with State and local agencies with monitoring and assessment responsibilities • Maintains a common set of all radiological monitoring data in an accountable, secure, and retrievable form and ensures the technical integrity of FRMAC data • Provides monitoring data and interpretations, including exposure rate contours, dose projections, and any other requested radiological assessments, to the coordinating agency and to the States • Provides, in cooperation with other Federal Agencies, the personnel and equipment to perform radiological monitoring and assessment activities, and provides on-scene analytical capability supporting assessments • Requests supplemental assistance and technical support from other Federal Agencies as needed • Arranges consultation and support services through appropriate Federal Agencies to all other entities (e.g., private contractors) with radiological monitoring functions and capabilities and technical and medical expertise for handling radiological contamination and population monitoring • Works closely with the Senior EPA representative to facilitate a smooth transition of the Federal radiological monitoring and assessment coordination responsibility to EPA at a mutually agreeable time and after consultation with the States and coordinating agency • Provides, in cooperation with other Federal and State agencies, personnel and equipment, including portal monitors, to support initial external screening and provides advice and assistance to State and local personnel conducting screening/decontamination of persons leaving a contaminated zone • Provides plume trajectories and deposition projections from the NARAC for emergency response • Provides source term estimates to the IMAAC and/or coordinating agency when limited or

[83] For more information of ESF #3, refer to: www.fema.gov/pdf/emergency/nrf/nrf-esf-03.pdf

Agency	Description
	no information is available, based on DOE's unique experience in developing source terms for INDs and RDDs • Upgrades, maintains, coordinates, and publishes documentation needed for the administration, implementation, operation, and standardization of the FRMAC • Maintains and improves the ability to provide wide-area radiation monitoring now resident in the Aerial Measurement System • Maintains and improves the ability to provide medical assistance, advisory teams, and training related to nuclear/radiological accidents and incidents now resident in the Radiation Emergency Assistance Center/Training Site • Maintains and improves the ability to provide predictive modeling of airborne hazards and to correct modeled results through integration of actual radiation measurements obtained from both airborne and ground sources, resident in the FRMAC; the NARAC maintains and improves their ability to model the direct results (blast, thermal, radiation, electromagnetic pulse of a nuclear detonation. • Maintains and improves the first-response ability to assess an emergency situation and to advise decisionmakers on what further steps can be taken to evaluate and minimize the hazards of a radiological emergency resident in the Radiological Assistance Program • Maintains and improves the ability to respond to an emergency involving U.S. nuclear weapons resident in the Accident Response Group • Maintains and improves the ability of Consequence Management Home Teams (CMHTs) and Consequence Management Response Teams to provide initial planning, coordination, and data collection and assessment prior to or in lieu of establishment of a FRMAC • Maintains and improves the ability of the DOE Nuclear/Radiological Advisory Team to provide advice and limited technical assistance, including search, diagnostics, and effects prediction, as part of a Domestic Emergency Support Team • Maintains and improves the ability of Radiological Triage to determine, through remote analysis of nuclear spectra collected on-scene, if a radioactive object contains special nuclear materials • Assigns a Senior Energy Official (SEO) for any response involving the deployment of the DOE/NNSA emergency response assets. The SEO will integrate into an appropriate position in the Incident Command/Unified Command (IC/UC) and is responsible for the coordination and employment of these assets at the scene of a radiological event. The deployed assets will work in support of and under the direction of the SEO.
U.S. Department of Health and Human Services (HHS)	(See the ESF #8 Annex[84] for additional information.) • Conducts epidemiological surveillance and provides guidance on methods to detect symptoms consistent with exposure to radioactive materials • Collects samples of agricultural products to monitor and assess the extent of contamination as a basis for recommending or implementing protective actions (through the FRMAC) • Provides advice on proper medical treatment of the general population and response workers exposed to or contaminated by radioactive materials • Provides available medical countermeasures through deployment of the SNS • Provides assessment and treatment teams for those exposed to or contaminated by radiation • Provides advice and guidance in assessing the impact of the effects of radiological incidents on the health of persons in the affected area

[84] For more information on ESF #8, refer to: www.fema.gov/pdf/emergency/nrf/nrf-esf-08.pdf

Agency	Description
	• Manages long-term public monitoring and supports follow-on personal data collection, collecting and processing of blood samples and bodily fluids/matter samples, and advice concerning medical assessment and triage of victims; tracks patient treatment and long-term health effects • Provides scientific advice on the health risks and "clean-up" of contaminated food, dietary supplements, medical devices, and other FDA regulated products • Assists State, tribal, and local response efforts by supplementing resources, making recommendations, and assisting with communication and coordination efforts • Provides scientific advice on the type and level of decontamination, clean-up, or remediation needed to areas exposed to radiation or contaminated with radioactive materials • WEAC – provides 24 hours-a-day, 7 days-a-week analysis capacity for detection of radionuclides in foods, drugs, and medical devices and serves as lead for radiological component of FERN • WEAC – is responsible for providing PPE to field personnel during a radiological/nuclear event
U.S. Department of Homeland Security (DHS)/Customs and Border Protection (CBP)	• For incidents at the border, maintains radiation detection equipment and nonintrusive inspection technology at ports of entry and Border Patrol checkpoints to detect the presence of radiological substances transported by persons, cargo, mail, or conveyance arriving from foreign countries • Through its National Targeting Center, provides extensive analytical and targeting capabilities to identify and interdict suspect nuclear/radiological materials • Through the CBP Weapons of Mass Destruction Teleforensic Center, provides 24 hours-a-day, 7 days-a-week support to DHS/CBP and other Federal law enforcement personnel in the identification of interdicted suspect hazardous material as well as providing a link for coordination with and triage to other Federal Agencies as appropriate for the type of incident • Through the CBP Laboratories and Scientific Services, staffs WMD Response Teams in strategic locations nationwide to screen and identify potential radiological threat materials as well as reduce the hazards that may exist by establishing temporary containment parameters
DHS/Domestic Nuclear Detection Office (DNDO)	• Supports the deployment of an enhanced global nuclear detection system to detect and report on attempts to import, possess, store, transport, develop, or use an unauthorized nuclear explosive device, fissile material, or radiological material in the United States • Through the DNDO Joint Analysis Center, provides a coordinated technical adjudication of a nuclear/radiation detection alarm and recommends technical Federal asset responses as required
DHS/Federal Emergency Management Agency (FEMA)	• Serves as the annex coordinator for the NRF Nuclear/Radiological Incident Annex
DHS/U.S. Coast Guard (USCG)	• Because of its unique maritime jurisdiction and capabilities, is prepared to provide appropriate security, command and control, transportation, and support to other agencies that need to operate in the maritime domain • Maintains the National Response Center, which is staffed by Coast Guard personnel who maintain a 24-hour-a-day, 365-day-a-year telephone watch
U.S. Department of the Interior (DOI)	• Provides resources, including personnel, equipment, and laboratory support, to advise and assist in evaluating processes affecting radioisotopes in soils • Provides resources, including personnel and equipment, to advise and assist in the development of geographic information systems databases to be used in the analysis and assessment of contaminated areas • Provides liaison between federally recognized tribal governments and Federal, State, and local agencies for coordination of response activities. Additionally, DOI advises and assists DHS on economic, social, and political matters in the U.S. insular areas should a

Agency	Description
	radiological incident occur in these areas.
U.S. Department of Justice (DOJ)/ Federal Bureau of Investigation (FBI)	• Has lead responsibility for criminal investigations of terrorist acts or terrorist threats by individuals or groups inside the United States, or directed at U.S. citizens or institutions abroad, where such acts are within the Federal criminal jurisdiction of the United States • Manages, leads, and coordinates all law enforcement and investigative activities with regard to the response to terrorist acts or threats, including tactical operations, crime scene investigation, crisis negotiation, and intelligence gathering and dissemination • Coordinates the activities of the law enforcement community to detect, prevent, preempt, and disrupt terrorist attacks against the United States • Further details regarding the FBI response are outlined in the Terrorism Incident Law Enforcement and Investigation Annex.
U.S. Department of Labor (DOL)/ Occupational Safety and Health Administration (OSHA)	• Provides advice and technical assistance to DHS, the coordinating agency, and State, tribal, and local governments concerning the health and safety of response workers implementing the policies and concepts in this annex • Provides assistance with developing site health and safety plans • Provides monitoring for emergency response workers through the Worker Safety and Health Support Annex • Provides technical assistance with emergency worker decontamination
U.S. Department of State (DOS)	• Serves as the USG lead in notification of the International Atomic Energy Agency (IAEA) in accordance with the Convention on Early Notification of a Nuclear Accident • Serves as the USG lead in notification to foreign governments. Will immediately notify Canada and Mexico to negotiate cooperative and collaborative cross-border activities • Serves as the USG lead in requesting or accepting assistance in accordance with the IAEA Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency
U.S. Department of Transportation (DOT)	(See the ESF #1 – Transportation Annex[85] for further information.) • Provides technical advice and assistance on the transportation of radiological materials and the impact of the incident on the transportation infrastructure
U.S. Department of Veterans Affairs (VA)	• Provides medical assistance using the Medical Emergency Radiological Response Team, which provides direct patient treatment; assists and trains local healthcare providers in managing, handling, and treatment of radiation-exposed and -contaminated casualties; assesses the impact on human health; and provides consultation and technical advice to local, State, and Federal authorities
U.S. Environmental Protection Agency (EPA)	(See the ESF #10 Annex[86] for additional information.) • Provides resources, including personnel, equipment, and laboratory support (including mobile laboratories) to assist DOE in monitoring radioactivity levels in the environment • Assists in the development and implementation of a long-term monitoring plan and long-term recovery plan • Provides nationwide environmental monitoring data from the RadNet for assessing the national impact of the incident • Develops PAG manuals in coordination with the FRPCC • Recommends acceptable emergency levels of radioactivity and radiation in the environment • Prepares health and safety advice and information for the public • Estimates effects of radioactive releases on human health and the environment • Provides, in cooperation with other Federal Agencies, the law enforcement personnel and equipment to conduct law enforcement operations and investigations for nuclear/radiological incidents involving criminal activity that are not terrorism related

[85] For more information on ESF #1, refer to: www.fema.gov/pdf/emergency/nrf/nrf-esf-01.pdf

Agency	Description
National Aeronautics and Space Administration (NASA)	• Partners with DOE when preparing for the launch of spacecraft involving significant quantities of DOE-owned nuclear material by providing additional specialized radiological monitoring equipment and radiological accident response personnel; however, NASA Centers maintain limited quantities of radiological monitoring equipment that could be utilized in response to radiological incidents. • In conjunction with EPA and the National Oceanic and Atmospheric Administration (NOAA), may task certain NASA orbiting assets to provide supplemental data to monitor incidents occurring in Earth's atmosphere
Nuclear Regulatory Commission (NRC)	• Provides technical assistance to include source term estimation, plume dispersion, and dose assessment calculations • Provides assistance in Federal radiological monitoring and assessment activities

Key Federal Radiological Resources/Assets[87]

Federal Radiological Monitoring and Assessment Center

The FRMAC is responsible for coordinating all environmental radiological monitoring, sampling, and assessment activities for the response. The FRMAC is a DOE-led interagency asset that is available on request to respond to nuclear/radiological incidents. DOE leads the FRMAC for the initial response, then transitions FRMAC leadership to EPA for site cleanup. The FRMAC is established at or near the incident location in coordination with DHS, the coordinating agency, other Federal Agencies, and State, tribal, and local authorities.

A FRMAC normally includes representation from DOE, EPA, the Department of Commerce, the DHS National Communications System, the U.S. Army Corps of Engineers, and Federal Agencies as needed. Regardless of who is designated as the coordinating agency, when the FRMAC is activated, DOE, through the FRMAC or DOE CMHT, coordinates all Federal environmental and agricultural radiological monitoring and assessment activities for the initial phases of the response. When the FRMAC is transferred to EPA, EPA assumes responsibility for coordination of radiological monitoring and assessment activities.

Some participating Federal Agencies have radiological planning and emergency responsibilities as part of their statutory authority. The monitoring and assessment activity coordinated by the FRMAC does not alter these responsibilities but complements them by providing for coordination of the Federal radiological monitoring and assessment response activities.

The Interagency Modeling and Atmospheric Assessment Center

The IMAAC is an interagency center responsible for production, coordination, and dissemination of the Federal consequence predictions for an airborne hazardous material release. Through a partnership of the Departments of Homeland Security, Energy, Defense, and Commerce (through NOAA), EPA, NASA, and NRC, IMAAC provides the single Federal atmospheric prediction of hazardous material concentration to all levels of the Incident Command. The IMAAC is an off-site resource that supports the incident response remotely. The DOE NARAC is the interim IMAAC.

[86] For more information on ESF #10, refer to: www.fema.gov/pdf/emergency/nrf/nrf-esf-10.pdf

[87] For more information on Key Federal Radiological Resources/Assets, refer to the NRF Nuclear/Radiological Incident Annex.

Advisory Team for Environment, Food, and Health

The Advisory Team for Environment, Food, and Health (Advisory Team) includes representatives from EPA, USDA, FDA, CDC, and other Federal Agencies. The Advisory Team develops coordinated advice and recommendations on environmental, food, health, and animal health matters for the IC/UC, DHS, the Joint Federal Office Unified Coordination Group, the coordinating agency, and/or State, tribal, and local governments as appropriate. The Advisory Team uses information provided by the IMAAC, FRMAC, and other relevant sources.

Appendix B: Winchester Engineering Analytical Center

1. Food Emergency Response Network – Radiological

FDA's WEAC radiological laboratory has analytical sample capacity during 24 hours-a-day, 7 days-a-week operation of several hundred gamma-ray analyses per day and tens of beta-or alpha-particle analyses per week. The FERN radiological laboratories are activated by the WEAC Center Director and the FERN National Program Office when analytical surge capacity is required.

FERN will integrate the Nation's food-testing laboratories at the local, State, and Federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. FERN, shared between USDA/Food Safety and Inspection Service (FSIS) and HHS/FDA, is organized to ensure ongoing Federal and State interagency participation and cooperation in the formation, development, and operation of the network. www.fernlab.org/

FERN plays a number of critical roles related to food security and food defense. These include:

- **Prevention.** FERN provides a national surveillance program that will offer early means of detecting threat agents in the American food supply.
- **Preparedness.** FERN prepares the Nation's laboratories to be able to respond to food-related emergencies.
- **Response.** FERN offers significant surge capacity that will strengthen the Nation's response towards widespread complex emergencies and international or inadvertent related agents in foods.
- **Recovery.** The FERN network of laboratories will enhance the ability of the country to restore confidence in the food supply following a threat or an actual emergency.

FERN comprises over 165 laboratories, including 35 radiological laboratories. ORA/WEAC in Winchester, MA, is the lead FDA field laboratory for the analysis of radionuclides in foods, drugs, and medical devices.

FERN radiological laboratory contact information, laboratory capability, and capacity are maintained on the FoodSHIELD Web site. www.foodshield.org/

Laboratory analyses, laboratory capability, and capacity will be dependent upon the type and scope of the emergency, i.e., the source of contamination, the radionuclides, the foods that may be contaminated, and the levels of contamination. Sample through-put is variable. For example, at the onset of the emergency, samples may be triaged through screening methods, or the use of gamma radioactivity analysis may be extremely rapid at the FDA DIL. In comparison, alpha and beta activity measurements in foods may take several days to complete.

Samples may be collected from onsite authorities or FDA, State, or local investigators and shipped to WEAC or FERN-activated laboratories.

2. Services Provided to FDA/Office of Regulatory Affairs Personnel

WEAC is responsible for the health and safety of workers in the field during a radiological/nuclear event. As such they provide the following services:

Personal Dosimetry and Monitoring

Thermoluminescent dosimeters (TLDs) are provided to field analysts and import investigators. The FDA/ORA TLD personal dosimetry program is managed through ORA Radiation Safety Officer at WEAC.

WEAC provides whole body counting—i.e., the measurement of radioactivity within the whole body. This service is offered to FDA personnel who may have ingested or inhaled gamma-emitting radioactive material. Contact the FDA/ORA Radiation Safety Officer for services.

Radiation Detection during Border Exams of Imported Products

FDA/ORA investigators performing inspections at ports of entry are equipped with personal radiation detectors. SOPs, e.g., Notification and Response Procedures, are provided to the investigators. FDA/ORA/WEAC and ORA/Division of Field Investigations (DFI) manage this program.

3. Winchester Engineering and Analytical Center Emergency Preparedness Plan (extract)

WEAC promotes laboratory readiness to analyze samples for radioactive contamination and advance preparation guides through WEAC SOPs.

These SOPs are readily available on the FDA/ORA/WEAC intranet Web site.

The SOPs provide the following:

- WEAC Contact Information
- Laboratory Capability and Capacity
- Investigational Guidance
  - Sample Collection Guidance and Instructions
  - Shipping Instructions
- Radiation Safety Program Information
  - Radiation Safety Information and Guidance
  - Personal Monitoring Information and Guidance

Appendix C: Activation/Notification of the Advisory Team for Nuclear/Radiological Emergencies

Background

FDA is a member of the Federal Advisory Team for the Environment, Food, and Health—an interagency advisory group that can be activated during radiological incidents to assist other Federal, State, tribal, and local organizations by interpreting radiological data and making PARs to protect the public. Any external organization can request the assistance of the Advisory Team by contacting the CDC EOC. CDC's EOC will then notify the other member agencies (USDA, EPA, and FDA) that Advisory Team assistance has been requested. This document describes the internal notification and activation procedures that the FDA EOC will follow after receiving notification from the CDC EOC.

Scope

This document applies to any radiological incident for which Federal assistance has been requested and Advisory Team participation is needed.

Procedure

1. Following a request for the Advisory Team, the CDC EOC will contact FDA's EOC at 301-796-8240 and send an e-mail to members of the FEMA Subcommittee for Environment, Food, and Health, which includes several FDA SMEs. CDC will notify FDA's EOC that the Advisory Team has been requested and will provide any available information about contacts, meetings, and/or conference calls and deployment logistics.
2. The FDA EOC Duty Officer will record the name of the caller, telephone number, and other pertinent information.
3. The Duty Officer will contact OCM or OCM/OEO Director to inform them of the incident and for further disposition.
4. OCM or OCM/OEO Director will initially make three telephone contacts within FDA and apprise the following individuals of the events and activities as they are known:
   a. FDA Radiological Emergency Response Coordinator (on OCM staff)
   b. CFSAN Emergency Coordinator and Radiological SMEs
   c. Regional Emergency Coordinator and Regional Food and Drug Director for the region where incident occurred
5. The CFSAN Emergency Coordinator will notify the EOC whether CFSAN has representation on the Advisory Team (in reachback status) and/or identify other SMEs that are available to support the Advisory Team.
6. The Regional Food and Drug Director will be asked to contact the RRHR and make arrangements for their deployment to the site of the emergency where they will coordinate with other onsite Advisory Team members.
7. Following the above three notifications, OCM or OCM/OEO Director will carry out a wider notification to the agency via e-mail, including the FDA Office of the Commissioner, all Center Directors, all Center Emergency Coordinators, all Regional Food and Drug Directors, and the District Directors in the area impacted by the incident.

8. FDA EOC may be activated according to existing procedures (see *FDA EOP*).[88]
9. For events involving EOC activation, the agency's Lead Radiological Emergency Response Coordinator will identify personnel at FDA headquarters to participate in Advisory Team conference calls and meetings to provide situational awareness and to represent the needs of the EOC for information (i.e., radiological data, maps, etc.).

Personnel

For notification after hours, OCM and OEO staff members will access FDA's electronic Redbook located on a server.

References

NRF

Nuclear/Radiological Incident Annex

Advisory Team for the Environment, Food, and Health CONOPS

FDA EOP

[88] For any radiological incident for which Federal assistance has been requested, including the Advisory Team, it is likely that the FDA EOC would need to be activated.

Appendix D: Protective Actions

1. Protective Action Guides

PAGs are projected (estimated) dose levels to individuals in the general population at which recommendation of protective actions may be warranted. FDA has one set of PAGs for the ingestion pathway. The current PAGs are 5 mSv for committed effective dose equivalent or 50 mSv committed dose equivalent to an individual tissue or organ, whichever is more limiting. These are also the internationally accepted consensus values ("intervention level of dose" is the international term). The EPA maintains PAGs for all exposure pathways, publishing them in their "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents" (publication number 400R92001, available at EPA's Web site, www.epa.gov/clariton/clhtml/pubtitle.html); however, EPA last revised its manual in 1991. Consequently, the information regarding food PAGs is out of date, and the information in FDA's guidance document, "Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies," August 13, 1998 (available at www.fda.gov/cdrh/dmqrp/84.html) supersedes it.

2. Derived Intervention Levels

The DIL refers to the concentration of radioactive contamination present in food which, if ingested at this level over a specified time, may result in the individual receiving a projected dose equal to the PAG. FDA uses the internationally accepted units of Becquerel per kilogram (Bq/kg) to express DILs, but it is common for radioactivity levels to also be expressed in units of picocuries per kilogram (pCi/kg). (One Bq equals 27 pCi.) The criteria used to calculate DILs include: established dose coefficients for different age groups in the population; the fraction of food intake assumed to be contaminated; and the quantity of food consumed by that age group in the specified time period. The lowest calculated value across all age groups and target organs is designated as the DIL for that radionuclide. The assumptions used to calculate the DILs are extremely conservative. Thus, using the DILs to control food intake would realistically result in a person receiving only a fraction of the PAG dose.

FDA has calculated and published DILs for the radionuclides expected to deliver the major portion of radiation dose via the ingestion pathway during the first year following an emergency. The types of situations for which FDA has calculated DILs are: a release from a nuclear power plant, nuclear fuel reprocessing plant, or nuclear waste storage facility; the detonation of a nuclear weapon; transportation accidents; and release of material from radioisotope thermoelectric generators or heater units.

Table D-1 depicts the DILs for the nine principal radionuclides expected to be major contributors from these types of emergencies. The DIL for each radionuclide group is applied independently. The DILs apply to foods as prepared for consumption. For dried or concentrated products, such as powdered milk or concentrated juices, one should adjust by an appropriate reconstitution factor. For spices, consumed in very small quantities, a dilution factor of 10 is recommended. DILs for other types of emergencies and the other radionuclides such as terrorist activities can be determined using the same methodology.

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3. Protective Action Recommendations

PARs refer to specific actions that public health officials or members of the public can take to limit the radiation dose from eating contaminated products. These recommendations focus on steps to avoid or reduce radionuclide contamination in or on food and animal feed.

Public health officials or members of the public can take protective actions before and/or after contamination confirmation. An example of a protective action taken before confirmation of contamination is a temporary, indefinite restriction on the movement of food out of a possibly contaminated region. With confirmation of contamination and specific identification of the contaminant, other protective actions may become appropriate. Assessing the extent and impact of contamination of food includes measuring activity levels in sampled foodstuffs and comparing against the relevant DILs. Depending on the specific circumstances, individuals can take a variety of protective actions, including holding of food for a specified time period to allow contamination to diminish through normal radioactive decay, removing surface contamination by washing, and diverting or destroying contaminated food. Federal Agencies may receive a request to provide PARs to State and local public health authorities. If there is a request for PARs for FDA-regulated products, FDA's RRHR, the agency's onsite liaison to the Advisory Team, works with the Advisory Team and in consultation with other FDA scientific and policy experts to develop them. PARs are given to State and local authorities via appropriate on-scene NIMS procedures. State and local officials determine specific protective actions for implementation.

Appendix E: Memorandum of Understanding

A Memorandum of Understanding (MOU) is a critical component of any formal arrangement for cooperation between two or more entities. A MOU usually describes, in broad general terms, an area of mutual interest or concern that two or more agencies or organizations may cooperatively address. MOUs generally do not include specific information regarding detailed scope of work or the exchange of funds or human resources.

A complete listing of **MOUs or other written, cooperative arrangements** with States, other Federal Agencies and foreign government counterparts, and the World Health Organization can be found at: www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/default.htm.

Memorandum of Understanding with the Nuclear Regulatory Commission

On December 12, 2002, an earlier MOU between FDA and NRC was renewed for an indefinite time. It clarifies the respective roles of each agency in regulating the safe use of radiopharmaceuticals and sealed sources or devices containing radioactive material. As a result, NRC and FDA have established liaison officers and identified key management and technical personnel for coordinating responses to emergencies or specific events of mutual interest. They have conducted joint inspections of medical events involving device failures and human- or computer-generated errors. Additionally, senior management meetings between the two agencies are conducted annually.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Food and Drug Administration

FDA PANDEMIC INFLUENZA ANNEX TO THE FDA EMERGENCY OPERATIONS PLAN

August 2010

OFFICE OF CRISIS MANAGEMENT

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Table of Contents

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A INTRODUCTION

Pandemic influenza has the potential to cause adverse health effects for large segments of the population and animals, either directly due to exposure to the virus or indirectly as a result of the social and economic disruptions caused by the pandemic. To mitigate the consequences of pandemic influenza, the Food and Drug Administration (FDA) must be prepared to respond, with potentially limited staff, to a greater-than-normal demand and a public health need for safe and effective medical products to prevent and treat pandemic influenza, as well as other FDA-regulated products.

The *FDA Pandemic Influenza Annex to the FDA Emergency Operations Plan (EOP)* establishes a single, comprehensive framework for the agency's management of pandemic influenza emergencies. It provides the measures, operating structures, roles and responsibilities, and mechanisms for direction and coordination of FDA resources before, during, and while recovering from an outbreak. The *FDA Pandemic Influenza Annex* is compatible with the scalable, flexible, and adaptable Federal Government emergency coordinating structures of the *National Response Framework (NRF)* and is consistent with the concepts, principles, and terminology of the *National Incident Management System (NIMS)*[89] and the *FDA EOP*. The *FDA Pandemic Influenza Annex* is to be used to assist FDA in conducting response operations for any pandemic influenza emergency.

A.1 MISSION

During an influenza pandemic emergency, FDA's mission may expand to include performance of specific, incident-related functions, such as:

- Facilitating the availability of approved and unapproved medical countermeasures, including evaluating and authorizing, as appropriate, emergency use authorizations (EUAs) for vaccine and antiviral medical countermeasures, personal protective equipment (PPE), and in-vitro diagnostics (IVDs)
- Working with manufacturers to expedite the development, licensure (if possible), and lot release of a vaccine specific to the pandemic strain
- Monitoring the availability of critically needed FDA-regulated medical products, such as respiratory protection devices

A.2 PURPOSE

The purpose of the *FDA Pandemic Influenza Annex* is to add more detailed guidance to the *FDA EOP* to provide a coordinated response to the adverse impact an influenza pandemic would have on FDA and the industry and products it regulates. To accomplish this, the plan describes specific actions that FDA's organizational components and personnel will take when responding to a pandemic influenza incident and enhances the agency's emergency preparedness and response capabilities.

The *FDA Pandemic Influenza Annex*:

- Is compatible with and expands on the *FDA EOP*
- Defines FDA influenza pandemic emergency operating structure and identifies the essential tasks of all FDA organizational components involved in prevention, protection, response, and recovery efforts
- Provides mechanisms for vertical and horizontal command, control, coordination, and communications

[89] For more information on the *NRF* and *NIMS*, refer to the "Authorities and References" section of the *FDA EOP* Plan.

- Ensures consistency with nationally recognized incident management policy and guidance

A.3 SCOPE AND APPLICABILITY

This annex applies to any pandemic influenza incident for which FDA provides assistance under Emergency Support Function (ESF) #8 of the *NRF*, the National Strategy for Pandemic Influenza, the National Strategy for Pandemic Influenza Implementation Plan, or under its own authority under the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), as amended.

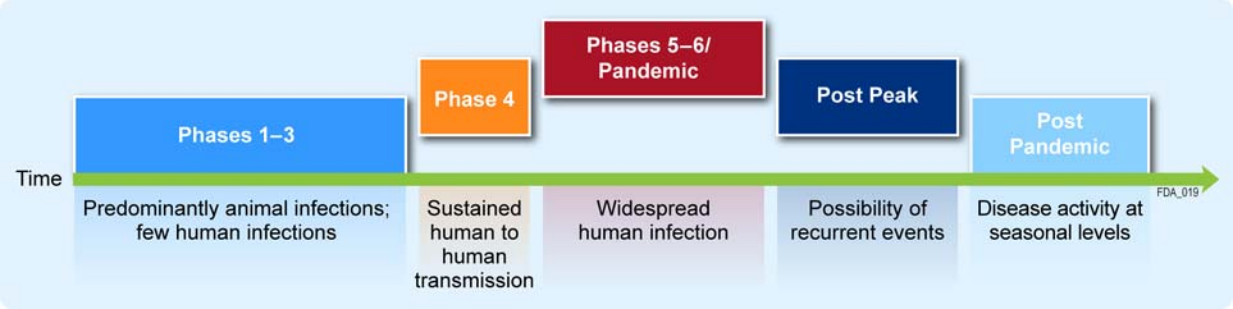
This annex applies to FDA's response activities that will assist in:

1. Stopping, slowing, or otherwise limiting the spread of a pandemic to the United States
2. Limiting the domestic spread of a pandemic and mitigating disease, suffering, and death
3. Sustaining infrastructure and mitigating the impact on the economy and the functioning of society

For the purpose of this plan, an influenza pandemic incident occurs when a novel strain of influenza virus emerges with the ability to infect and efficiently spread among humans. Because humans lack immunity to the new virus, a worldwide epidemic or pandemic can occur.

The *FDA Pandemic Influenza Annex* guides FDA personnel, explaining FDA's response activities and procedures for a cluster of novel influenza cases in verified human-to-human transmission during the World Health Organization (WHO) level of influenza pandemic, including the pandemic alert and pandemic periods in **Figure A-1** below. In the event of an influenza pandemic emergency, FDA headquarters and regional/district staffs will follow these response procedures. For the purpose of planning, Phase 4 is considered the Pandemic Alert Period and Phases 5 and 6 the Pandemic Period.

Figure A-1. WHO Pandemic Influenza Phases



Phase	Definition
1	No viruses circulating among animals have been reported to cause infections in humans.
2	An animal influenza virus circulating among domesticated or wild animals is known to have caused infection in humans, and is therefore considered a potential pandemic threat.
3	An animal or human-animal influenza reassortant virus has caused sporadic cases or small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks. Limited human-to-human transmission may occur under some circumstances; for example, when there is close contact between an infected person and an unprotected caregiver. However, limited transmission under such restricted circumstances does not indicate that the virus has gained the level of transmissibility among humans necessary to cause a pandemic.

Phase	Definition
4	Phase 4 is characterized by verified human-to-human transmission of an animal or human-animal influenza reassortant virus able to cause "community-level outbreaks." The ability to cause sustained disease outbreaks in a community marks a significant upwards shift in the risk for a pandemic. Any country that suspects or has verified such an event should urgently consult with WHO so that the situation can be jointly assessed and a decision made by the affected country if implementation of a rapid pandemic containment operation is warranted. Phase 4 indicates a significant increase in risk of a pandemic, but does not necessarily mean that a pandemic is a foregone conclusion.
5	Phase 5 is characterized by human-to-human spread of the virus into at least two countries in one WHO region. While most countries will not be affected at this stage, the declaration of Phase 5 is a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short.
6	The pandemic phase is characterized by community-level outbreaks in at least one other country in a different WHO region in addition to the criteria defined in Phase 5. Designation of this phase will indicate that a global pandemic is under way.
Post-Peak Period	Pandemic disease levels in most countries with adequate surveillance will have dropped below peak observed levels. The post-peak period signifies that pandemic activity appears to be decreasing; however, it is uncertain if additional waves will occur and countries will need to be prepared for a second wave.
Post-Pandemic Period	Influenza disease activity will have returned to levels normally seen for seasonal influenza. It is expected that the pandemic virus will behave as a seasonal influenza A virus. At this stage, it is important to maintain surveillance and to update pandemic preparedness and response plans accordingly. An intensive phase of recovery and evaluation may be required.

Source: www.who.int/csr/disease/avian_influenza/phase/en/index.html

A.4 PLANNING ASSUMPTIONS

The *FDA Pandemic Influenza Annex* is based on the following planning assumptions:

- During the WHO Phases 1 – 3, FDA will perform its routine functions.
- During the WHO Phase 4 in addition to routine functions, many FDA Offices and Centers will begin performing pandemic influenza response activities described in this annex.
- During the WHO Phases 5 – 6, U.S. Pandemic Period, routine functions may continue based on staffing availability, but pandemic influenza response activities will take priority.
- Susceptibility to the pandemic influenza virus will be universal.
- An influenza pandemic will cause simultaneous outbreaks across the United States, limiting the ability to transfer assistance from one area to another.
- Widespread illness in communities may increase the likelihood of significant shortages of personnel (in health and non-health sectors) who provide other essential community services.
- A pandemic will pose significant challenges to FDA employees responsible for sustaining FDA's essential functions due to widespread absenteeism.
- An influenza pandemic may require FDA staff members to sustain some essential functions from home.
- Some information systems supporting FDA operations may not be available.
- Due to the uniqueness of their positions, not all essential employees will have a backup.

- The adverse impact of pandemic influenza on the availability of safe and effective FDA-regulated products requires an immediate response by FDA. Protection of the affected or potentially affected population is the highest priority during response operations.
- Epidemics would last 6 to 8 weeks in affected communities. Multiple waves of illness (periods during which community outbreaks occur across the country) are likely to occur with each wave lasting 2 to 3 months. As many as 40 percent of FDA employees and FDA-regulated industry employees in a geographic area could be absent from work at any point during a pandemic. This could also adversely impact the donor pool necessary for availability of blood and tissue products.
- Greater product demand and increased worker absenteeism in the FDA-regulated industry could lead to shortages of commercial food products and medical products that are used to prevent and treat pandemic influenza.
- Quarantining of critical FDA-regulated facilities and large geographic areas may result. This may affect other countries, requiring extensive coordination with State, local, and foreign governments, in conjunction with other Federal Agencies.
- FDA Public Health Service Commissioned Corps personnel may be deployed, as necessary, to support U.S. Department of Health and Human Services (HHS) pandemic influenza response efforts.
- Regional Food and Drug Directors, District Directors, and Center/Office Directors may activate their individual organizational component's emergency operations or pandemic influenza plan without activation of the FDA Pandemic Influenza Annex.

A.5 ACTIVATION

The Public Health and Medical Services (ESF #8) response to an outbreak of pandemic influenza will be directed by the HHS Office of the Secretary, in coordination with the U.S. Department of Homeland Security (DHS), which is responsible for managing the U.S. Government (USG) response. FDA is a subordinate Operating Division (OPDIV) of HHS, and it will align its response activities with those of HHS. FDA will use the full spectrum of its resources to accomplish assigned roles, responsibilities, functions, goals, and missions.

This annex will be consulted and implemented together with the *FDA EOP* when there is an influenza pandemic threat abroad or in North America or a declaration of Phase 4 by WHO.

A.6 SUPERSEDENCE

The *FDA Pandemic Influenza Annex* (2010) supersedes the FDA Pandemic Influenza Emergency Response Plan (2007).

B CONCEPT OF OPERATIONS

The scope of FDA emergency operations response to an influenza pandemic involves a wide array of products regulated simultaneously by the agency. The following concept of operations (CONOPS) section of this annex describes the principal authorities governing agency emergency functions that FDA conducts to perform its incident-related influenza pandemic operations.

B.1 EMERGENCY AUTHORITIES

FDA Emergency authorities are listed in the *FDA EOP*.

B.2 EMERGENCY OPERATIONS PHASES

The following three phases comprise the entire spectrum of FDA emergency operations: ***Prevention and Protection, Response,*** and ***Recovery.*** When a global pandemic may occur or does occur, FDA employees are expected to follow the activities described in the *FDA EOP*, Section B.*2., Emergency Operation Phases.* Although emergency operations may involve each of these phases over the course of a pandemic influenza incident, the nature and severity of an event and FDA's organizational component(s) responding will determine the specific order, actions, and responsible parties required for each.[90] The following sections describe additional resources available during FDA's emergency operations for Prevention and Protection specific to a potential pandemic or pandemic event.

B.2.1 Prevention and Protection

B.2.1.1 Surveillance and Detection

During a pandemic influenza event, FDA may use the following Surveillance and Detection Systems described in *FDA EOP* Table B-1.

Adverse Event Reporting System (AERS)
Biological Product Deviation Reporting (BPDR) System
Center for Devices and Radiological Health (CDRH) Product Availability (Shortages) Database
Emergency Operations Network Incident Management System (EON IMS)
Manufacturer and User Facility Device Experience (MAUDE) System
MedWatch
National Biosurveillance Integration System (NBIS)
New Drug Application (NDA) Field Alert Program
Veterinary Adverse Drug Experiences (ADE) Reporting System

[90] Refer to FDA EOP, Section C, "Organization and Assignment of Responsibilities," for an overview of FDA organizational component roles and responsibilities during an emergency.

B.2.1.2 Consumer Product Protection

In addition to the activities designated to deter intentional and unintentional acts against FDA-regulated products and to protect consumers from potential public health hazards, as described in the *FDA EOP*, FDA takes the following actions during an influenza pandemic:

- Expedited review of applications for vaccines, antivirals, masks, and IVD
- Aggressive surveillance to identify and take action to stop fraudulent promotion of products to prevent, diagnose, or treat influenza

B.2.1.3 Medical Countermeasures

FDA Centers and Offices shall perform the general functions related to medical countermeasures mentioned in the *FDA EOP*, Section B.2.1.3. Medical Countermeasures.

B.2.1.4 Increased Surveillance of FDA- Regulated Pandemic Influenza Medical Products

During an influenza pandemic, FDA may increase its surveillance of FDA-regulated medical products used to prevent, diagnose, or mitigate adverse health effects of the pandemic influenza virus. Examples of such products include antivirals, vaccines, respiratory protection devices, other types of PPE, and IVD kits. Increased surveillance may include, but is not limited to, pharmacovigilance, such as tracking of vaccine adverse events or emergence of antiviral resistance; product quality, such as tracking of counterfeit products and fraudulent claims; and product availability, such as shortages of antivirals, masks, and essential medical materiel. The increased surveillance could be a result of conditions, such as the use of a product by a larger or different population; the use of products for other than their labeled indication; or concerns about the potential development of resistance to a product, such as antivirals or antibiotics. A specific concern is resistance developing to any antiviral drug in use for the pandemic influenza strain.

B.2.2 Response

B.2.2.1 Gain and Maintain Situational Awareness

B.2.2.1.1 Alert and Notification

FDA employees are expected to follow the activities described in the *FDA EOP*, Section B.*2.2.1.1 Alert and Notification*. In addition, FDA's Office of Administration is to be notified of a pandemic event.

B.2.2.1.2 Administrative Alert and Notification

The FDA Office of Management, within the Office of the Commissioner (OC), serves as the agency's focal point for distributing information to agency staff concerning their safety and health to maintain staff agency mission support. Examples of such information include:

- Flexible Workplace Agreements Activities
- PPE and other medical countermeasures, such as vaccines and antivirals
- Building closures

B.2.2.2 Coordination of Response Actions

FDA response coordination during a pandemic will follow the *FDA EOP,* which will be augmented by the following coordination and response activities.

B.2.2.2.1 FDA Headquarters Response

The FDA OC Offices, Centers, and Office of Regulatory Affairs will follow the *FDA EOP*, Section B.2.2.3 Coordination of Response Actions, which will contains contacts for information dissemination, resource coordination, and priority setting. In addition, the following steps will be taken for a pandemic:

- Examine all foreign travel and restrict if necessary
- Review plans and update all essential personnel listings
- Ensure employees are familiar with emergency procedures

B.2.2.2.2 Medical Countermeasures Expanded Access and Emergency Use Authorization

FDA response regarding medical countermeasures availability and use will follow the *FDA EOP*, Section B.2.2.3.5 and will be augmented by OC EUA Standard Operating Procedure (SOP).

B.2.2.3 Demobilization

The FDA OC Offices, Centers, and Office of Regulatory Affairs will follow the *FDA EOP*, Section B.2.2.4 Demobilization, and return to an agency-wide Task Force structure led by the Office of Counterterrorism and Emerging Threats (OCET).

B.2.3 Recovery

The FDA OC Offices, Centers, and Office of Regulatory Affairs will follow the *FDA EOP*, Section B.2.3 Recovery, and return to an agency-wide Task Force structure led by OCET.

C ORGANIZATION AND ASSIGNMENT OF RESPONSIBILITIES

This section identifies the essential roles and functions of FDA Centers and Offices responding to an influenza pandemic alert period (WHO Phase 4) or pandemic (WHO Phases 5 – 6). An essential employee is one who supports the accomplishment of a Center or Office's pandemic influenza essential functions. Centers and Offices have provided descriptions of their PI essential functions for inclusion in the PI Annex. For an employee to be considered essential to the accomplishment of PI essential functions, the employee need not to be assigned solely to PI-related work.

FDA Centers and Offices work closely with OC and with industry and Government partners to ensure the safety and efficacy of products for human use to prevent, diagnose, and treat the public health effects of pandemic influenza in the United States or worldwide, using novel and expeditious approaches to product regulation for optimized availability and use in all populations. During a pandemic response, issues may arise that involve more than one Center or Office. The Centers and Offices listed in the annex have additional tasks in supporting Command and Control Operation during a pandemic that were not identified in the *FDA EOP*.

C.1 OFFICE OF THE COMMISSIONER

Several organizational components within OC will play a significant role in supporting the agency's emergency response to a pandemic, such as the Office of Crisis Management (OCM), OCET, Office of External Affairs, and the Office of Public Affairs (OPA). In addition, other OC offices, such as the Office of the Chief Counsel (OCC), the Office of International Programs (OIP), and Office of Administration [Office of Management (OM), Office of Financial Management (OFM), and the Office of Information Management (OIM)] can provide valuable assistance during FDA's response to a pandemic influenza emergency. A number of agency officials will be considered essential employees specific to influenza pandemic emergency response activities. They include the following:

Office of the Commissioner Essential Employees	

• Chief Counsel
• Chief of Staff
• Deputy Commissioner for Policy, Planning, and Budget
  – Assistant Commissioner for Planning
  – Assistant Commissioner for Policy
  – Assistant Commissioner for Budget
• Counselor to the Commissioner
  – Director, Office of Crisis Management
• Associate Commissioner Special Medical Programs
• Associate Commissioner for External Affairs
  – Assistant Commissioner for External Relations
  – Assistant Commissioner for Public Affairs
• Deputy Commissioner for Foods
  – Associate Commissioner for Food Protection
  – The Foods Program Outbreak Director
• Chief Scientist and Deputy Commissioner for Science and Public Health
  – Assistant Commissioner for Counterterrorism and Emerging Threats
	• Deputy Commissioner for International Programs
	  – Associate Commissioner for International Programs
	• Deputy Commissioner for Administration
	  – Director, Office of Financial Management
	  – Director, Office of Financial Services
	  – Chief Information Officer (CIO)
	  – Assistant Commissioner for Management
	  – Director, Office of Security Operations
	• Associate Commissioner for Regulatory Affairs
	• Director, Center for Biologics Evaluation and Research
	• Director, Center for Drug Evaluation and Research
	• Director, Center for Devices and Radiological Health
	• Director, Center for Food Safety and Applied Nutrition
	• Director, Center for Veterinary Medicine
	• Director, National Center for Toxicological Research

In addition, it is expected that each Center and Office will maintain a detailed list of essential employees, to include necessary support staff for the essential employees. The detailed lists of essential employees

will be responsible for the agency's continuity of business during an influenza pandemic and should be provided to OM.

C.1.1 Office of the Chief Counsel

Office of the Chief Counsel Essential Employees	
Associate General Counsel Deputy Chief Counsel Deputy Chief Counsel for Program Review Deputy Chief Counsel for Litigation Associate Deputy Chief Counsel for Drugs and Biologics Associate Deputy Chief Counsel for Devices, Food, and Veterinary Medicine Associate Deputy Chief Counsel for Litigation Executive Officer Senior Attorneys (One from each of these teams)	
Counseling Animal Products Biologics Devices Drugs Foods	Litigation Criminal Civil

OCC provides legal services involving the agency's regulatory activities. FDA lawyers support the agency's public health and consumer protection missions in two primary ways: handling litigation and providing counseling advice. OCC performs the same functions mentioned in the *FDA EOP* to support FDA's response to an influenza pandemic.

C.1.2 Office of Legislation

Office of Legislation Essential Employees
Assistant Commissioner for Legislation
Senior Advisor
Supervisory Congressional Affairs Specialist
Congressional Affairs Specialists (2)

The Office of Legislation (OL) provides Congress with information related to FDA's pandemic influenza response activities. OL performs the same functions described in the *FDA EOP* to support FDA's response to an influenza pandemic.

C.1.3 Office of Policy, Planning, and Budget

The Office of Policy, Planning, and Budget is responsible for advising the Commissioner and other key agency officials on matters relating to FDA policies, rulemaking, and budgetary matters.

C.1.3.1 Office of Budget

Office of Budget Essential Employees
Director
Deputy Director
Financial Advisor
Senior Analyst

In the event of pandemic influenza, FDA will likely need a supplemental budget request to support unforeseen expenses during this critical time. The OB will facilitate this process by working with senior management and Centers/Offices to identify resource needs, implementing the process to formulate the budget request, providing essential support during the review and clearance process, and responding to questions from congressional and other stakeholders.

Staffing needs will vary, based on the amount of information that OB will need to obtain and the level of analysis that is necessary. The OB will likely be able to formulate a supplemental request with about three to four OB staff.

The OB will need computer and network access and access to the facility.

If OB is debilitated by the pandemic, then it can either work with the budget analysts at HHS to assist in facilitating the supplemental budget request or use the FDA Center analysts (if they are available), some of whom have worked with OB in some capacity.

Because a supplemental budget request can have numerous variables and a supplemental request must be reviewed and cleared very quickly, it is difficult to provide expanded services without an additional level of investment. A supplemental budget request must be completed in its entirety.

In the event of an influenza pandemic, the budget liaison function is an essential activity in order to communicate budget needs and information. The OB will facilitate that process by conducting outreach and coordinated communications; gathering information; and communicating with senior FDA management, Centers and Offices, HHS, the Office of Management and Budget (OMB), and the congressional staff.

Staffing needs will vary based on the situation; however, three to five OB analysts can facilitate the liaison process using several different channels. During an influenza pandemic, the basics of the budget liaison function can be done with OB at half the level of staffing.

Quality of work, timeframes, and milestones may slip as a result of reduced staffing. The quality and consistency control function will be important to support any budget proposals and budget information provided to others in FDA, the Administration, Congress, and stakeholders. The OB will facilitate that process by using OB historical data repositories.

Staffing needs will vary based on the situation; however, the quality level of review will depend upon the number of available staff.

If OB is debilitated by an influenza pandemic, it will then work with some of the Center analysts to review budgetary documents for quality and consistency.

The OB can provide training to Center analysts on how it performs its quality and consistency functions, such as cross-checking budget documents and numbers.

Office of Budget Response Activities
Pandemic Alert Period

- Track pandemic influenza budget requests and appropriations
- Respond to questions from Congress and stakeholders
- Analyze the adequacy of the FDA budget to prepare for pandemic influenza
- Align annual budget requests to meet pandemic influenza obligations
- If necessary, develop and advance a supplemental budget request to support unforeseen expenses related to preparing for an influenza pandemic.

Office of Budget Response Activities
Pandemic Period

- All pandemic alert activities as appropriate

C.1.4 Office of the Counselor to the Commissioner

Office of the Counselor to the Commissioner Essential Employees
Counselor to the Commissioner

The Counselor to the Commissioner provides top-level leadership for FDA's emergency and crisis management policies and programs for pandemic influenza to ensure that a structure exists for rapid response to an influenza pandemic and to ensure the availability of FDA-regulated products needed to protect the public and prevent the spread of illness.

C.1.4.1 Office of Crisis Management

Office of Crisis Management Essential Employees
Director, Office of Crisis Management
Deputy Director, Office of Crisis Management
Director, Office of Emergency Operations (OCM/OEO)
Deputy Director, OCM/OEO
Special Assistant to OCM Director
Two OCM/OEO Staff Supervisors
Four Emergency Coordinators

OCM consists of the OCM Director (and staff) and the OEO. OCM and OCM/OEO are responsible for developing crisis and emergency management policies and procedures and managing agency emergencies when they occur. OCM manages the FDA Emergency Operations Center (EOC).

Emergency Operations Center

The FDA EOC will be the coordination point for FDA's response to a pandemic influenza incident.

Office of Crisis Management Response Activities
Pandemic Alert Period

- Maintain situational awareness of U.S. and worldwide pandemic influenza cases
- Serve as agency focal point for coordination of all emergency response activities
- Manage the agency's EOC and activate as needed
- Manage the EON IMS to provide agency officials access to large volumes of data related to pandemic events
- Create geographic information system (GIS) maps to enhance response activities
- Manage FDA's National Consumer Complaint System
- Provide incident command training to OCM staff and other agency staff involved in emergency response activities
- Participate in external emergency exercises, including pandemic influenza, and coordinate internal FDA exercises, including pandemic influenza
- Participate in and support HHS Office of Preparedness and Response pandemic influenza planning activities

- Identify agency pandemic influenza needs and goals in an agency priority setting process
- Lead and/or assist in the development and implementation of FDA Strategy for pandemic influenza
- Lead the emergency preparedness and response component of the FDA Pandemic Influenza Preparedness Task Force
- Lead the development of agency-wide pandemic influenza plans
- Advise senior FDA officials on preparedness requirements for pandemic influenza
- Provide updates to the Commissioner, other senior agency officials, and agency emergency coordinators regarding DHS, HHS, and Centers for Disease Control and Prevention (CDC) preparedness activities for potential U.S. pandemic influenza cases
- Develop plans for establishment of FDA Incident Management System (IMS) for pandemic influenza and prepare for possible activation of FDA's EOC

Office of Crisis Management Response Activities
Pandemic Period

- All pandemic alert activities as appropriate
- Give priority attention to pandemic influenza-related work and life-threatening/sustaining work associated with each of the activities listed above for pandemic alert periods
- Communicate with other Federal, State, and local governments as they request technical and material support from FDA and coordinate the agency's response to the requests
- Provide FDA liaison to Secretary's Operations Center (SOC) or other Federal EOCs as needed
- Provide daily Situational Reports to the HHS SOC
- Represent FDA on HHS ESF-8 Pandemic Influenza Planning Group
- Establish FDA IMS and activate FDA's EOC if needed
- Provide leadership for Planning and Operations Sections of IMS
- Expedite triaging of incoming consumer complaints for adverse events associated with FDA-regulated products intended for preventing, treating, mitigating, or containing pandemic influenza
- Provide guidance on proper handling, marking, processing, and storing of classified pandemic influenza materials
- Work with OM/Office of Security Operations to verify security clearances for FDA liaisons working at other Government EOCs, liaisons from other agencies working in FDA's EOC, and FDA staff working at Joint Operations Centers (JOCs) in the field.

C.1.5 Office of Special Medical Programs

Office of Special Medical Programs Essential Employees
Associate Commissioner Special Medical Programs

C.1.5.1 Office of Combination Products

Office of Combination Products Essential Employees
Director
General Attorneys (2)
Biologists (2)

The Office of Combination Products (OCP) ensures the prompt assignment of combination products to agency Centers, the timely and effective premarket review of such products, and consistent and appropriate post-market regulation of like products subject to the same statutory requirements to the extent permitted by law. OCP performs the same functions mentioned in the *FDA EOP* to support FDA's response to an influenza pandemic.

C.1.6 Office of External Affairs

Office of External Affairs Essential Employees
Associate Commissioner for External Affairs
Deputy Associate Commissioner for External Affairs
Special Assistant to the Associate Commissioner
Senior Management Officer

The Offices of External Affairs (OEA) works with outside groups in providing information related to FDA's pandemic influenza response activities and ensures up-to-date public health advice and guidance is provided to consumers and targeted audiences.

C.1.6.1 Office of External Relations

Office of External Relations Essential Employees
Assistant Commissioner for External Affairs
Deputy Assistant Commissioner
Senior Advisors (4)
Director, Consumer Health & Information Staff
Visual Information Specialist
Writer-Editors (3)
Program Analyst

- Collaborate with OPA/FDA, HHS, and Assistant Commissioner for External Relations, Deputy Assistant Commissioner for External Relations, Senior Staff Advisors – Stakeholder Outreach (4), Writer-Editor (1), Director, Consumer Health Information, Consumer Health Information Writers (3), Consumer Health Information Graphics Specialists (2), and other Federal, State, and local government agencies and industry partners to protect consumer well-being and decrease the risk of illness, disease, or death by ensuring that the official influenza pandemic messages of the USG reach FDA stakeholders
- Develop and distribute Consumer Update articles that will help stakeholders and their audiences prepare for and manage pandemic flu issues
- Develop Memorandums of Understanding (MOUs) that will ensure rapid response and support, when needed, during pandemic flu period
- Ensure that Office of External Relations (OER) staff is prepared for operations, as needed, including operations from staff members' homes and other offsite locations, as necessary.

C.1.6.2 Office of Public Affairs/Media Relations

Office of Public Affairs Essential Employees
Assistant Commissioner for Public Affairs
Supervisory Public Affairs Specialist
Senior Advisor
Program Support Specialists (3)
Press Officers (13)

OPA serves as FDA's primary liaison with the news media and develops much of the material FDA uses to communicate its public health and consumer protection messages to the public. OPA performs the following essential functions to support FDA's response to an influenza pandemic:

- Collaborate with HHS Assistant Secretary for Public Affairs (ASPA) on and ensure appropriate integration with the official influenza pandemic messages of the USG, www.flu.gov
- Maintain and update emergency/after-hours SOPs and contact lists for essential media relations personnel throughout FDA
- Ensure that SOPs involving clearance of communications materials include clear indicators of when materials are ready for release and who has the authority to approve those indicators; collaborate with FDA Center communications staffs to develop boilerplate talk points that will allow quick messages to be released
- Develop emergency backup plan that clearly indicates the primary contact, secondary contact, and contacts on deck in case of sickness, infrastructure failure, or other instances of unavailability
- Ensure that OIM has assessed the technical infrastructure and is prepared for 24 hours-a-day, 7 days-a-week operations, operations from staff members' homes, and other offsite locations

C.1.6.2.1 Web Site Management Staff

Office of Public Affairs/Web Site Management Staff Essential Employees
Director, Web Communications
Deputy Director
Senior Advisor/Public Affairs Specialist
Visual Information Specialist
Program Analysts (6)
Technical Information Specialist

The OC Web Site Management Staff oversees the content, design, and management of FDA's external Web site (www.fda.gov). OC Web Site Management Staff performs the same functions described in the *FDA EOP* to support FDA's response to an influenza pandemic.

C.1.6.3 Office of Special Health Issues

Office of Special Health Issues Essential Employees
Director, Office of Special Health Issues
Deputy Director
Medical Advisor
Technology Information Specialist
Program Analyst
Health Programs Coordinators (7)
Interdisciplinary Scientist
Health Promotion Officer

Public Health Specialist Pharmacist

The Office of Special Health Issues (OSHI) serves as a liaison between the FDA and patients, patient advocates, health professionals, and their representative organizations. OSHI staff encourages and supports active participation of these stakeholders in forming FDA regulatory policy to ensure that the agency's decisions are based upon a full range of perspectives. OSHI is also responsible for communicating important safety and regulatory information to health professionals and patients.

- Collaborate with FDA, HHS, and health professional and patient advocacy organizations to ensure that the official influenza pandemic messages of the USG reach health professional and patient advocacy organizations
- Deliver and distribute health professional articles that will help stakeholders and their audiences prepare for and manage pandemic flu issues
- Organize teleconferences to inform stakeholders of topics of interest for pandemic influenza (i.e. emergency use authorizations, shortages, compounding)
- Ensure that the OSHI staff is prepared for operations, as needed, including operations from staff members' homes and other offsite locations, as necessary

C.1.7 Office of the Chief Scientist

Office of the Chief Scientist
Chief Scientist and Deputy Commissioner for Science and Public Health

The Office of the Chief Scientist (OCS) serves as the agency's focus for scientific, medical, and related activities within OC.

C.1.7.1 Office of Counterterrorism and Emerging Threats

Office of Counterterrorism and Emerging Threats Essential Employees
Assistant Commissioner for Counterterrorism and Emerging Threats Senior Regulatory Counsel Medical Officer Senior Policy Advisor/Analyst

The role of OCET is to protect the public health through the development and implementation of policies and plans that safeguard food and medical products from adulteration or disruption of supplies due to pandemic influenza and terrorist activities and that facilitate the availability of safe and effective public health emergency medical countermeasures. OCET performs the following essential functions to support FDA's response to an influenza pandemic:

Office of Counterterrorism and Emerging Threats Response Activities
Pandemic Alert Period

- Coordinate the portfolio of FDA policy initiatives on pandemic influenza
- Serve as the point of entry to FDA for pandemic influenza policy communications
- Facilitate intra- and interagency communications on policies for pandemic influenza, including issues, such as EUA
- Promote pandemic influenza goals and needs in the agency priority-setting process
- Develop and implement a comprehensive FDA strategy for pandemic influenza

- Provide strategic input on pandemic influenza budget formulation
- Advise senior FDA officials on policies related to pandemic influenza
- Advise on FDA policies related to pandemic influenza in the event of an emergency or crisis situation
- Activate and lead the FDA Pandemic Influenza Task Force
- Participate in the development of pandemic influenza risk communication strategies
- Activate internal OCET planning for pandemic preparedness, including identifying essential functions, identifying essential personnel with adequate tiers for redundancy, and equipping essential personnel with necessary requirements to complete essential functions from decentralized worksites

FDA OCET Response Activities
Pandemic Period

- Perform all pandemic alert activities
- Activate and implement OCET emergency response plans, as appropriate
- Participate in the command structure for the Pandemic Influenza Incident Management System
- Inventory human capital and determine the welfare of staff and need for reassignment of duties within the office as OCET staff shortages begin to occur
- Prioritize policy issues related to the ongoing crisis
- Respond to EUA requests and associated policy issues
- Conduct public outreach to stakeholders, as appropriate
- Coordinate agency activities for emergency use of medical countermeasures

C.1.8 Office of International Programs

Office of International Programs Essential Employees
Deputy Commissioner for International Programs
Associate Commissioner for International Programs
Deputy Director, Office of International Programs

OIP is responsible for coordinating, and if appropriate and permitted, communicating appropriate emergency-related information to foreign governments and international organizations, such as WHO. OIP also receives information and requests for information (RFIs) from foreign governments. OIP performs the following essential functions to support FDA's response to an influenza pandemic:

- Maintain contacts and efficient channels for communications with FDA counterpart agencies and FDA staff in other countries to assess the impact of the pandemic on FDA and advise on appropriate actions
- Monitor and report on relevant international development and resources

Office of International Programs Response Activities
Pandemic Alert Period

- Exchange information with foreign counterparts to ensure compliance with FDA laws, regulations, and policies and consistency in responses to an influenza pandemic
- Monitor and report on relevant international developments and resources

- Coordinate and advise on international technical cooperation, assistance, and capacity-building activities
- Establish policies and procedures pertaining to international travel and processing international travel requests

Office of International Programs Response Activities
Pandemic Period

- Conduct international pandemic alert activities
- Follow the *FDA Pandemic Influenza Annex to the EOP* and other relevant advice
- If staff is limited, OIP functions will be restricted to:
  - Communicating with foreign governments and international organizations, including foreign embassies and consulates in the United States
  - Exchanging information with foreign counterparts to ensure compliance with FDA laws, regulations, and policies and consistency in responses
  - Implementing policies and procedures pertaining to international travel and processing international travel requests; OIP will process only international travel that is consistent with requirements and limitations pertaining to the pandemic situation

C.1.9 Office of Administration

Office of Administration Essential Employees
Deputy Commissioner

The Office of Administration provides executive direction, leadership, coordination, and guidance for the day-to-day operations of FDA; manages overall budgets and resources; and oversees management and business activities agency wide as well as OC. The Office of Administration also ensures proper conduct of FDA's administrative and financial management activities.

C.1.9.1 Office of Acquisition and Grants Services

Office of Acquisition and Grants Services Essential Employees
Director, Office of Acquisition and Grants Services Director, Office of Financial Services

The Office of Acquisition and Grants Services (OAGS) will ensure appropriate support services and supplies are acquired to support the agency's response to the pandemic. These include, in priority order:

1) **P-Cards (formerly IMPAC).** OAGS manages the program and serves as the central POC between FDA and the Central Bank. Program offices use P-cards to make micro-purchases (less than $3,000). In the event of an emergency, certain OAGS employees will also have P-cards with higher transaction limits.
2) **Simplified Acquisitions.** OAGS awards these through warranted contracting officers. The bulk of FDA's acquisitions are purchase orders. There are fewer statutory requirements associated with these than with contracts, which make them easier and faster to award than contracts. In the event that the OAGS workforce is drastically reduced or it is impossible to come into the office (e.g., under quarantine, caring for sick a family member), simplified acquisitions should be awarded whenever possible. Though the limit for a simplified acquisition is generally $100,000, this threshold may be raised to $250,000 in the event that a Contingency Operation is declared by the President, Secretary of Defense, or a designee. Additionally, commercial items worth up to $5 million can be bought using

simplified acquisition procedures. The absolute number of purchase orders will probably decrease or stay the same, even if the simplified acquisition threshold is raised.

3) **Contracts.** OAGS COs negotiate, award, and administer contracts. Whenever an acquisition exceeds the relevant simplified acquisition threshold, goods and services must be purchased using contracts. Contracts typically take longer than simplified acquisitions to award, but there are procedures, such as limiting competition on the basis of unusual and compelling urgency, that can accelerate the process.
4) **Interagency Agreements.** OAGS negotiates and is responsible for all administrative and business-related matters associated with Interagency Agreements (IAGs) between FDA and other Federal Agencies. In the event of severely reduced staffing, it is likely that agencies will need to leverage the resources of other offices. FDA may leverage the resources of other agencies, e.g., reaching out to other HHS OPDIVs to take over exceptionally critical FDA functions if FDA's staff is too small to handle them independently. OAGS will ensure it has sufficient staff with the knowledge to execute and administer IAGs.
5) **Grants.** OAGS administers FDA's grant program. In the event of an emergency, grants may be awarded for research or education activities that support FDA's pandemic influenza response work.
6) **Technology Transfer.** Technology transfer encourages partnerships for collaborative research. This strengthens FDA's research efforts and increases resources for mission-related projects. In the event of a pandemic, this is less of a priority than ensuring that mission-critical programs have the supplies that they need.

C.1.9.2 Office of Financial Operations

C.1.9.2.1 Office of Financial Management

Office of Financial Management Essential Employees
Director, OFM
Business Continuity Coordinator (Ancillary Duty)
Division Director, Financial Support Services
Division Director, Budget Execution
Division Director, Accounting
Division Director, Business Transformation, Administration and Management

C.1.9.3 Office of Information Management

Office of Information Management Essential Employees
CIO, FDA
Deputy CIO, FDA
Director of Division of Business Partnership and Support, FDA
Deputy Director of Division of Business Partnership and Support, FDA
Director of Division of CIO Support, FDA
Deputy Director of Division of CIO Support, FDA
Director of Division of Infrastructure, FDA
Deputy Director of Division of Infrastructure, FDA
Director of Division of Systems, FDA
Deputy Director of Division of Systems, FDA
Director of Division of Technology, FDA
Deputy Director of Division of Technology

OIM enables FDA's strategic efforts to transform and improve information technology (IT) systems and infrastructure needed to support critical agency operations. OIM performs the following essential functions to support FDA's response to an influenza pandemic:

- Implementing and enhancing common IT systems to support FDA's response to an influenza pandemic
- Maximizing the availability and use of IT that increases electronic access for the public, as well as the full span of FDA's other external (public consumers, industry, government, academic, and others) and internal customer bases, while maintaining effective security
- Aligning IT investments to agency pandemic influenza response work
- Consolidating, modernizing, and optimizing FDA's IT infrastructure to strengthen its pandemic influenza response work
- Providing the platform required for FDA to meet agency-wide IT initiatives for pandemic influenza response

Office of Information Management Response Activities

Pandemic Alert and Pandemic Periods

During an influenza pandemic alert and pandemic periods, OIM tactical activities will include:

- **Command and Control of Reporting Offices.** OIM will define and manage the emergency while ensuring that the operations of the Center and Office are maintained as required (Levels 1 – 3) and essential functions are maintained (Level 4).
- **Computer Room Facilities.** OIM will ensure the computer room facilities function and will coordinate with the Program Support Center (PSC) and building management. If cooling, generator, and power services are not available to the Parklawn Data Center, then all IT resources in the data center are also not available.
- **Information Technology Security Services.** OIM will ensure IT security services are available that are essential to protect FDA's IT assets. Increased attacks on FDA's IT resources are likely during a perceived time of weakness. Personnel will focus their efforts on security measures, such as firewall connectivity and others, ensuring that security controls for hardware, software, and telecommunications are effective and protect privacy, confidentiality, and availability of FDA data. Personnel will monitor firewall, intrusion detection, anti-malware, and security controls for critical and high-impact FDA systems, providing incident response of those potential issues that would have a severe impact on FDA operations. These services are dependent on the computer room facilities.
- **Local and Wide Area Networks.** OIM will ensure the availability of LAN/WAN that will be critical for both field and local users to access agency IT resources. Demand may be reduced due to fewer numbers of employees in the office. This service is dependent on the computer room facilities and IT security services. Network teams will focus their support efforts on those buildings declared operational and will not monitor or respond to network failures in buildings that are unoccupied. Networking resources can be leveraged between the Network Control Center and the LAN team.
- **Internet Services.** OIM will maintain Internet services that are critical to the agency's ability to communicate with regulated industry and provide access to FDA's internal and external IT resources. The demand for these services will be greater because most staff will revert to accessing these resources remotely through the Internet. Services are dependent on outside vendors and the users' local Internet service provider. Networking resources can be leveraged

between the Network Control Center and the LAN team. If additional bandwidth is needed, the agency will request that the provider increase bandwidth. During a pandemic event, any reengineering of the network and service segments will cease so that efforts are focused on supporting this service.

- **Active Directory.** OIM will ensure Active Directory availability as it provides authentication services when users log on to the FDA systems. Although the demand for this service may not be great, access to IT systems will not occur if this application is down. Active Directory is dependent on computer room facilities, IT security services, LAN/WAN, and Internet services.
- **Telephone.** OIM will ensure telephone availability, a critical need. It is estimated that voice and video services will increase. Within Government facilities, usage will increase substantially with the possibility of employees being ill and more working from home during a pandemic period. This service is dependent on computer room facilities; IT security services; LAN/WAN networks; Internet services; the local exchange carriers; Verizon; and the National Institutes of Health (NIH), which manage the Parklawn voice switch. This function is covered by two groups that manage Integrated System Digital Network (ISDN) and Voiceover Internet Protocol (VoIP).
- **E-mail/ BlackBerry Services.** OIM will ensure the continuity of operations (COOP) for FDA e-mail and BlackBerry services. In addition to the growing demand for e-mail and BlackBerry services, coordination of both services is critical because each service backs the other. As of October 2009, the FDA e-mail system is no longer operated by HHS. This change will allow OIM to improve service and COOP for both e-mail and BlackBerry services. In the event of an e-mail failure, expert support will troubleshoot and resolve outages. In addition to communications being sent out through e-mail and BlackBerry services, alternate communication avenues will be used, including the FDA Internet, intranet, and recorded announcements at the Employee Resource and Information Center (ERIC), to ensure necessary information is communicated to employees. These alternate communication vehicles are dependent on computer room facilities (Parklawn Data Center), IT security services, LAN/WAN, and Internet services, the local exchange carriers, Verizon, NIH (which manages the Parklawn voice switch), and Research in Motion BlackBerry pin-to-pin services. There may be a need to have an adequate supply of additional BlackBerry devices to distribute to essential personnel during an influenza pandemic.
- **Outlook Web Access.** OIM will monitor the availability of Outlook Web Access (OWA), since this is another method of accessing FDA e-mail from non-FDA-issued computers that have access to the Internet. In order to use OWA, users will need their Remote Secure Access (RSA) SecureID Token. OWA gives FDA employees greater freedom to access their e-mail from most personally owned or public-access PCs because it does not require that the computer be FDA-issued or that a connection be made to the FDA network.
- **Help Desk Services.** OIM will manage and maintain Help Desk services where demand is expected to increase substantially as the agency executes its response plans. Though most problems may be resolved remotely, there will be fewer onsite Help Desk technicians available for support within FDA buildings. There will also be a great demand from remote logon users who have not logged into the systems in more than 6 months. An estimated 1:200 person ratio will be needed to service users. These services are dependent on building closures, numbers of users who are working in the office, and numbers who are working from home or other alternate worksites.
- **Secure Remote Access System Infrastructure.** OIM will ensure a Secure Remote Access System (SRAS) infrastructure that will support 3,000 concurrent broadband users and about 350 dial-in users, though these numbers will increase as funding is increased. Once an order is given to shelter at home, there will be a very high demand for SRAS and, consequently, a likely surge overcapacity for dial-in service and considerable stress on broadband bandwidth. Dial-in service

is not the recommended method of remote access due to the slow performance associated with this connection. This service is dependent on all essential IT infrastructure components being online, the users' local Internet provider, and the phone company having enough capacity to support the demand.

- **Storage Management.** There are many FDA applications that will need access to data storage devices. OIM staff may have limited capabilities to respond to all demands. A prioritized list of all applications will need to be derived to ensure adequate support of key applications.
- **Application Services.** Users will have to access FDA applications during a pandemic outbreak. OIM staff may have limited capabilities to respond to all of the demands. A prioritized list of all applications will need to be derived to ensure adequate support resources are available. Support for this service will be dependent on the number of critical applications needed to support a response to a pandemic outbreak. Once those applications are determined, a support plan will be published that identifies the servers and storage devices that will need support. Additionally, there are other applications, though not directly supporting a pandemic outbreak, which will need to be supported, such as the Prior Notice System. These services are dependent on all critical IT resources being operational. Because FDA.gov is hosted externally, OIM will need to coordinate with the vendor to ensure continuity of service.
- **File/Print Services.** File and print services are dependent on accessibility to the network drive and will be dependent on all critical IT resources being operational. OIM will work diligently to ensure that all network drives and printers are accessible. However, there may be times, such as during a scheduled or emergency maintenance outage, that certain network drives and printers will not be available. In order to ensure that employees have access to files and documents necessary to carry out their duties at all times, OIM explores secure technologies, such as the Ironkey device, that will allow employees to save and retrieve documents and files securely to and from an external drive.
- **Communication Services.** OIM will continue communication services that are essential for overall information dissemination as well as for technical and project management during a pandemic influenza event. Technical IT operations information, currently issued through the OIM News and Flash accounts, will continue to provide information on status and outages to users. Other news and notices from OC will be issued by the Office of Shared Services (OSS) and the Office of Executive Operations staff. OIM can leverage the other communication officers in the Office of Operations. Announcements via e-mail are dependent on HHSMail services.
- **Contracts/Procurements Coverage.** OIM will ensure coverage for contracts/procurements that are essential, as there may be a need to procure additional contract services or hardware/software components. This function, although important, may be performed by another OM component. This service is dependent on the availability of OAGS and key OIM staff. OIM can leverage other organizations to handle agency procurement needs.
- **Critical Patch Management.** Patches reduce or correct IT security threats or system problems. All efforts will be made to identify and apply patches that will address the most critical security vulnerabilities. All others will be prioritized and applied at the earliest convenience. This service is dependent on test servers and the availability of the network and server teams to load the patches.

C.1.9.4 Office of Management

Office of Management Essential Employees
Assistant Commissioner for Management
Deputy, OIM
Director, Employee Resource & Information Center – Admin
Director, Division of Public Services
Director, Office of Equal Employment Opportunity and Diversity Management
Director, Employee Resource and Information Center
Director, Division of Technical Services
Director, Division of Dockets Management
Director, Division of Freedom of Information (FOI)
Director, Office of Business Operations and Human Capital Programs
Director, OM Programs
Director, Office of Security Operations
Chief of Shared Services
Director, Office of Real Property Services
Safety Occupation Health Manager
Director, Office of Public Information & Library Services
Director, FDA Biosciences Library
Branch Manager, Center for Food Safety and Applied Nutrition (CFSAN) Branch Library

OM will provide workforce guidance and support to FDA Offices and Centers during a pandemic influenza emergency so that the agency's essential functions can continue with a potentially reduced number of employees. OM performs the following essential functions to support FDA's response to an influenza pandemic:

- **Shared Services.** The OSS will provide Call Center services for non-IT-related support, facilities management, mail delivery, fleet management, Freedom of Information Act (FOIA) coordination and responses, dockets management, and biosciences library services to agency Centers and Offices during a pandemic influenza emergency.
- **Facilities Management.** The OSS will ensure that FDA facilities are safe and available for FDA staff. Temporary facilities may be acquired, if necessary. Flexibility should be built into current leases and/or custodial contracts to address cleaning and maintenance of facilities' needs in the event of an emergency and/or have adequate supplies on hand such that FDA employees can perform these types of activities themselves.

– Agency safety coordination
– Building, operations, and maintenance
– Alterations to FDA space
– Real estate management (leasing)

- **Dockets Management.** The Dockets Management staff will continue to post critical public information to the *Federal Register* in accordance with Federal law.
- **Freedom of Information Act.** The FOI staff will continue to respond to new requests, denials, provide appeals and litigation support; FOI and Privacy Act Policy; and will assist OPA as needed to review possible public announcements prior to their dissemination.
- **Library Services.** The FDA Biosciences Library staff will ensure that mission-critical information services are available for FDA staff, including:

– Literature searches
– Access and delivery of electronic resources, i.e., journals, books, databases

- Maintenance of library's intranet site (contingent upon availability of FDA network and servers)

- **Employee Administrative Resources Support.** The ERIC staff will provide critical support to FDA personnel, Offices, and Centers during a pandemic influenza emergency, including:

- **Fleet Services:** Ensuring essential ground transportation/fleet is available and accessible to meet critical needs
- **Mail Services:** Ensuring critical mail pick-up and delivery
- Call Center support for critically needed administrative services

- **Other OM Essential Services.** From highest priority to lowest:

1) Commissioned Corps deployment
2) *Federal Register* posting
3) Special Government Employees (SGEs)/Conflict of Interest Advisory/Outside Activity Determinations relative to the agency's pandemic influenza response work
4) Delegation of Authority

Office of Management Response Activities
Pandemic Alert Period

- Interact with HHS as appropriate
- Provide active internal planning for pandemic preparedness, including review and communication of OM's pandemic influenza emergency response plan to OM employees, ensuring essential personnel are equipped with necessary requirements to complete essential functions from decentralized worksites
- Conduct disaster response training and scenario walkthroughs
- Work with other FDA components to ensure emergency plans are ready and tested
- Coordinate training for agency staff regarding prevention (PPE, social distancing, hygiene, etc.) and emergency operating procedures
- Provide information to staff on personal hygiene and prevention

Office of Management Response Activities
Pandemic Period

- Perform all interpandemic period and pandemic alert activities as appropriate and if requested by HHS
- To the extent possible, activate and implement OM pandemic influenza COOP plan, as appropriate
- Serve as agency liaison to HHS in obtaining appropriate medical countermeasures, such as vaccines, antivirals, and PPE for agency staff
- Address the health and safety of staff, in particular, essential staff that may not have the option for teleworking by providing countermeasures through occupational health services, if necessary
- Manage coordination of timekeeping functions and liaise with the Rockville Human Resources (HR) Center and the PSC to ensure FDA employees continue to receive compensation
- Ensure that key vendors are paid for their services to prevent termination of essential services and supplies, damaging the FDA pandemic response capability.
- Ensure that FDA facilities are safe and available for FDA staff

- OM will continue to post critical public information to the *Federal Register* in accordance with Federal law

C.1.9.4.1 Office of Shared Services

Office of Shared Services Response Activities
Pandemic Alert Period

- Coordinate phone numbers and services with building leasers, property management vendors, and contractors to verify their plans during the pandemic period (back-up contract services)
- Ensure essential personnel are equipped with necessary equipment to work from alternative locations, if possible
- Advise employees planning leave or travel to take laptop home
- Conduct scenario walkthroughs

Office of Shared Services Response Activities
Pandemic Period

- Activate the OSS Emergency Response Coordination Center
- Keep employees informed of critical information as it becomes available
- Ensure essential ground transportation/fleet is available and accessible to meet critical needs
- Ensure critical mail pick-up and delivery
- Ensure that FDA facilities are safe and available for FDA staff
- Ensure the FDA Building Operations Hotline is updated as circumstances warrant and post building closures and reopenings on FDA's intranet
- Continue to post critical public information to the *Federal Register* in accordance with Federal law
- Post information and maintain access to FDA's Federal Dockets Management System (FDMS) and Regulations.gov where the public can access information
- Ensure critical library research services are available to support FDA Centers/Offices
- Ensure well-being of staff, and particularly, essential staff personnel who may not have the option for teleworking
- Ensure critical administrative functions are supported through the Call Center

C.2 OFFICE OF REGULATORY AFFAIRS

Office of Regulatory Affairs Essential Employees	
Associate Commissioner for Regulatory Affairs	Director of Import Operations Branch
Deputy Associate Commissioner(s) for Regulatory Affairs	Investigator/Consumer Safety Officer
Office Director	Criminal Investigator/Special Agent
Division Director	Consumer Complaint Coordinator
Regional Director or equivalent	Recall Coordinator
District Director	Director of Cooperative Programs
Laboratory Director	Regional Specialists/Cooperative Programs (milk, shellfish, retail, radiological health)
Director of Investigations Branch	Laboratory Analyst
Director of Compliance Branch	Laboratory Branch Director
Compliance Officer/Import Compliance Officer	Industrial Hygienist
Legal Instrument Examiner	Staff Assistants
Administrative Officer	National Health Fraud Coordinator
Supervisory Consumer Safety Officer	Public Information Branch Representative/Manager
Regional Food and Drug Director or Deputy	Director, Headquarters/OCI Public Affairs Specialist
Emergency Response Coordinator	Program Support as needed for response
Laboratory Supervisor	Timekeeper
Special Assistant to District Director	Sample Custodian
Commissioned Corps Officers	Emergency Response Coordinators
Special Agent in Charge (SAIC) Office of Criminal Investigations (OCI) Headquarters/Investigative Operations Division	
SAIC OCI Headquarters/Administrative Operations Division	
SAIC OCI Office of Internal Affairs	
Senior Operations Manager (SOM) OCI/Headquarters COOP Coordinator	

Office of Regulatory Affairs (ORA), led by the Associate Commissioner for Regulatory Affairs (ACRA), serves as the focal point for all FDA field offices and four Headquarters offices (the Office of Regional Operations, OCI, the Office of Resource Management, and the Office of Enforcement [OE]) as well as five regional and 20 district offices. ORA Emergency Response Coordinators act as liaisons across FDA operating divisions as well as with State entities during emergency response. In addition, ORA maintains a database of FDA-regulated establishments. This database will enable FDA to rapidly identify establishments adversely affected by a pandemic influenza incident. In the event of product shortages, ORA database can assist the agency in identifying firms with needed production capabilities or product inventory. ORA performs the following essential functions to support FDA's response to an influenza pandemic:

- Investigating and pursuing enforcement action against fraudulent or counterfeit pandemic influenza products
- Initiating surveillance and follow-up activities for fraudulent pandemic products sold over the Internet
- Conducting post-market surveillance activities related to vaccines (team biologics)

Office of Regulatory Affairs Response Activities
Pandemic Alert Period

- Conduct domestic and foreign inspections, import entry review, field exams, sample collections, and analyses, and take appropriate enforcement actions against violative firms or products of

heightened concern because of their relation to pandemic influenza (for instance, vaccines and influenza drugs) to ensure compliance with applicable regulations

- Investigate and pursue enforcement action against fraudulent or counterfeit pandemic influenza products, both domestic and foreign
- Provide incident command training to essential staff and other staff involved in emergency response activities
- Participate in internal FDA and external pandemic influenza emergency exercises, including pandemic influenza
- Ensure that staff members have equipment and supplies needed in order to work from home
- Participate in educational outreach activities for industry, our regulatory counterparts, and other external customers
- ORA management to carefully examine all foreign travel and restrict, if necessary
- Maintain situational awareness of pandemic influenza cases worldwide through OCM
- Activate internal ORA planning for pandemic preparedness, including the establishment of a pandemic influenza emergency response plan; identify essential functions and essential personnel with adequate tiers for redundancy; and equip essential personnel with necessary equipment to complete essential functions for decentralized worksites
- Participate in educational outreach activities for industry, our regulatory counterparts, and other external customers

Office of Regulatory Affairs Response Activities
Pandemic Period

- All activities stated above during alert period also apply, as appropriate, and if requested by HHS and the Homeland Security Council (HSC)
- Intensify efforts to identify fraudulent, harmful, or ineffective products that are promoted for preventing, diagnosing, or treating pandemic influenza
- Give priority attention to pandemic influenza-related work and life-threatening/sustaining work associated with emergency response coordination activities
- To the extent possible, activate and implement the pandemic influenza emergency response plan, COOP plan, and other emergency response plans, as appropriate

C.2.1 Office of Regulatory Affairs Laboratories

ORA laboratories will provide analytical support for agency efforts to identify counterfeit or fraudulent pandemic influenza products and to support their removal from the marketplace. ORA laboratories will also participate in shelf-life extension and related programs associated with the maintenance of national stockpiles of critical influenza products.

C.3 FDA CENTERS

FDA product Centers are responsible for the regulation of a defined set of products. Their professional staff includes both clinical and scientific experts. This expertise (analytical, laboratory, sampling procedures, subject matter expertise, and industry knowledge) is available for critical consultation should a pandemic influenza emergency occur. National Center for Toxicological Research (NCTR) primarily conducts regulatory and applied research based on agency needs.

During an influenza pandemic, Centers are responsible for scientific evaluations and policy decisions (in cooperation with FDA EOC, OCET, and ORA) in their respective program areas. FDA product Centers participate in an emergency response when the response includes, or may include, regulatory activities or products under their jurisdiction.

Common Center Pandemic Influenza Response Activities
Alert and Pandemic Period

- Increase monitoring of the safety and effectiveness of pandemic influenza medical countermeasures
- Manage Center responsibilities
- Provide administrative support services (IT/Internet/LAN/database, telephones, safety/security, budget execution, personnel, procurement, payroll, facility management, mail)
- Post and maintain critical information on Center home page
- Examine all domestic/foreign travel and restrict if necessary

C.3.1 Center for Biologics Evaluation and Research

Center For Biologics Evaluation And Research Essential Employees
Center Director
Deputy Director
Associate Directors
Emergency Operations Coordinator
International Affairs Advisor
Program Manager for Pandemic Influenza
Senior Advisor for Counterterrorism/Medical Countermeasures
Director, Office of Management
Director, Office of Vaccine Research and Review
Director, Office of Blood Research and Review
Director, Office of Compliance and Biologics Quality
Director, Office of Communications, Outreach, and Development
Director, Office of Biostatistics and Epidemiology
Director, Office of Cellular, Tissue, and Gene Therapies
CBER-Office of Information Management Liaison

The Center for Biologics Evaluation and Research (CBER) ensures the safety, efficacy, and quality of biological products potentially used as medical countermeasures during a pandemic influenza emergency. CBER performs the following essential functions to support FDA's response to an influenza pandemic:

Center For Biologics Evaluation And Research Response Activities

Pandemic Alert Period

- Participation through the WHO Global Influenza Surveillance Network (GISN) to obtain, identify, and characterize influenza wild-type (WT) viruses of pandemic potential
- Work with the WHO Collaborating Centers (CCs) and WHO Essential Regulatory Laboratories (ERLs) to generate, calibrate, and cross-calibrate reference reagents for vaccine formulation as necessary
- Continue internal capacity building efforts, including development of novel reassortants (animal H1, H2, H5, H7, H9, etc.) suitable for vaccine production, methods development to improve assays for clinical assessment, and assays necessary for product release
- Providing guidance to sponsors regarding new and/or advanced product development and clinical trials research, including novel vaccines and therapies
- Conduct post-marketing surveillance and enforcement activities relating to biological products in accordance with pandemic guidance, as appropriate
- Industry outreach for purposes of increasing vaccine production and fill/finish capacity to meet pandemic demand
- Provide CBER management that will carefully examine all domestic and foreign travel to restrict if necessary
- Collaborate with HHS, other parts of the USG, and other international organizations, such as WHO, on the framework and method for appropriate selection of pandemic reference strains for vaccine production
- Collaborate with HHS regarding stockpile issues, including labeling, appropriate usage, shelf-life considerations, product performance, pharmacovigilance and monitoring, use in special populations, and other evolving issues
- Provide active internal planning for pandemic preparedness, including the establishment of a pandemic influenza emergency response plan and continual updates as needed, identifying essential functions, identifying essential personnel with adequate tiers for redundancy, and equipping essential personnel with necessary requirements to complete essential functions from decentralized worksites
- To the extent possible, assess the availability of biological products and take steps to divert or mitigate the impact of shortages
- Provide training to staff regarding prevention (PPE, social distancing, hygiene, etc.) and emergency operating procedures
- Play an integral part in any global harmonization of regulatory processes within our existing framework for pandemic activities, should this be necessary

Center For Biologics Evaluation And Research Response Activities

Pandemic Period

- Engage in pandemic activities as appropriate and if requested by HHS and the HSC
- To the extent possible, activate and implement CBER pandemic influenza COOP plan and other emergency response plans, as appropriate
- To the extent possible, ensure well-being of staff, and particularly, essential staff personnel who may not have the option for teleworking (such as those involved in laboratory work supporting

vaccine production, quality control, and release) by the provision of countermeasures through occupational health services in coordination with OC's OM

- Respond to and process EUA requests after a declaration of public health emergency by the Secretary
- Using a risk-based approach, prioritize allocation of review and inspectional resources for licensure and emergency use of medical countermeasures, as well as other essential activities that will confer maximum and most beneficial public health impact
- Ensure timely information flow within CBER, as well as other organizations within the USG
- Facilitate dialogue and information exchange with industry and international entities, as well as participation in global efforts to develop consensus approaches, to the extent possible, for clinical trial designs and adverse event reporting that can guide vaccination strategies
- Conduct public outreach to domestic and foreign public health authorities, the public, and other stakeholders regarding pandemic vaccines and other biological products

C.3.2 Center for Drug Evaluation and Research

Center for Drug Evaluation and Research Essential Employees
Center Director
Deputy Director
Director, Office of Regulatory Policy
Director, Office of Communications
Director, Office of Planning and Informatics
Director, Office of Counterterrorism and Emergency Coordination
Director, Office of Compliance
Director, Office of Pharmaceutical Science
Director, Office of Surveillance and Epidemiology
Director, Office of Translational Sciences
Director, Office of New Drugs
Deputy Director, Office of New Drugs
Director, Office of Antimicrobial Products
Associate Director, Center for Drug Evaluation and Research (CDER) Drug Shortage Program
Director, Office of Management

CDER ensures the safety, efficacy, and quality of drugs and therapeutic biologic agents for use as medical countermeasures in response to outbreaks of influenza virus. CDER performs the following essential functions to support FDA's response to an influenza pandemic:

CDER Response Activities
Pandemic Alert Period

- Perform drug approval activities—review of investigational and new drug applications, associated labeling, and advertising and guidance for field inspections
- Perform drug safety activities, including adverse event monitoring, drug product quality activities, and postmarket surveillance
- Perform compliance activities, including regulatory surveillance assessments and actions and coordination of actions, involving recalls, shortages, tampering, fraudulent or counterfeit products, and inspections

- Perform emergency response coordination/activities for all CDER-regulated products, liaison to the Strategic National Stockpile (SNS), maintenance of the CDER Situation Room (CSR), and program responsibility for classified documents and security clearances; coordination of EUAs
- Monitor for drug shortages
- Facilitate communication with manufacturers of pandemic influenza products on issues of availability, adverse event reporting, and potential new products
- Collaborate with HHS regarding stockpile issues, including labeling, appropriate usage, shelf-life and expired product considerations, product performance, pharmacovigilance and monitoring, use in special populations, and other evolving issues
- Process pre-EUAs in anticipation of declared emergencies
- Activate internal planning for pandemic preparedness, including the establishment of a Continuity of Business Operations Plan (COBOP): identifying essential functions and essential personnel with adequate tiers for redundancy, and equipping essential personnel with necessary equipment/procedures to complete essential functions from decentralized worksites

CDER Response Activities
Pandemic Period

- Continue to perform drug approval activities—review of investigational and new drug applications, associated labeling, and advertising and guidance for field inspections
- Perform all interpandemic period and pandemic alert activities as appropriate and if requested by HHS and the HSC
- To the extent possible, activate and implement CDER COBOP, CDER Pandemic Administrative Operating Plan, and other emergency response plans, as appropriate
- Inventory human capital and the capability of staff to work
- Focus the Center's remaining workforce on issues related to products associated with the ongoing crisis; significant, life-saving products; and new generic drugs to prevent shortages; and respond to significant adverse event incidents, EUA requests, and emergency response coordination issues
- Conduct public outreach to industry, foreign public health authorities, the public, and other stakeholders regarding antiviral drugs

C.3.3 Center for Devices and Radiological Health

Center for Devices and Radiological Health Essential Employees
Center Director
Deputy Director
Senior Associate Director
Director, Office of Management Operations
Office Director, Office of Device Evaluation
Office Director, Office of In-Vitro Diagnostic Device Evaluation and Safety
Office Director, Office of Compliance
CDRH COOP Leader
Division Director, Division of Anesthesia General Hospital Infection Control and Dental Devices
Office Director, Office of Surveillance and Biometrics
Office Director, Office of Communication, Education, and Radiation Programs

CDRH ensures the safety, efficacy, and quality of medical devices used during a pandemic influenza emergency. CDRH performs the following essential functions to support FDA's response to an influenza pandemic:

Center for Devices and Radiological Health Response Activities
Pandemic Alert Period

- Educate device users on how to use influenza-related devices safely and effectively
- Communicate influenza-related device activities and information to industry and consumers
- Process pre-EUAs in anticipation of declared emergencies
- Facilitate device development, regulatory review, and production of devices that may be needed during an influenza pandemic
- Conduct postmarket surveillance to monitor the safety and effectiveness of influenza-related devices (including devices used for diagnosis, devices used to administer therapeutics, PPE, and devices used for supportive care)
- Lend technical expertise and assistance to international efforts to prepare for a potential influenza pandemic
- Support efforts to ensure an adequate supply of influenza-related devices through cooperative interactions with manufacturers and distributors and coordination with the SNS to determine the adequacy of stocks and actions required to meet targeted amounts
- Use an Emergency Shortages Database to identify and monitor needed supplies
- Collaborate with public health agencies regarding product stockpile issues, appropriate usage, labeling, product performance, monitoring, use in special populations, and other evolving issues
- Collaborate with HHS regarding stockpile issues related to medical devices
- Activate internal plans for pandemic preparedness in regards to staff communication and readiness, including teleworking during the pandemic
- Provide training for staff on prevention and protection techniques for the influenza pandemic that must be followed in the workplace

Center for Devices and Radiological Health Response Activities
Pandemic Period

- Perform all pandemic alert activities as appropriate
- Process EUAs for products after a declaration of public health emergency by the Secretary

- Conduct postmarket surveillance to monitor the safety and effectiveness of influenza-related devices (including devices used for diagnosis, devices used to administer therapeutics, PPE, and devices used for supportive care)
- Support efforts to ensure an adequate supply of influenza-related devices through cooperative interactions with manufacturers and distributors and coordination with the SNS to determine the adequacy of stocks and actions required to meet targeted amounts
- Use an Emergency Shortages Database to identify and monitor supplies of certain devices that have the potential to be in demand, but in short supply during influenza outbreaks

C.3.4 Center for Food Safety and Applied Nutrition

Center for Food Safety and Applied Nutrition Essential Employees
Center Director
Deputy Directors
Director, Office of Management Systems
Director, Office of Food Defense Communication and Emergency Response
Center Emergency Coordinator
Office Directors
CFSAN COOP Leader

CFSAN, in conjunction with the agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the Nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and labeled properly. CFSAN has the authority to regulate food producers and distributors involved in interstate commerce and also determines whether data collected by another agency or organization are adequate for FDA decisions regarding food and cosmetic issues in an emergency. CFSAN performs the following essential functions to support FDA's response to an influenza pandemic:

- Develop and evaluate analytical methods for identifying influenza virus in foods
- Prohibit the extra-label use of influenza antiviral drug products in animals when such use presents a risk to the public health

Center for Food Safety and Applied Nutrition Response Activities
Pandemic Alert Period

- Develop and evaluate analytical methods for identifying influenza in food
- Identify foods and feeds that are at elevated risk of contamination and investigate the effectiveness of food and feed processing and preparation practices for inactivating influenza viruses
- Develop and disseminate recommendations on measures to prevent the spread of influenza virus via FDA-regulated foods
- Activate internal planning for pandemic preparedness, including the establishment of a pandemic influenza emergency response plan (identifying essential functions, identifying essential personnel with adequate tiers for redundancy, and equipping essential personnel with necessary requirements to complete essential functions from decentralized worksites)
- Coordinate food and feed safety activities and plans with Federal and State agencies, industry, and others
- Food safety activities, including outbreak surveillance, inspections, and monitoring
- Disseminate accurate information about food safety emergencies, which is vital to minimize the adverse impacts of threats or public health emergencies

Center for Food Safety and Applied Nutrition Response Activities
Pandemic Period

- Perform all pandemic alert activities as appropriate and if requested by HHS and the HSC
- To the extent possible, activate and implement CFSAN Emergency Response Plan, as appropriate
- Inventory human capital and determine the well-being of staff
- Focus the Center's remaining workforce on issues related to products associated with the ongoing crisis; significant focus on ensuring food security, safety, and defense; and emergency response coordination issues
- Conduct outreach to the public, industry, foreign public health authorities, and other stakeholders regarding food safety
- Provide cadre of trained CFSAN personnel for rapid deployment to FDA EOC, to HHS, and to external organizations to provide support for contingency functions

C.3.5 Center for Veterinary Medicine

Center for Veterinary Medicine Essential Employees
Center Director
Executive Director
Senior Advisor for Science
Associate Director for Policy and Executive Programs
Senior Policy Analyst and Director, CVM Executive Secretariat
Director, CVM Communications Staff
Executive Officer and Director, OM
Director, Office of Surveillance and Compliance
Director, Division of Animal Feeds
Director, Division of Compliance
Director, Office of Research
Director, Office of New Animal Drug Evaluation

Center for Veterinary Medicine (CVM) ensures the safety, efficacy, and quality of drugs for animals, including food-producing and companion animals, animal food and feed, and medical devices used on animals potentially threatened by an influenza outbreak. CVM performs the following essential functions to support FDA's response to an influenza pandemic:

- Maintaining essential international program activities
- Collaborating with public health agencies (e.g., CDC, HHS, and the U.S. Department of Agriculture [USDA]) regarding feed contaminant, tissue residue programs, and other monitoring programs for meat and poultry involved in influenza outbreaks
- Providing advice in the assessment of animal drug or feed product possibly affected by influenza
- Providing advice to pet owners regarding animal safety measures related to influenza

Center for Veterinary Medicine Response Activities
Pandemic Alert Period

- Coordinate food and feed safety activities and plans with Federal and State agencies, industry, and others
- Identify foods and animal feeds that are at elevated risk of contamination and investigate the effectiveness of food and feed processing and preparation practices for inactivating influenza viruses

- Prohibit the extra-label use of influenza antiviral drug products in animals when such use presents a risk to the public health
- Manage CVM laboratory capabilities and provide this information to the FDA EOC
- Develop and disseminate recommendations on measures to prevent the spread of influenza virus via FDA-regulated foods and animal feeds

Center for Veterinary Medicine Response Activities
Pandemic Period

- Perform all pandemic alert activities as appropriate

C.3.6 National Center for Toxicological Research

National Center for Toxicological Research Essential Employees
Center Director
Executive Officer
Associate Director, Office of Research
Associate Director, Regulatory Compliance and Risk Management
Director, Division of Microbiology
Physical Security Officer and COOP Administrator
Research Microbiologist, Division of Microbiology,
Director of Veterinary Services
Chief of Facilities, Engineering and Maintenance Activities

NCTR conducts FDA mission-critical scientific research to support and anticipate FDA's current and future regulatory needs. This research is targeted to develop a scientifically sound basis for regulatory decisions and to reduce risks associated with FDA-regulated products. It includes fundamental and applied research on biological mechanisms associated with chemicals and microorganisms or associated toxins. NCTR performs the following essential functions to support FDA's response to an influenza pandemic:

- Strategic planning, including developing and implementing a comprehensive FDA strategy for counterterrorism, pandemic influenza, and other emerging threats
- Policy leadership, including promoting counterterrorism; pandemic influenza; and emerging threats, goals, and needs in the agency priority-setting process
- Maintenance of facility infrastructure with reduced staff

National Center for Toxicological Research Response Activities
Pandemic Alert Period

- Strategic planning to ensure the maintenance of facilities infrastructure to support anticipated need for pandemic response

National Center for Toxicological Research Response Activities
Pandemic Period

- If the local (commuting) area experienced a severe outbreak, consideration would be given to teleworking where possible. NCTR will review, and initiate as necessary, plans to maintain the facility and animal resources with essential personnel.

D DIRECTION, CONTROL, AND COORDINATION

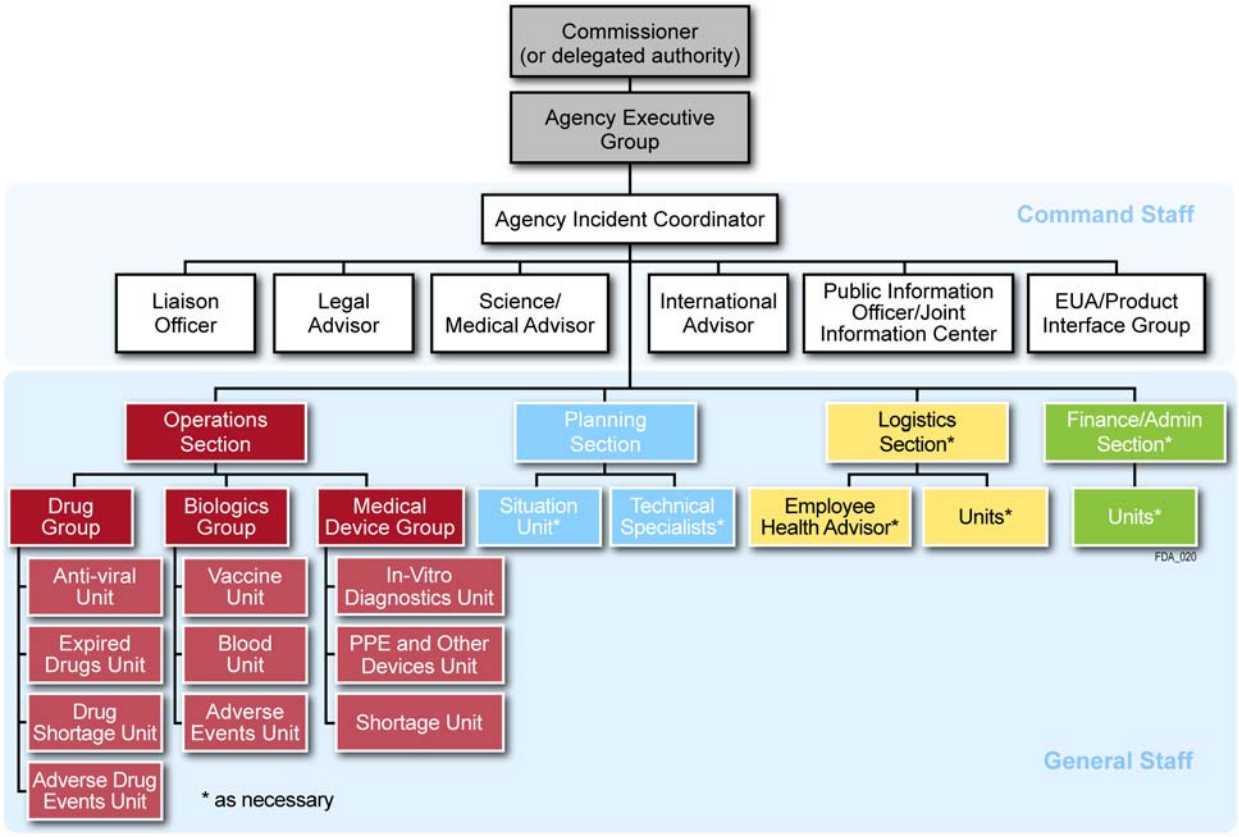
This section provides a description of Incident Command System (ICS) positions and groups, which are specific to a pandemic influenza response and describes their primary roles and responsibilities.

FDA response operations for major incidents, such as pandemic influenza, are based on the concepts, practices, and principles of NIMS and its organizational structure, the ICS. Among other things, NIMS prescribes what types of information FDA should provide the HHS SOC and in what format, including Situational Reports and Incident Action Plans. NIMS also requires the use of universal terminology to ensure a common understanding of requirements and requests in an interagency environment. The ICS organizational structure provides standard nomenclatures for both teams and individual positions. *For a complete listing of the FDA ICS structure (Incident Management Group,)*[91] *refer to FDA EOP, Section D, Direction, Control, and Coordination.*

Expansions of the FDA response structure for a pandemic influenza response may vary according to numerous considerations and operational factors. ICS offers flexibility in determining the right structural approach for the specific circumstances of the incident at hand. Dependent on the incident objectives established and strategies developed, the Incident Management Group may include Logistics and Finance/Administrative as part of the response and expand FDA's command structure operations section, including any one of the groups described in Section D.

[91] For more information on specific roles and responsibilities of each ICS position, refer to FDA EOP, Appendix K "Job Action Sheets"

Figure D-1. Pandemic Influenza Incident Management Group Structure



D.1 COMMAND STAFF

The FDA Command Staff includes a Public Information Officer, Liaison Officers (LNOs), and relevant Technical Advisors, such as Science/Medical Advisors, EUA who report directly to the Agency Incident Coordinator: Science/Medical Advisors, EUA/Product Interface Advisor, International Advisors, and Legal Advisor.[92]

D.1.1 Pandemic Influenza-Specific Liaisons

When activated, the FDA EOC serves as the agency-wide focal point for pandemic influenza emergency operations, coordination, and communications. External liaisons from the CDC or other agencies may be present at the FDA EOC. FDA may also send liaisons to the coordinating agency for the event or participate in the response coordination if an incident or unified command is set up.

D.1.2 Legal Advisor

D.1.2.1 Legal Group

The Legal Group works to address the following issues related to pandemic influenza in support of the Legal Advisor:

- Adverse event reporting guidance
- Fraudulent products-warning letters and enforcement actions

[92] See FDA EOP, Section D.3.4. Technical Advisors, for descriptions of these positions.

- FDA-regulated products used during an influenza pandemic: export and import, overriding patents, and public informational statements
- EUAs
- Occupational issues (agency recommendations for employees, ensuring harmonization of multiple guidance for employees provided by multiple entities)
- Preparation for congressional hearings

D.2 GENERAL STAFF

The General Staff is responsible for the functional aspects of the FDA ICS. The General Staff consists of the Operations, Planning, Logistics, and Finance/Administration Sections, which comprise designated FDA headquarters and field emergency staffs. Individual position assignments within these Sections are discussed in the *FDA EOP*.

D.2.1 Operations Section

The Operations Section is responsible for coordinating all agency activities related to regulated products in response to an influenza pandemic event. **Figure D-1** depicts FDA's Operations Section during a pandemic influenza response. The groups listed below could possibly be established when the number of resources exceeds the manageable span of control of the Incident Management Group and the Operations Section Chief. Groups are established to divide the incident into functional areas of operation. Additional levels of supervision may also exist below the Group level. Resources may be organized and managed by Task Forces depending on the requirements of the incident. Task Forces comprise any combination of resources assembled in support of a specific mission or operational need. All resource elements within a Task Force must have common communications and a designated leader. The use of Task Forces is encouraged, when appropriate, to optimize the use of resources, reduce the span of control, and reduce the complexity of incident management coordination and communications.[93]

D.2.1.1 Drug Group

The Drug Group addresses drug issues, such as adverse event reporting, labeling changes, whether EUAs for drugs are appropriate, and what restrictions should be placed on uses authorized under EUAs related to an influenza pandemic operational response. Some potential Units, led by CDER staff, which may be needed to manage mitigation and recovery issues include:

D.2.1.1.1 Anti-Viral Unit

The Anti-Viral Unit addresses issues concerning the availability of antiviral drugs and EUA requests, and manages adverse event reporting and monitoring.

D.2.1.1.2 Expired Drugs Unit

The Expired Drugs Unit deals with such issues as use of expired antiviral drugs and drugs out of specification, including those in the SNS. This Unit would have input in discussing whether an EUA should/can include private sector stockpiles (e.g., hospital associations, large employers) or whether a separate authorization is needed. The Expired Drugs Unit would also monitor labeling and Shelf-Life Extension Program (SLEP) issues related to the event.

[93] DHS NIMS (Dec. 2008)

D.2.1.1.3 Drug Shortage Unit

The Drug Shortage Unit is responsible for reporting on the availability and surge capacity for antiviral drugs, monitoring commercial inventory, and working with manufacturers of influenza drug products to prepare for possible increases in demand. The Unit would contact intravenous antibiotics, intravenous fluid manufacturers, and other critical care drug manufacturers in order to prepare for possible increased needs.

D.2.1.1.4 Adverse Drug Events Unit

The Adverse Drugs Events Unit assists with the monitoring of adverse drug events specifically to identify undesired side effects and unexpected adverse effects from a drug product used to treat influenza.

D.2.1.2 Biologics Group

The Biologics Group addresses vaccines, blood, and other biologics issues as part of an influenza pandemic operational response. Some potential Units, with team leaders from CBER staff, may be needed to manage mitigation and recovery issues.

D.2.1.2.1 Vaccine Unit

The Vaccine Unit works with U.S.-licensed manufacturers of influenza vaccines concerning the regulatory and scientific aspects of the development and licensure of vaccines for the novel influenza virus. They participate in various recurring meetings facilitated by the Biomedical Advanced Research and Development Authority (BARDA), The National Vaccine Program Office (NVPO), CDC, WHO, and international regulators, such as European Medicines Agency (EMEA) and Health Canada.

In addition, the Vaccine Unit works to address any issues related to:

- Preparation of reference strains from which manufacturers can make viral seeds for vaccine production
- Production of reagents to test vaccine potency
- Providing strains for assays and manufacture as necessary
- Standardization of clinical trials
- Vaccine production
- Discussion with manufacturers, when needed, regarding the information needed to potentially support the use of unapproved vaccines in a declared emergency under an EUA

D.2.1.2.2 Blood Unit

The Blood Unit is responsible for providing guidance related to blood and tissue donations and use of such products when impacted by a pandemic. The Unit also works with outside groups to address any blood shortages that might arise.

D.2.1.3 Medical Device Group

The Medical Device Group would manage issues related to an influenza pandemic operational response. Potential Units, with team leaders from CDRH staff members, that may be needed to manage mitigation and recovery issues are: In-Vitro Diagnostics Unit, Personal Protective Equipment and Other Devices Unit, and Shortage Unit.

D.2.1.3.1 In-Vitro Diagnostics Unit

The IVD Unit performs the following:

- Respond to triage EUA requests
- Respond to inquiries regarding EUA requests from
  - The CDC, U.S. military, and domestic and international commercial sources for IVDs claiming to subtype or detect the novel viral strain or to detect virus mutant variants
  - Manufacturers regarding instruments to be used in the development of IVDs
  - Clear tests and instruments for the availability of detection of the novel influenza, including rapid tests and other influenza testing-related products, such as viral transport media/swabs
- Monitor reagent and system shortages on a short-term (daily or weekly) basis as well as a long-term (monthly) basis
- Monitor claims for detection and differentiation of the influenza virus
- Review data and labeling of cleared or approved devices for which a company proposes new claims and changes
- Work with the CDC to monitor availability of new Influenza Subtype Panels from CDC/American Type Culture Collection for use by assay developers
- Conduct rapid review of any promising influenza devices capable of differentiating novel subtypes, particularly those that are rapid or point-of-care tests, and those for detection of mutant variants of the virus
- Address fraudulent claims by monitoring Web sites and complaints regarding claims to diagnose novel influenza and issuing warning letters, as appropriate
- Support the development of Lab Developed Tests for virus diagnosis

D.2.1.3.2 Personal Protective Equipment and Other Devices Unit

The PPE and Other Devices Unit performs the following:

- Exchange information with CDC/SNS, States, and manufacturing sector, and provide real-time monitoring of consumption/utilization rates of PPE during emergencies
- Respond to State and private sector inquiries about perceived shortages during public health emergencies
- Anticipate and plan for future surges in demand for N95 devices
- Track and trace status of N95 devices released from SNS
- Meet with manufactures about the development of new PPEs
- Address shortages of PPE by working with industry to update current manufacturing capabilities and assist with long-term planning by the manufacturing sector to meet demands for a potential surges

D.2.1.3.3 Shortage Unit

This Unit would be created if shortages of IVDs, PPEs, and other devices are too extensive to be managed by the above Units alone.

D.2.2 Logistics Section

D.2.2.1 Employee Health Advisor

The Employee Health Advisor is a staff member of OCET or OM and addresses appropriate health protection for high-risk FDA employees. The Advisor works with HHS and U.S. Public Health Service's Federal Occupational Health Services to ensure that adequate medical countermeasures are made available to protect responders.

E AUTHORITIES AND REFERENCES

E.1 HOMELAND SECURITY PRESIDENTIAL DIRECTIVES

- HHS, CONOPS Plan for ESF-8, Response during a Pandemic

E.2 NATIONAL STRATEGIES

E.2.1 National Strategy for Pandemic Influenza

On November 1, 2005, the President issued a National Strategy for Pandemic Influenza that called for comprehensive and coordinated pandemic preparedness planning at all levels of Government and the private sector. It outlines how the Nation intends to prepare, detect, and respond to a pandemic. This Strategy describes the important roles to be played not only by the Federal Government, but also by State and local governments, private industry, our international partners, and individual citizens. HHS was identified as the lead department for medical response.

http://www.flu.gov/professional/federal/pandemic-influenza.pdf

E.2.2 National Strategy for Pandemic Influenza Implementation Plan

In May 2006, the HSC published the National Strategy for Pandemic Influenza Implementation Plan. The introductory letter signed by the President cited more than 300 critical actions to address the threat of pandemic influenza. Chapter 6, "Protecting Human Health," includes actions on: 1) achieving national goals for producing and stockpiling vaccine and antiviral medications; and 2) prioritizing and distributing limited supplies of vaccine and antiviral medications. It details how the Nation is currently preparing for, and how it detects and responds to, a potential pandemic influenza outbreak.

http://www.flu.gov/professional/federal/pandemic-influenza-implementation.pdf

E.3 FEDERAL PLANS AND GUIDANCE

E.3.1 HHS Pandemic Influenza Plan, Part I: Strategic Plan

HHS Pandemic Influenza Plan, November 2005, Part I – Strategic Plan,
http://www.hhs.gov/pandemicflu/plan/

This plan contains a summary of major pandemic response roles for HHS officials, agencies, and divisions. The major pandemic response roles for FDA include the following:

- Regulating manufacturing processes
- Evaluating and licensing pandemic vaccines
- Evaluating and approving antiviral drugs for influenza
- Facilitating the development, evaluation, and clearance or approval of diagnostic tests and devices
- Preparing reagents to standardize the potency of inactivated influenza vaccines
- Preparing reference strains appropriate for vaccine manufacturing
- Reviewing antiviral drug and pandemic vaccine supply issues
- Evaluating and issuing EUAs when appropriate
- Monitoring vaccine adverse events

- Monitoring antiviral drug adverse events
- Maintaining close communication with drug and vaccine manufacturers
- Evaluating investigational new drug (IND) applications and investigational device exemptions (IDEs) for medical products that diagnose, treat, prevent, or mitigate influenza
- Evaluating new manufacturing sites and processes for antiviral drugs
- Making necessary changes in prescribing and patient information, including dosing, target populations, and other directions for use, for antiviral drugs and pandemic vaccines based on research and adverse events
- Evaluating long-term stability of stockpiled antiviral drugs for purposes of shelf-life extension
- Monitoring to protect against the distribution of counterfeit antiviral drugs and pandemic vaccines

E.3.2 HHS Pandemic Influenza Implementation Plan

HHS Pandemic Influenza Implementation Plan, November 2006,
http://www.hhs.gov/pandemicflu/implementationplan

This plan provides a roadmap for the Department's pandemic preparedness and response. It outlines specific steps to implement the actions identified in the HHS Pandemic Influenza Plan, Part I: Strategic Plan.

E.4 FDA SUPPORTING DOCUMENTATION

E.4.1 FDA Pandemic Influenza Preparedness Strategic Plan

This plan is the basis for FDA pandemic influenza implementation strategy. It identifies and describes the roles and responsibilities of FDA's Centers and selected Offices (updated in Section III of this *FDA Pandemic Influenza Annex*).

- FDA Pandemic Influenza Preparedness Strategic Plan, March 2008,
http://www.fda.gov/EmergencyPreparedness/Flu/ucm165686.htm

E.4.2 FDA Operational Division Section to HHS Pandemic Influenza Operational Plan

- FDA OPDIV Section to HHS Pandemic Influenza Operational Plan, November 21, 2006
- This document includes essential functions that FDA Centers and Offices must continue to perform to ensure COOP in the event of an influenza pandemic (updated in Section C of the Annex*)*.

E.4.3 Center/Office Emergency Plans and Procedures

The following plans support implementation of the *FDA EOP Pandemic Influenza Annex,* and they are available to assist FDA personnel during prevention, preparedness, protection, response, and recovery activities.

- CBER-COOP Annex I: Pandemic Influenza Plan
http://inside.fda.gov:9003/downloads/Administrative/EmergencyCOOP/COOP/UCM038481.pdf
- OC/Office of Administration (OA)/Office of Financial Operations (OFO)/OFM – Business Continuity Plan
http://aims.oc.fda.gov:8080/webtop/component/drl?objectId=0b0026f880183dd3&ReLoad=1246304368576

Appendix A – Protection of Workers: Guidance on Preparing the Workplace and Workers for an Influenza Pandemic

I. Introduction

An influenza pandemic occurrence will cause large numbers of employees to be absent from work because of illness, because they may have to care for ill family members, because schools or day-care centers are closed, or because they are afraid to come to work.

It is estimated that during a period of peak influenza pandemic illness, approximately 30 to 40 percent of employees working in a particular office or organization could be absent. An outbreak in a particular geographic area could last from 6 to 8 weeks. There is little way of knowing when an influenza pandemic will occur, or how severe it will be in the population.

Planning for an influenza pandemic should assume a worst case scenario that would be characterized by a high level of illness and absenteeism, social disruption, and economic loss in the public, private, and nonprofit sectors of the economy. The level of risk experienced by employees in the various FDA Centers and Offices will depend on the nature of their occupations and the degree to which they have occupational exposure to people potentially infected with the pandemic influenza virus.

II. Action Steps

Expanding teleworking by employees and "social distancing" are two actions that can be taken by managers to facilitate continuation of an agency's essential functions despite high workforce absenteeism. Social distancing refers to employee behavior to reduce the frequency, proximity, and duration of contact between people (both employees and customers) in order to reduce the chances of spreading influenza from person-to-person.

III. Spread of Influenza

It is important that employees understand how influenza can be spread among people. It is spread primarily through large droplets (droplet transmission) that directly contact the nose, mouth, or eyes. Droplets are produced when infected people cough, sneeze, or talk. This sends relatively large infectious droplets and very small sprays (aerosols) into the nearby air and into contact with other people. The large droplets can only travel around 6 feet. Consequently, people should limit close contact with others to a distance no closer than 6 feet. A second way that influenza is transmitted is by individuals touching objects that have been contaminated with influenza viruses and then transferring the infected material from their hands to their nose, mouth, or eyes. A third way of transmitting influenza is through the spread of very small infectious particles (aerosols) that travel in the air. Employees need to understand these three principal means of transmission of influenza so that they can take steps, to the maximum extent possible, to protect themselves against infection.

IV. Occupational Safety and Health Administration Guidance

The U.S. Department of Labor (DOL) Occupational Safety and Health Administration (OSHA) has issued a document entitled *Guidance on Preparing Workplaces for an Influenza Pandemic* (OSHA 3327-02N 2007 and updated version 3227-05R 2009), which provides detailed, but strictly advisory, guidance for employers on preparing their workplaces to minimize the impact of an influenza pandemic on their workers and operations. This guidance will help employers and employees identify the pandemic influenza risk levels in their individual workplace settings. OSHA identifies appropriate control measures for pandemic influenza; these measures include good hygiene, cough etiquette, social distancing, the use of PPE, and staying home from work when ill.

Although the work of the FDA Centers and Offices differs from other USG agencies and among themselves, there are many pandemic preparedness recommendations in the OSHA guidance publication that are applicable to all FDA elements. They include:

- Be aware of and review other USG, State, and local health department pandemic influenza plans; incorporate appropriate actions from these plans into workplace disaster plans.
- Prepare and plan for operations with a reduced workforce.
- Work with your suppliers to ensure that you can continue to operate and provide services.
- Develop a sick leave policy that does not penalize sick employees, thereby encouraging employees who have influenza-related symptoms to stay home so that they do not infect other employees; recognize that employees with ill family members may need to stay home to care for them.
- Identify possible exposure and health risks to your employees: Are your employees expected to have a lot of contact with the general public?
- Minimize exposure to fellow employees or the public.
- Identify business-essential functions and people required to sustain business-necessary functions and operations; prepare to cross-train or develop ways to function in the absence of these positions; it is recommended that employers train three or more employees to be able to sustain business-necessary functions and operations.
- Plan for downsizing services, but also anticipate any scenario that may require a surge in your services.
- Some employees will have individual risk factors that should be considered by employers as they plan how the organization will respond to a potential pandemic (e.g., immuno-compromised individuals and pregnant women).
- Stockpile items such as soap, tissue, hand sanitizer, cleaning supplies, and recommended PPE; when stockpiling items, be aware of each product's shelf life and storage conditions and incorporate product rotation into your stockpile management program (*Guidance on Preparing Workplaces for an Influenza Pandemic,* pp.13 – 15).

OSHA's *Guidance on Preparing Workplaces for Pandemic Influenza* notes that the two most effective ways of protecting employees from pandemic influenza depend upon emphasizing proper hygiene (i.e., disinfecting hands and surfaces) and practicing social distancing as described above. OSHA describes a "hierarchy of controls" as the most effective way of dealing with a workplace hazard. This concept places a high priority on intervention strategies by management and on attempts to remove the hazard from the workplace rather than to rely primarily on the employees to reduce their exposure. Depending on the nature of the work of each FDA Center and Office, the strategies for work practice and engineering controls, administrative controls, work practices, and PPE will differ in both cost and effectiveness.

V. Centers for Disease Control and Prevention Guidance

The CDC has issued a document entitled *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States,* which provides interim planning guidance for State, territorial, tribal, and local communities. This planning focuses on several measures other than vaccination and drug treatment that might be useful during an influenza pandemic to reduce its harm. This interim guidance introduces a Pandemic Severity Index to characterize the severity of a pandemic, provides planning recommendations for specific interventions that communities may use for a given level of pandemic severity, and suggests when these measures should be started and how long they should be used.

The pandemic mitigation interventions described in the Interim Guidance document include:

- **Isolation and Treatment.** Isolation may occur in the home or healthcare setting, depending on the severity of an individual's illness and/or current capacity of the healthcare infrastructure.
- **Home Quarantine.** Households should voluntarily quarantine members in these households with confirmed or probable influenza case(s) and consider combining this intervention with prophylactic use of antiviral medications, provided sufficient quantities of effective medications exist and that a feasible means of distributing them is in place.
- **Dismissal of Students from School.** Reductions of out-of-school social contacts and community mixing should occur.
- **Social Distancing.** Individuals should take social distancing measures to reduce contact between adults in the community and workplace, including cancellation of large public gatherings and alternation of workplace environments and schedules to decrease social density and preserve a healthy workplace to the greatest extent possible without disrupting essential services.
- **Individual Infection Control Measures.** Community-based strategies should be used in combination with individual measures, such as hand washing and cough etiquette.

The CDC also has available the *Guide for Community and Faith-based Organizations,* developed in response to H1N1: http://pandemicflu.gov/professional/community/.

VI. Hierarchy of Controls

OSHA defines work practice controls as "procedures for safe and proper work that are used to reduce the duration, frequency, or intensity of exposure to a hazard." Managers and supervisors should solicit suggestions from employees on ways to implement safe work practice controls. Engineering controls are preferred over all others because "they make permanent changes to reduce exposure to hazards and do not rely on employee or customer behavior." These types of controls involve making permanent changes to the work environment to reduce work-related hazards.

Administrative controls include "controlling employees' exposure by scheduling their work tasks in ways that minimize their exposure levels." Examples of administrative controls include discontinuation of nonessential travel to locations with high illness transmission rates, implementing work practices such as e-mail, Web sites, and teleconferences that minimize face-to-face contact between employees, and adopting flexible work arrangements, such as telecommuting or flexible work hours, to reduce the number of employees who must be at work at one time or in one specific location.

PPE is considered appropriate for employees during certain types of exposures, but is no replacement for other types of prevention interventions, such as engineering controls, cough etiquette, and hand hygiene. Examples of the types of PPE appropriate for a pandemic influenza include: gloves, goggles, face shields, and respiratory protection devices.

Each of the above types of work practices and controls may be appropriate for implementing in FDA Centers and Offices. However, there is no single list of these four prevention strategies that would necessarily be appropriate for implementing in each FDA organization. Rather, it is incumbent upon the director of each Center and Office to engage the employees and supervisors in their unit to examine how the work of their organization can be modified to provide maximum protection for the staff should an influenza pandemic occur.

All actions taken by FDA managers and supervisors must be consistent with and not conflict with other Federal, State, and local health department pandemic influenza plans. As appropriate, portions of these other plans may be incorporated into individual pandemic influenza plans developed for individual FDA Centers and Offices.

HHS, Office of Personal Management (OPM), and General Services Administration (GSA) have documents and Web sites that provide policy and guidance applicable for emergency situations, such as an influenza pandemic. Human capital management, leave, temporary closing of work spaces and treatment of absences, and telework are all functions that may need to be implemented during the course of an influenza pandemic that may impact FDA Centers and Offices. As needed, directors and supervisors should consult the following documents/Web sites:

- The OPM Guidelines, *Human Capital Management Policy for a Pandemic Influenza.* www.opm.gov/pandemic/agency/quick_reference.asp
- OPM and GSA Policy on Telework www.telework.gov
- HHS Telecommuting Program Policy http://intranet.hhs.gov/ohr/telework/policy.html
- *Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States,* http://www.flu.gov/professional/community/commitigation.html

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Food and Drug Administration

FDA CRISIS MANAGEMENT ANNEX TO THE FDA EMERGENCY OPERATIONS PLAN

August 2010

OFFICE OF CRISIS MANAGEMENT

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A INTRODUCTION

The U.S. Food and Drug Administration (FDA) ensures the safety, quality, and effectiveness of over $1 trillion worth of products, which account for 25 cents of every dollar spent annually by American consumers. Given the large volume of products regulated by the agency and today's global economy and complex geopolitical environment, it is increasingly likely that crisis situations impacting or involving FDA-regulated products will occur. The FDA Crisis Management Annex to the *FDA Emergency Operations Plan (EOP)* [94] establishes a structure and methodology for responding to crises involving FDA-regulated products. This annex is compatible with the scalable, flexible, and adaptable emergency coordinating structures of the National Response Framework (NRF), and is consistent with the concepts, principles, and terminology of the National Incident Management System (NIMS)[95] and the *FDA EOP*. The FDA Crisis Management Annex is to be used, in conjunction with the *FDA EOP* and other *FDA EOP* Annexes when applicable, to assist FDA in conducting response operations for any crisis.

A.1 MISSION

FDA's public health mission as described in the *FDA EOP*, Section A.1, applies to this annex; however, during a crisis, the agency may be required to temporarily discontinue or curtail some amount of its routine non-critical day-to-day operations in order to redirect resources needed to support its crisis response operations.

A.2 PURPOSE

The FDA Crisis Management Annex is intended to be used in conjunction with the *FDA EOP* and other *FDA EOP* Annexes and is not intended to be a "stand-alone" plan. The purpose of the FDA Crisis Management Annex is to describe FDA responsibilities and operations specific to a crisis in order to provide a coordinated and consistent agency approach to managing response operations for incidents that have reached a critical level. To accomplish this, the FDA Crisis Management Annex:

- Is compatible with and expands on the *FDA EOP*
- Describes the process by which FDA identifies and designates a crisis
- Explains the agency's crisis response roles and responsibilities of senior-level officials and components
- Describes additional resources and capabilities for response to a crisis

A.3 SCOPE AND APPLICABILITY

For purposes of the Crisis Management Annex, a "crisis" is defined as an incident or event involving an FDA-regulated product that poses a significant threat to the public's health and exceeds the agency's ability to respond through the use of emergency procedures and resources.

The FDA Crisis Management Annex covers the requirements in anticipation of or in response to a crisis that impacts or involves an FDA-regulated product, whether the crisis is the result of an inadvertent or deliberate action. It applies to the need for the Commissioner and senior-level officials to resolve unprecedented legal, regulatory, policy, and resource problems and impasses brought about by the emergency and which impact the agency's ability to respond effectively.

[94] For more information on how the FDA responds to emergencies, refer to the FDA EOP.

[95] For more information on the *NRF* and *NIMS*, refer to the FDA EOP, Section G, Authorities and References or visit www.fema.gov/emergency/nrf/.

A.4 PLANNING ASSUMPTIONS

The FDA Crisis Management Annex is based on the same planning assumptions stated in the *FDA EOP*. In addition, the agency's use of emergency procedures and resources described in the *FDA EOP* are insufficient for response to a crisis.

A.5 ACTIVATION

The Commissioner and OCM Director, in consultation with the Counselor to the Commissioner and any already established Agency Executive Group (AEG) or other appropriate senior officials, will determine if an incident meets the definition of a crisis as provided in Section A.3. The Office of Crisis Management (OCM) Director will then activate the Crisis Management Annex to augment the use of the *FDA EOP* in response to the incident.

Combined factors that may lead to activation of the Crisis Management Annex include, but are not limited to, the following:

- Widespread fatalities, illnesses, or injuries associated with an FDA-regulated product
- Widespread public panic related to an unsafe FDA-regulated product
- A situation or conditions that warrant ongoing direct involvement of the Commissioner or Deputy Principal Commissioner
- The need for a level of response that exceeds the agency's technical, budgetary, or staffing resource capabilities
- The reassignment of staff (non-Incident Command System [ICS]) from non-critical duties to duties that support the accomplishment of response objectives
- Ongoing reports of illness, injury, or deaths associated with product(s) for which a source or cause of the problem cannot be determined

A.6 SUPERSEDENCE

The Crisis Management Annex supersedes the FDA Crisis Management Plan (November 2004).

B CONCEPT OF OPERATIONS

The following concept of operations (CONOPS) section of this annex describes the principal authorities governing agency emergency functions and the components of FDA's crisis management process.

B.1 EMERGENCY OPERATIONS PHASES

Three phases comprise the entire spectrum of FDA emergency operations: ***Prevention and Protection, Response, and Recovery.*** When an emergency has evolved into a crisis, FDA employees are expected to follow the activities described in the *FDA EOP*, Section B.*2. Emergency Operation Phases.* Although emergency operations may involve each of these phases over the course of an incident, the nature and severity of a crisis event typically result in the need for operations to focus on the Response Phase. The following sections describe additional Response activities FDA would perform during a crisis event.

B.1.1 Response

B.1.1.1 Gain and Maintain Situational Awareness

B.1.1.1.1 Alert and Notification

As with emergencies, OCM's Office of Emergency Operations (OEO) Emergency Operations Center (EOC) serves as the focal point for the coordination of agency emergency operations, and receives notifications of potential emergencies involving FDA-regulated products as well as reports of potential crises involving FDA-regulated products.

To ensure a clear understanding that a determination has been made for the agency to respond to an incident as a crisis, the Commissioner, Principal Deputy Commissioner or their designee, or the Office of the Counselor to the Commissioner will issue written communication to senior agency officials informing them of the crisis determination, that the Crisis Management Annex is activated, and that a Crisis Management Team (CMT) is established to provide strategic policy leadership for the agency's response to the crisis.

B.1.1.2 Activation and Deployment of Resources and Capabilities

Upon activation of the Crisis Management Annex, the Commissioner, Principal Deputy Commissioner or their designee, or the Counselor to the Commissioner will activate a CMT. The CMT will comprise senior FDA leaders who provide strategic and policy direction for the crisis response. For more detailed information about the composition of the CMT, please see Section D of this annex.

If an already established Incident Management Group (IMG) reported to an AEG or if an IMG is newly appointed, the IMG will report to the CMT and any previously established AEG will be demobilized.

B.1.1.3 Coordination of Response Actions

Coordination of FDA response actions while the CMT is activated will follow the *FDA EOP*, Section B, augmented by the following coordination and response activities at FDA headquarters.

The CMT makes strategic and policy decisions regarding the handling of a crisis, including issues presented to it by the IMG. The CMT establishes clear, written objectives for the response effort, identifies metrics for determining when the objectives are met, and develops plans for the demobilization and termination of crisis response operations.

The CMT ensures that the Commissioner and other senior FDA leaders are adequately informed about the crisis and, where appropriate, are involved in decisionmaking. The CMT also provides strategic direction on the management of the agency's public communications to ensure that consistent information is disseminated about the crisis and FDA's response efforts. This may include determining what critical messages/information should be disseminated to news media, industry, health professionals, and

Congress about the incident, FDA's response efforts, and the guidance that is to be provided to consumers to help protect themselves as needed.

B.1.1.4 Demobilization

The FDA CMT will demobilize when it is no longer needed to resolve legal, regulatory, policy, and resource problems and impasses brought about by the emergency and which impact the agency's ability to respond effectively. If needed, an AEG may be established to provide strategic policy direction and guidance and to approve important policy decisions.

C ORGANIZATION AND ASSIGNMENT OF RESPONSIBILITIES

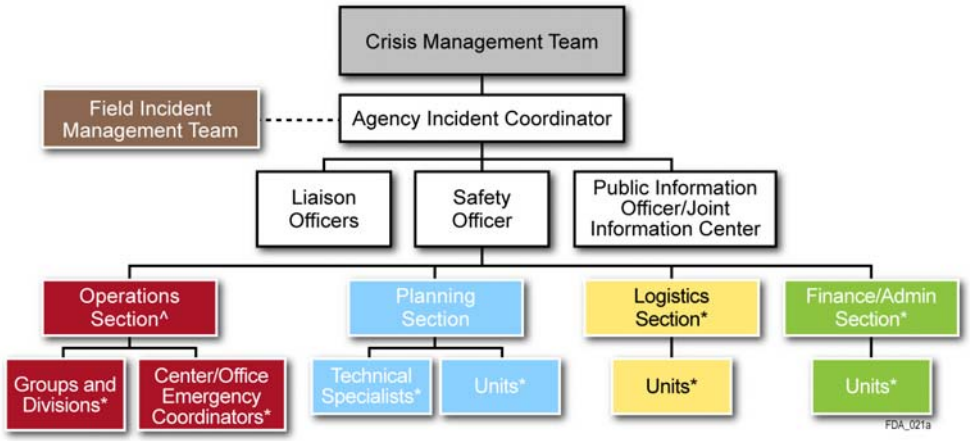
This section identifies the essential roles and functions of FDA Centers and Offices responding to a crisis. The Centers and Offices listed in this annex have additional tasks in supporting Command and Control Operations during a crisis that were not identified in the *FDA EOP*, Section C.

During a crisis, the Commissioner or Principal Deputy Commissioner will play a greater role in overseeing the agency's response efforts and authorizing actions to resolve legal, regulatory, policy and resource problems and impasses. Several organizational leaders within the Office of the Commissioner (OC) will play a significant role in participating in the CMT as core members. They are the Commissioner or Principal Deputy Commissioner, Counselor to the Commissioner, OCM Director, and Associate Commissioner for Regulatory Affairs. Depending on the scope of the incident, additional OC leaders who may be called upon are Chief Scientist and Deputy Commissioner for Science and Public Health, Deputy Commissioner for Foods, Deputy Commissioner for International Programs, Deputy Commissioner for Administration, Assistant Commissioner for Counterterrorism & Emerging Threats, Associate Commissioner for External Affairs, and Chief Counsel.

D DIRECTION, CONTROL, AND COORDINATION

This section provides a description of the CMT and additional IMG roles and responsibilities specific to a crisis response. FDA response operations for major incidents are based on the concepts, practices, and principles of the *NIMS* and its organizational structure, the ICS. The establishment of a CMT does not change the agency's incident command structure as described in the *FDA EOP,* Section D. *For a complete listing of the FDA ICS structure (IMG),*[96] *refer to the FDA EOP,* Section D, Direction, Control, and Coordination.

Figure D-1. Incident Management Group Structure with a Crisis Management Team



*as necessary
^This section may become the Information and Intelligence Gathering Section

D.1 CRISIS MANAGEMENT TEAM

To facilitate the agency's management of a crisis, a CMT is established by the Commissioner, Principal Deputy Commissioner, or their designee. The CMT comprises senior FDA leaders who provide strategic and policy direction for the crisis response.

Members of an already existing AEG may be appointed to the CMT by the Commissioner, Principal Deputy Commissioner, or their designee; but, at a minimum, the CMT will include the following:

- Commissioner or Principal Deputy Commissioner
- Counselor to the Commissioner
- Director(s) of Center(s) involved in the response
- Associate Commissioner for Regulatory Affairs and
- OCM Director

Depending on needed expertise and leadership, the Commissioner, Principal Deputy Commissioner, or their designee may appoint additional senior officials to the CMT, including, but not limited to the:

- Chief Scientist and Deputy Commissioner for Science and Public Health
- Deputy Commissioner for Foods
- Deputy Commissioner for International Programs
- Deputy Commissioner for Administration
- Assistant Commissioner for Counterterrorism & Emerging Threats
- Associate Commissioner for External Affairs
- Associate Commissioner for Legislation
- Chief Counsel

[96] For more information on specific roles and responsibilities of each ICS position, refer to the FDA EOP Appendix K "Job Action Sheets"

The CMT makes strategic and policy decisions regarding the handling of a crisis, including issues presented to it by the IMG. The CMT should establish clear, written objectives for the response effort, identify metrics for determining when the objectives are met, and develop plans for the demobilization and termination of crisis response operations.

The CMT ensures that the Commissioner and other senior FDA leaders are adequately informed about the crisis and, where appropriate, are involved in decisionmaking. The CMT also provides strategic direction on the management of the agency's public communications to ensure that consistent information is disseminated about the crisis and FDA's response efforts. This may include determining what critical messages/information should be disseminated to news media, industry, health professionals, and Congress about the incident and FDA's response efforts and what guidance is to be provided to consumers to help protect themselves as needed.

The demands associated with serving as a member of the CMT may call for CMT members to designate someone to serve as their alternate in the performance of duties associated with their official agency positions.

D.1.1 Crisis Management Team Lead

The Commissioner, Principal Deputy Commissioner, or his/her designee, or the members of the CMT will designate one of the members to be the CMT Lead. The CMT Lead is responsible for directing the CMT's strategic and policy management of the agency's response to the crisis. The CMT Lead convenes meetings of the CMT, seeks to achieve consensus in decisionmaking whenever possible, and resolves any decisionmaking conflicts that emerge, consulting with the Commissioner as needed. The CMT Lead has the authority to make decisions if a consensus cannot be reached**,** except that any CMT member may request that the Commissioner make the final decision.

D.2 COMMAND STAFF

D.2.1 Incident Management Group Coordinator

If an IMG is established as part of the agency's response to a crisis, the IMG Coordinator serves within chain-of-command reporting to the CMT. In addition to the roles and responsibilities described in the *FDA EOP*, the IMG Coordinator will:

- Participate in CMT meetings, discussions, and decisionmaking relative to the strategic management of the agency's crisis response efforts
- Provide input into the development of strategic plans and direction relative to the roles and responsibilities of the IMG (See *FDA EOP*, Section D.)
- Ensure that the CMT's strategic response plans and direction are accurately and effectively communicated to the IMG
- Report to the CMT on the status of the IMG's implementation of strategic plans
- Inform the CMT what impact the implementation of CMT strategic plans has had on the agency's ability to respond effectively to the crisis
- Make recommendations to the CMT regarding needed changes to CMT's strategic plans based on IMG efforts to implement the plans
- When appropriate, request IMG Section Chiefs to provide briefings to the CMT on their functional areas' activities

E COMMUNICATIONS AND INFORMATION MANAGEMENT

E.1 PUBLIC MESSAGING

Because communicating with the broad public during a crisis can be one of the most effective tools the agency can use to help mitigate the public health impact of the incident, the CMT will provide strategic guidance for public messaging. Communications will be a key component of the CMT's strategic planning process. During a crisis, it is paramount that the information the agency provides to various stakeholder groups about the crisis and FDA's response work is consistent, accurate, relevant to audience needs, and updated as a timely basis.

As described in the *FDA EOP,* Section E.3*,* the Offices of Public Affairs and External Relations within the OC Office of External Affairs are the focal point for the coordination, development, issuance, and dissemination of information to the general public and for targeting relevant audiences. The Office of Legislation is responsible for communication with Congress. In addition, other FDA Offices and Centers provide input into the development of public messages and the identification of target audiences.

Based on their situational awareness of a crisis, the CMT may provide these Offices with direction and guidance relative to:

- An agency communications strategy with goals and objectives specific to the incident
- The identification of key stakeholders with whom the agency should communicate about the crisis and the agency's response efforts; examples of key stakeholder groups include, but are not limited to, consumers, the news media, Congress, other Federal Agencies, State and local governments, industry and consumer groups.
- The identification of broad topics from which to create key messages that can be used with targeted stakeholder groups and audiences
- Various mechanisms and media through which to communicate, such as news releases, Internet posting of questions and answers and fact sheets, social media, and participation in press conferences and briefings with other government officials
- Establishing a daily "lid" for communications with media and stakeholders (a time each day after which no new information will be released) as a means of managing the accuracy, consistency, and integrity of information related to the crisis

Most crises, by nature, are volatile and constantly changing. An anxious public looks to government officials for accurate and updated information to help them determine what personal risk is posed by the incident and what they can do to protect themselves and to gain an understanding of what FDA is doing to alleviate the crisis.