CHAPTER 8 - INVESTIGATIONS

CONTENTS

SUBCHAPTER 8.1 - INVESTIGATIONS

This Chapter contains specific information on many types of investigations and each section provides additional guidance for you on how to investigate particular issues, special reporting requirements and where additional assistance can be obtained. Recall work, a special type of investigation, is covered in Chapter 7. There is an on-line training course in Investigations which covers many types of investigations and provides additional information.

An investigation is an information gathering activity you conduct for many different reasons. The purpose of any investigation is to determine and document facts concerning a particular issue so the Agency can make informed and sound decisions. Investigation is a general term and can apply to a very general activity or a specific type of information gathering process. Some specific types of investigations include a complaint investigation, a disaster investigation, a health fraud investigation and a product tampering investigation. Investigations can be distinguished from inspections because usually you will not need to issue an FDA 482, you will be working somewhere other than a manufacturing plant, you may be visiting retail establishments, consumers, or other government agencies. On rare occasions, you may be conducting an investigation without advising individuals you are a FDA employee. Keep in mind that investigations can not all be categorized and there will be times when you do issue an FDA 482, such as when you are at a manufacturing site or doing work similar to an inspection. Experience gained on the job will help you determine the proper course of action for these special situations.

Reporting an investigation is almost always done using a memorandum see Exhibit 5-17. The format is not as defined in sections as an inspection report. A good rule of thumb to follow is to first summarize what you did, why or give the reason for the investigation and briefly state the findings. After this, you can go into detail about how you conducted the investigation and what you found. Reporting the course of your investigation and your findings chronologically works in many situations. For long narratives, using headings will make it easier for the reader to follow your reporting. Some types of investigations have forms that need to be completed in addition to the narrative. Your report will be in English, see IOM 1.1.

SUBCHAPTER 8.2 - COMPLAINTS

A complaint is notification that a product in commercial distribution may be in violation of the laws and regulations administered by FDA.

Complaints are received from various sources, including consumers, other government agencies, Congress on behalf of their constituents, trade associations, etc. Enter complaints into the FACTS Consumer Complaint System. Complaints should be promptly acknowledged in written format, by telephone or visit. See Field Management Directive (FMD) 119.

Consumers contacting field offices with complaints of injury or illness should receive a prompt, courteous response and assurance their complaints will receive appropriate consideration. An immediate follow-up may be warranted when there is an indication of, a serious illness or injury. Unless a visit to the complainant is assigned, any and all information should be obtained during a telephone call with the consumer. Do not rely on the consumer to freely offer all pertinent information. Use critical thinking skills and ask pertinent questions to aid in identifying the problem and where it may have occurred. Record information on the consumer complaint form in FACTS.

Obtain sufficient information to enable evaluation of the complaint, determination of appropriate follow-up, and, if possible, enough facts to permit further FDA evaluation and response without subsequent contact with the complainant. If a complaint cannot be resolved immediately, determine if the complainant expects further contact. If so, report the best time to reach the complainant. For complaints involving special nutritional products (i.e., infant formula, medical foods and dietary supplements, complete the FACTS Adverse Event Questionnaire, see Exhibit 8-1). See IOM 8.4.5.2.2 for additional instructions regarding special nutritional complaints.

The FDA Office of Crisis Management/Office of Emergency Operations (OCM/OEO) HFA-615, 301-796-8240 must be notified immediately of all significant injury, illness and suspected tampering complaints. OCM/OEO must also be notified of all complaints regarding infant formula/baby food.

Significant injury/illness includes, but is not limited to, any life threatening event; seizures; severe respiratory distress syndrome including broncho-constriction or bronchospasm; acute asthmatic attacks, anaphylactic or hypotensive episodes; unconsciousness or coma, or any event requiring medical treatment. Also to be included are behavioral or mood disorders of sufficient intensity to alter the daily activities of the consumer. These complaints require immediate and thorough follow-up, unless specifically directed otherwise by OCM/OEO. OCM/OEO is also to be kept advised of the status of all such follow-up investigations. Information about complaints nationwide is available in FACTS and from OCM/OEO and may be helpful in determining appropriate follow-up.

Complaints concerning products which do not present a hazard to health may be investigated by the home district during the next planned inspection of the responsible firm.

If the complaint concerns a matter not under FDA jurisdiction, or one which would more properly be handled by another agency, refer the complainant to the appropriate organization whenever possible.

8.2.1 - COMPLAINT CATEGORIES

Complaints can be divided into two categories.

8.2.1.1 - Injury/Illness Complaints

A complaint indicating a serious injury, illness, hospitalization, or death requires immediate reaction. It will, in all likelihood, require immediate investigation. It may include the accumulation of epidemiological data and prompt liaison with other appropriate federal, state and local agencies.

A complaint that clearly indicates an illness resulting from consuming a FDA regulated product, and manifested by symptoms such as nausea, vomiting, fever, or diarrhea, should receive prompt follow-up by FDA or cooperating officials.

Conversely, some illnesses are considered psychological in nature (e.g., a consumer finds a foreign object in a product and becomes ill because it is revolting). For purposes of conducting follow-up and reporting to headquarters, these should be handled as non-injury/ illness complaints and do not need to be reported to the OCM/OEO.

8.2.1.2 - Non-Injury/Illness Complaints

These do not require immediate follow-up at the consumer level. Follow-up may include examining the parent lot, referral to another FDA district, state, or local agency, or deferral until the next regularly scheduled inspection. Examples include mold in beverages, obvious filth or insects in canned goods, etc. It may be possible that adequate investigation would be contacting the dealer, advising them of the nature of the complaint and requesting notification of any action taken. Non-injury/illness complaints do not need to be reported to the OCM/OEO unless product tampering is suspected or the product is a baby food or infant formula.

8.2.2 - INFANT FORMULA AND BABY FOOD

There is a continued sensitivity to all reported incidents involving infant formula or baby food. All complaints involving either infant formula or baby food are to be thoroughly investigated on a high-priority basis. This will include follow-up at the doctor or hospital (if an injury/illness is involved), with the collection and analysis of appropriate samples. Complaints involving baby food that is regulated by USDA should be referred to USDA for appropriate follow-up. See IOM 8.3.1.3 and 3.2.1.2.

There are two exceptions for collecting samples as part of the follow-up to infant formula/baby food complaints:

1. Complaints involving outdated product in the marketplace, with no associated injury or illness. These do require investigation to ensure all outdated product has been removed from the identified retail and/or wholesale source.
2. Complaints involving an illness associated with normal appearing product, but follow-up investigation discloses a physician's diagnosis that the event does not

appear to be product related, or that the event was an allergic response to a properly labeled product.

Also see the following:
1. IOM 8.4.5.2- Dietary Supplements
2. IOM 8.3.1- Foodborne Outbreaks

8.2.3 - COMPLAINTS INVOLVING ALCOHOLIC BEVERAGES

All tampering complaints involving alcoholic beverages should be entered as a consumer complaint in FACTS. OCM/OEO and OCI should be notified immediately. For all other complaints involving alcoholic beverages, please see IOM 3.2.8.1 for guidance.

8.2.4 - OFFICE OF EMERGENCY OPERATIONS GUIDANCE

The FDA Office of Crisis Management/Office of Emergency Operations (OCM/OEO) HFA-615, 301-796-8240 must be notified immediately of all serious injury/illness and suspected tampering complaints. The OCM/OEO is also to be kept advised of the status of all such follow-up investigations. Information about complaints nationwide is available in FACTS and from the OCM/OEO and may be helpful in determining appropriate follow-up.

As unique situations arise, OEO provides guidance concerning the type of follow-up to be made. This guidance should be kept on file by the district consumer complaint coordinator.

8.2.5 - INTERVIEWS

The key to a thorough consumer complaint investigation is complete interviews with the complainant and/or others knowledgeable about the incident (other family members, health professionals, law enforcement officials, etc.). In addition, in preparation for any consumer complaint interviews, you should take your personal safety into consideration. Refer to IOM 5.2.1.2 for more information.

8.2.5.1 - Basic Information to Obtain

The basic information to be obtained is in the FACTS Consumer Complaint Report which replaces the 2516 and the Consumer Complaint Follow-Up Report which replaces the 2516a. See IOM Exhibit 8-2 and 8-3. Obtain an accurate and complete description of the product, e.g., brand name, product name, flavor or variety, how packaged, storage conditions required (i.e., refrigerated or shelf stable) etc. Enter this description in the Brand Name and Product Name sections of the FACTS complaint form.

It is important to accurately determine the sequence of events leading up to the complaint. This includes a 72-hour food history (for food related illness); whether the complainant has used the product before (cosmetic or drug products); condition of the product when purchased or consumed (tampering complaints, mold in foods, possible mishandling, product abuse in the home, etc.); and storage of the products (if filth is the subject of the complaint).

8.2.5.2 - Injury/Illness Complaints

There are additional considerations with injury/illness complaints. The prior medical history of the complainant may provide indications regarding allergies, drug side effects or drug-food/drug-drug interactions which may be responsible for the illness or injury. Medical verification should be sought in these situations. Food illnesses are frequently associated with the most recent food consumed, food that didn't appear or smell right, or a food consumed only by the ill person. Additional interviews may be required to identify other suspect foods, especially if the food implicated is not a likely vehicle for illness. Familiarity with items previously associated with illness or injuries is helpful in pursuing the investigation; such as pet turtles or occupational sources for Salmonella; incompatibility of soft contact lenses with lens solution or other eye products not specifically approved for use with them; production of acetic acid by aspirin as it decomposes; and the bitter or burning taste of calcium chloride-contaminated frozen ice cream novelties. Consider that individuals differ in sensitivity to bacterial levels or toxins, and not everyone using or consuming a contaminated product will show symptoms.

8.2.5.3 - Additional Information to Obtain

Additional information to be obtained for adverse events involving foods, dietary supplements, botanicals and cosmetics is contained in the FACTS Adverse Event Questionnaire and the Cosmetic Questionnaire, IOM Exhibits 8-1 and 8-4. This information should be entered into FACTS by the District receiving the complaint prior to forwarding the complaint to the home district of the manufacturer.

8.2.5.4 – Complainant Access to Report/ Results

The complainant may request a copy of your investigative report or sample results. Inform the complainant that they can receive the results of any sample collected from them, in accordance with the Freedom of Information Act (FOIA), after the Agency has determined that there is no consideration of criminal prosecution or such consideration has occurred and the matter is closed. Also inform them there may be a slight charge for the investigatory report as required by the FOI Regulations. See IOM 1.4.4.

8.2.6 - MEDICAL RECORDS

In investigating complaints where the complainant was seen by a health professional, contact the health professional concerning the nature of the alleged illness/injury, and the relationship to the product. You may occasionally find the complainant has not mentioned the product as a potential cause of the illness or injury to the health professional. Use judgment as to the usefulness of collecting medical records. Examples of medical records to collect include: Admission History and Physical; Emergency

Room/Clinic Record of the event if patient not admitted; Discharge Summary; Autopsy Report; and, Death Certificate. See also IOM 5.3.8.6.

If collection of medical records is necessary, use the FDA 461, Authorization for Medical Records Disclosure, signed by the patient or someone authorized to act for the patient. See IOM Exhibit 8-5. It may be necessary to use multiple forms if medical records are at different locations. Have at least three FDA 461 forms available for patient signature. If you encounter resistance from the medical professionals in providing records, you may refer them to 45 CFR 164.512(b) which explains the exemptions allowing FDA access to the medical records.

The FDA 461 is not required to obtain records from the Department of Defense (DoD) medical facilities. Identify yourself to the Commanding Officer of the facility or representative and request authorization to examine and copy records. DoD Directive 6040.2, Release of Information from Medical Records, authorizes release of medical information to government agencies.

NOTE: Many states require statements concerning other subjects besides those covered on the FDA 461. If the hospital does not accept the FDA version of the Authorization for Medical Records Disclosure, obtain and complete one of their forms for use at their facility.

Collect all medical records pertinent to the investigation.

8.2.7 - SAMPLE COLLECTION

Sample collection authority, definitions and procedures are discussed in detail in IOM Chapter 4.

Prior to initiating sampling collection, you may consider contacting the home district of the manufacturing plant. They may be aware of an existing issue related to the product and problem.

A thorough investigation will provide information to form a hypothesis as to the cause of the illness, injury, or product problem and will assist in determining what sample(s) to collect. Adequate samples should be collected immediately, while they are available. Do not overlook sampling any product which may be remotely implicated in the incident. Consult with your servicing laboratory for guidance on specific sample sizes. See IOM 8.4.5.2 for guidance on sampling dietary supplements.

In addition to the consumer portion, intact containers of products of the same lot should be collected from the retail and wholesale levels. These samples provide more useful information regarding the product in consumer channels, and may prove useful in any future legal action. Refer to IOM 4.3.5.1 for information concerning collection of consumer portions.

8.2.8 - RECORDING COMPLAINTS/FOLLOW-UPS

The FACTS Consumer Complaint Report and Follow-Up Report are used for recording and investigating all complaints (except drug reactions - see IOM 8.4.2.1), unless previously reported through one of FDA's other post-marketing surveillance systems. See IOM Exhibits 8-2 and 8-3.

SUBCHAPTER 8.3 - INVESTIGATION OF FOODBORNE OUTBREAKS

8.3.1 - FOODBORNE OUTBREAKS

If you become aware of a foodborne outbreak, contact the OCM/OEO 301-796-8240 immediately. Generally, epidemiological investigations are conducted by state and local public health authorities. Epidemiological investigative techniques have been established to assist in determining the cause of a foodborne outbreak or illness. The information presented describes the standard methods for gathering and evaluating data. In fact, these techniques are useful in investigating all types of complaints.

8.3.1.1 - Outbreaks on Foreign Flag Vessels

If a suspect outbreak involving a foreign flag vessel or a US flag vessel with an international itinerary comes to your attention, report it to your supervisor and OCM/OEO 301-796-8240 immediately. The Centers for Disease Control and Prevention (CDC) assumes primary jurisdiction for foreign flag (non-US registry) and US flag vessels with international itineraries entering the US and traveling in US waters. See IOM 3.2.4.3.

8.3.1.2 - Outbreaks Involving Interstate Conveyances

Reports of illness attributed to travel on an interstate conveyance (plane, bus, train, or vessel) are a shared responsibility of FDA and CDC. When a report of illness is received, notify OCM/OEO at 301-796-8240 and you are encouraged to share the report with state and local public health officials. The following procedures are to be coordinated with local/state public health officials:

Interviews with the ill passenger, family members (well and ill), caregivers, and/or health professional (as appropriate) should be sufficiently probative to hypothesize if the food, water or an environmental transmission is related to the illness. Transmission of illnesses, particularly viral diseases, by ill employees and contaminated environmental surfaces can result in illness carryover between successive trips and should be considered. Factors such as time of onset of symptoms, symptoms, food history for the 72 hours prior to onset of the first symptom, any clinical laboratory results, and other potential exposures should be documented. The carrier should also be contacted to determine if other reports of illness have been received (passengers and employees). Obtain any illness logs from the carrier. The information developed should be evaluated to determine if further follow-up is necessary. On those carriers where a reservation system is used, obtain the names and phone numbers of passengers. It may be necessary for the state/local health authorities,

CDC or FDA to contact other passengers to determine if they became ill.

If additional cases are uncovered during these contacts, immediately notify the OCM/OEO and the state and local public health authorities in all of the affected states. FDA will work cooperatively with these authorities and request their assistance in conducting an epidemiological investigation and collecting patient specimens. Note: If at any time the local/state public health officials are unable to assist with an investigation, notify the OCM/OEO, who will contact CDC and request assistance in the epidemiological investigation.

8.3.1.3 - Cooperation with Other Agencies

One of FDA's functions is to assist local, State, and other Federal agencies in conducting investigations, collecting samples, and conducting plant inspections if warranted.

In addition to state and local health departments, the following federal agencies may also become involved in investigating foodborne disease outbreaks:
1. U.S. Department of Agriculture (USDA)
2. Centers for Disease Control and Prevention (CDC)
3. Environmental Protection Agency (EPA)

Whenever a complaint is received involving any meat-containing product, including such items as soups, combination infant foods, frozen dinners, etc., evaluate the need to contact USDA. Most products containing red meat or poultry are regulated by USDA. The exceptions include:
1. Products containing meat from game animals, such as venison, rabbits, etc.;
2. Meat-flavored instant noodles;
3. The product "pork and beans" (which contain only a small amount of pork fat and is regulated by FDA); and
4. Closed face sandwiches.

Determine from the consumer if there is a round "shield" on the label with the USDA Establishment Number. Alternatively, the establishment number may be identified in the lot number. Red meat products under USDA jurisdiction will often contain the abbreviation "EST" followed by a one to four digit number; poultry products under USDA jurisdiction will contain the letter "P" followed by a number.

IOM 3.2.1 and 3.2.4.3 provide information for reporting suspected outbreaks to USDA and CDC. In addition, FDA and CDC have an agreement that FDA will be immediately advised whenever CDC ships botulism antitoxin anywhere in the United States or its possessions.

Whenever the source water is suspected as a likely origin of the agent of an illness outbreak, Environmental Protection Agency (EPA) should be notified. For example, when investigating a foodborne outbreak on a vessel passenger conveyance, you may find the water used in food preparation to be from a land-based source or from an on-board water treatment plant. Both of these sources would fall under EPA jurisdiction. See IOM 3.2.11.

8.3.1.4 - Outbreaks Associated with Salmonella Enteritidis (SE) in Eggs

All reports regarding SE outbreaks, including any epidemiological and environmental data associated with whole shell eggs are to be referred to the OCM/OEO, 301-796-8240, (emergency.operations@fda.gov). The OEO will notify CFSAN Emergency Coordination and Response Staff immediately, who will serve as the lead CFSAN contact.

8.3.2 - FOLLOW-UP GUIDANCE

8.3.2.1 - Preparation

Investigator kits with proper equipment should be maintained in the district to facilitate immediate investigation of foodborne outbreaks. The kits should be re-stocked on a schedule recommended by FDA laboratory personnel to ensure continued sterility of sampling equipment. A supply of commercially available environmental sampling swabs containing transport media should be readily available as part of the investigation kit. These tubes provide a transport medium that will help preserve the environmental and food swabs.

If an alert or complaint indicates a large outbreak, inform your servicing laboratory immediately that samples will probably be collected and give the approximate time they are expected to arrive at the laboratory. This will assist laboratory managers planning work schedules, equipment and supplies.

Each district may have individuals specifically trained in epidemiological investigations who can provide advice on investigations. If not, consult with OCM/OEO at 301-796-8240 and the state and local public health authorities.

8.3.2.2 - Interviews

Health professionals, hospital personnel, or consumers may report suspected cases of foodborne illness. Regardless of the source of the report, the diagnosis must be verified by a thorough case history and, if possible, by examination of appropriate food samples and clinical specimens. This verification is done by public health professionals.

8.3.2.2.1 - CONTACTING THE COMPLAINANT

Upon contacting the affected person, identify yourself and explain the purpose of the visit or call. Neat attire, pleasant manner of speech, professional attitude and confidence in discussing epidemiology and control of foodborne illnesses are important in developing rapport with an affected person or family. Exhibit a genuine concern for persons affected, and be sincere when requesting personal and confidential information. Communicate a sense of urgency, and emphasize the positive contribution already made by the complainant toward the control and prevention of foodborne illness.

8.3.2.2.2 - SETTING COMMUNICATION LEVEL

Set your level of communication based on the person being interviewed. Tact is essential. Phrase your questions so the person(s) interviewed will describe their illness, and the foods and events which they feel were associated with it, in their own way. Use open ended questions. Never suggest answers by the way you phrase your questions.

Ask specific questions to clarify the affected person's comments. Realize people are sometimes sensitive to questions about age, gender, special dietary habits, ethnic group, excreta disposal and housing conditions. Phrase questions thoughtfully. Some information may usually be deduced from observations, but if doubt remains, confirm your hypothesis by asking questions. Information on recent travel, gatherings, or visitors may indicate common sources or events.

8.3.2.2.3 - INFORMATION TO GATHER

Gather information about all meals and snacks eaten seventy-two hours before onset of illness. The food, even the meal, which precipitated the illness, might not be obvious. The type of illness will sometimes give a clue.

If the first and predominant symptoms are nausea and vomiting, concentrate questions on foods eaten recently.

If the first and predominant symptoms are diarrhea and abdominal cramps, foods eaten six to twenty hours before onset of illness are suspect.

If diarrhea, chills and fever predominate, foods eaten twelve to seventy-two hours before onset of illness are suspect.

Remember that these suggestions relate to common foodborne illnesses. The more unusual illnesses often present different clinical patterns. For instance, some illnesses such as Typhoid Fever and Hepatitis A, have incubation periods greater than 72 hours. Refer to IOM Exhibit 8-6.

Use this detailed interview approach with every person identified in the initial complaint or alert, even though some may not have been ill, until you have sufficient information to determine if there is a foodborne disease outbreak.

8.3.2.3 - Medical Records

Physicians' and hospitals' records can be useful in verifying reported signs, symptoms and other clinical data and can sometimes rule out the possibility of foodborne illness. See IOM 8.2.6 and IOM Exhibit 8-5.

8.3.3 - SAMPLING PROCEDURES

CAUTION: Never taste any of the food products, and handle all samples with caution to prevent accidental ingestion of even minute amounts of the contaminated or suspect product.

8.3.3.1 - Sample Collection

During investigations of foodborne diseases, cooperate with other health officials in collecting samples of items that may be associated with the outbreak.

Use a menu or data from an attack-rate table to determine which of the foods from the implicated meal are most suspect and collect samples of the suspect foods. Check storage areas for items that may have been overlooked. Check garbage for discarded foods or containers. Suspect foods often are discarded by an operator if he thinks someone may have become ill as a result of eating in his establishment. Because one of the primary tasks of the investigator is to prevent further illness, take appropriate action to prevent distribution or serving of any suspect food until it has been proven safe. If no foods remain from the suspect meal or lot, try to collect samples of items prepared in a similar manner, but subsequently to the suspect lot. Collect ingredients or raw items used in the suspect food. Determine supplier, distribution, and code information on ingredients and packaged foods to aid any investigation of the same lot in distribution channels.

Collect samples aseptically. If foods are to be examined for organophosphate pesticides or heavy metals, do not use plastic containers. Use glass jars with foil lined lids because substances from the plastic can leach into the food and interfere with analysis.

The following are examples of articles normally collected:

1. Remaining portions of all suspect foods;
2. Parent stocks of suspect foods;
3. Insecticides, rodenticides, or other poisons which may be involved.
4. Suspect food containers such as cans, bottles, etc.;
5. Utensils or materials used in the preparation and storage of the suspect food;
6. Table scrapings and food residues from equipment such as slicing machines, cutting boards, etc.

NOTE: Clinical specimens such as vomitus, stools, swabs of nasal and throat passages or open sores or lesions of food workers are collected by local, state, or CDC health officials or private physicians.

8.3.3.2 - Sample Size

In general, follow the IOM SAMPLE SCHEDULE in Charts 1, 2, and 3 (IOM, Chapter 4). Where only small amounts of items remain, such as bits of leftovers, empty containers with adhering particles, etc., collect all or as much as possible by scraping from utensils, equipment or containers. It may also be necessary to collect the empty containers. See IOM 8.3.4.6.

8.3.3.3 - Sample Handling

Record the temperature of the room, refrigerator, or warmer in which the food was stored, and record the temperature of the food that remains after a sample is collected.

Inform the laboratory of the type and number of samples, and discuss methods to preserve and transport samples, time of arrival, and the person who will receive the shipment.

Samples of products frozen at the time of collection should be maintained frozen until analyzed. Samples of perishable foods, which are not frozen at the time of collection, should be cooled rapidly to a temperature of 4.4°C (40°F) and maintained at this temperature if they can be analyzed within eight hours. If analysis cannot be started within eight hours, and you suspect microbial contamination, contact your servicing microbiology laboratory for proper handling procedures.

Transport refrigerated or frozen samples to the laboratory in insulated containers, packed with an appropriate refrigerant to maintain the desired temperature during transit. Send samples to the laboratory by the most expeditious means. Clearly mark: "PERISHABLE FOOD SAMPLE FOR MICROBIAL EXAMINATION - RUSH," "PRIORITY." Label specimens according to applicable regulations governing transport of hazardous material. See IOM 4.5.5.8.6.

If the suspect food is a commercial product, examine the original package or container for coding information to identify the place and time of processing. Your district may notify all agencies responsible for regulating the products alleged or suspected to have caused the illness. Collect additional packages bearing the same code number for analyses for microorganisms, toxins, seam defects, vacuum, leaks, or other conditions. Be as specific as possible in requesting the type of analysis.

8.3.4 - EPIDEMIOLOGICAL ASSOCIATIONS

Conduct a preliminary evaluation of your epidemiological data as soon as possible. If your data suggests an outbreak has occurred, develop a hypothesis about the causal factors. Test your hypothesis by obtaining additional information to prove or disprove its validity.

8.3.4.1 - Outbreak Determination

An outbreak is an incident in which two or more individuals have the same disease, have similar symptoms, or excrete the same pathogens; and there is a time, place, and/or person association between these individuals. A foodborne disease outbreak results from ingestion of a common food by such individuals. However, a single case of suspected botulism, mushroom poisoning, paralytic shellfish poisoning, rare disease, or a disease which can be definitely related to ingestion of a food, may be considered as an incident of foodborne illness which warrants investigation.

Sometimes it will be obvious from an initial report that a foodborne disease outbreak has occurred, simply because of the number of individuals displaying certain symptoms at or near the same time. Many complaints, however, involve illness in only one or two individuals, and determining a particular food was responsible, or its consumption and the onset of illness was only coincidental, is often difficult. Certain diseases that are highly communicable from person to person, such as epidemic viral gastroenteritis, or those associated with a common place, such as carbon monoxide poisoning, may simulate a foodborne illness.

If additional complaints connected with the same food or eating establishment are received, food is almost certainly involved. A food-related or enteric disease alert/complaint log assists in determining if similar complaints have been received.

Time associations primarily refer to onset of similar illnesses within a few hours or days of each other. Place associations deal with buying foods from the same place, eating at the same establishment, residing at the same place, or attending the same event. Person associations have to do with common experiences, such as eating the same foods or being of the same age, gender, ethnic group, occupation, social club, or religion. Once some of these associations become obvious, verify the outbreak by identifying and interviewing other individuals who were at risk by virtue of their association with the ill persons.

8.3.4.2 - Assistance

If the outbreak affects a large number of individuals or food establishments, consult with your supervisor regarding the need to seek assistance from other health professionals. A team consisting of an epidemiologist, microbiologist or chemist, sanitarian, and others may be required to make a sufficiently detailed foodborne illness investigation. Such personnel may be provided by local, state or provincial, or national agencies concerned with health, food and drug, environment, fish or agriculture.

8.3.4.3 - Additional Case History Interviews

Seek and interview additional individuals both ill and well, who had time, place, or person associations with the identified cases. If the suspect meal was served during a particular occasion, determine the name of the person in charge. That person may have a list of names, addresses, and telephone numbers of persons who attended. Obtain menus of suspect meals as soon as possible. Additional cases may be identified by checking reservation books and credit card receipts. Review the districts food-related, enteric disease alert/complaint log for recently received complaints which may be related to the outbreak. Consult with your supervisor as to further contact with other health agencies, hospital emergency rooms, poison control centers, and local physicians to find additional cases. At this stage of the investigation, interviews can be accelerated by reviewing the event itself to stimulate each individual's memory. Inquire about specific symptoms known to be common to the suspected syndrome, and mention each food served at the event or meal.

The number of individuals to be interviewed depends on the proportion of attendees who are probably affected. As a rule of thumb, if no more than 100 people attended the meal, an effort should be made to interview everyone. If

several hundred were present, a random, representative number should be interviewed.

Prepare a separate FDA 3042, Food Illness Investigation Report, for each person interviewed. See IOM Exhibit 8-7. The FDA 3042 is intended as a guide to supplement a complete narrative report. Do not be restricted to this form in obtaining details during investigations. Information can be extracted from this form to compile an Attack Rate Table to pinpoint the suspect food. See IOM Exhibit 8-8.

8.3.4.4 - Establishment Investigation

When botulism or other foodborne outbreak is reported, and an establishment is inspected, the initial impact of the incident can create confusion at the plant, and conflicting instructions if too many individuals become involved.

To reduce the confusion, one investigator should be designated as the team leader. A supervisor should be the coordinator for overall district activities, and the district contact for headquarters personnel. All communications from FDA field or other offices to the firm's management should be channeled through the supervisor. The lead investigator should be responsible for all phases of the physical inspection of the facilities, and briefing the supervisor as to his progress. See IOM 5.1.2.5.2.

Upon arrival at the establishment where the suspect food was processed or prepared, the implicated meal was served, identify yourself to the person in charge and state your purpose. Emphasize the purpose of the investigation is to determine what contributed to the outbreak, so preventive measures can be taken. Attempt to create a spirit of cooperation. Consider the position, feelings, and concerns of the manager and his staff; defensive reactions are common.

Many factors could have contributed to contamination before foods came under the control of the manager. Assure him these possibilities will also be investigated. Inform the manager of the activities proposed and benefits which may be gained for educating his workers.

Review of distribution records and examination of warehouse stock are two important aspects of a botulism follow-up inspection. Each of these operations should be monitored by an investigator reporting directly to the team leader. These two monitoring investigators are responsible for all reports from their assigned areas, regardless of the number of investigators assisting them. Field examination should also include an inventory by code of all stock on hand. When conducting field examinations, follow instructions in IOM Sample Schedule Chart 2 (IOM, Chapter 4).

When preparing the report, follow instructions in IOM 5.1.2.5.1.

8.3.4.5 - Food Handlers Interviews

If a food is already suspect, interview separately all persons who were directly involved in processing, preparing, or storing of the food and others who could have observed preparation and storage. Ask questions in a sequence that discloses the flow of food from the time it was received until it was served or distributed. Especially inquire about foods that were prepared several hours or days before being served with the suspect meal. Ask similar questions, suitably modified, of the managers or workers who were involved in producing, transporting, processing, preparing, or storing food at other levels of the food chain, as well as individuals who prepared the food at home.

Food workers who fear criticism or punitive action because of their possible role in the outbreak do not always accurately describe the food handling as it actually happened. Their descriptions should be plausible, account for possible sources of contamination, and indicate possibilities of survival and potentials for growth of pathogens. If the description does not contain all the information desired, rephrase the questions and continue the inquiry. Seek confirmation of one person's story by talking to others who have knowledge of the food operation, or by watching the food preparation or processing practices. Be alert for inconsistencies among the accounts, as told by different individuals.

8.3.4.6 - Possible Contamination Source

It is important to have an understanding of the pathogen and the factors that contribute to the contamination that resulted in the foodborne illness. Some pathogens, such as Shigella, are associated with human fecal contamination, while other pathogens, may be more commonly associated with a particular food source (e.g. raw meat and E. coli O157:H7). Exhibit 8-6 and microbiologists can help provide useful information on sources and contributing factors.

8.3.4.6.1 - PESTS

Pests are a possible contamination source and can be an indication of poor hygiene, sanitation, food storage, handling and preparation practices. These pests include certain rodents, flies, cockroaches or other pests that:

1. Occur around human settlements.
2. Occur indoors as well as outdoors.
3. Are attracted to potential sources of pathogens (garbage, drains, excrement, etc.) and to human food.
4. Travel back and forth between possible sources of pathogens and food or food contact surfaces.

Evaluate whether a pest is a potential contributing factor to the outbreak by comparing your direct observations of pest activity combined with other evidence of pest activity (excreta, urine, gnawing, etc.) to the above criteria. A pest species that appears to meet all four of the above criteria is a possible source of pathogen contamination. It is helpful to collect specimens of any insect pest that meets these criteria for identification to determine if the pest species is one that is known to carry foodborne pathogens. See Appendix A.

8.3.4.6.2 - RAW MEAT

Raw poultry, pork, and other meats are often contaminated when they come into kitchens. If any of these agents are suspected in an outbreak, samples of meat and poultry, meat scraps, drippings on refrigerator floors, and deposits on saws or other equipment can sometimes be helpful in tracing the primary source. Swabbing food contact surfaces of equipment (as tables, cutting boards, slicing machines) which had contact with the suspect food may establish links in the transmission of contamination. This is especially true if a common utensil or piece of equipment is used for raw and cooked foods. Swab these surfaces with sterile swabs, moistened with a sterile solution (such as sterilized 0.1% peptone water or buffered distilled water). Break off the tip of the swab into a tube containing 5 to 10 ml of this solution or into a tube of enrichment broth for specific pathogens. Samples or swabs from air filters, drains, vacuum sweepings, food scrap piles, dried deposits on equipment, and dead ends of pipe lines may reflect the presence of organisms previously in the establishment.

8.3.4.6.3 - POOR SANITATION

Evaluate the cleanliness, manner, and frequency of cleaning equipment. Seek possible routes of cross-contamination between raw and cooked foods. As ingredients may be the initial source of pathogens, determine which were added before, and which were added after any cooking or heat processing.

8.3.4.6.4 - WORKERS

Workers can be a source of foodborne pathogens. Enterotoxigenic Staphylococcus aureus strains are carried in the nostrils of a large percentage of healthy persons. They are also found on the skin and occasionally in feces. Clostridium perfringens can be recovered from the feces of most healthy persons. Workers are sometimes infected with other enteric pathogens. Employee food safety training and knowledge should be investigated. Poor hygiene practices among food workers (e.g. not washing their hands), continues to be a major contributing factor to foodborne illnesses. See IOM Exhibit 8-6. If the same type of pathogenic organism is recovered from a fecal specimen of a worker and the suspect food, do not immediately conclude the worker was the source. A worker who ate some of the implicated food could be one of the victims. A history that includes a skin infection (boil or carbuncle) or a gastrointestinal or respiratory disturbance preceding the preparation of the suspect food would be more incriminating. Employee attendance and sick leave records may provide additional information.

Look for pimples, minor skin inflammation, boils and infected cuts and burns on unclothed areas of the body; ask if there are any infections in other areas.

8.3.4.7 - Pathogen Growth Factors

In addition to tracing sources of contamination, the circumstances which permitted survival and growth of foodborne pathogens in the implicated foods must be identified. This information is vital to develop preventive measures. Factors usually contributing to outbreaks of specific foodborne illnesses are cited in IOM Exhibit 8-6. Identify these factors by careful and diligent interviews of food workers; close observation of employees' food handling practices; checking temperatures of foods during processing and equipment in which the foods were held; and by conducting studies to determine time-temperatures relationships during processing and storage. Consider times and temperatures which were involved in freezing, thawing, cooking or thermal processing, hot and cold holding, chilling, reheating, and any other steps in the processing operations. It is important to know the survival and growth characteristics of the pathogen that caused the illness outbreak. For example, viruses do not replicate outside of the body and therefore will not "grow" regardless of the temperature. However, their survival characteristics should be considered. You should consult with a microbiologist or OCM/OEO prior to your investigation in order to understand the characteristics of the pathogen and focus on the relevant contributing factors.

8.3.5 - ANALYZING DATA/HYPOTHESIS FORMULATION

Organize and group the data obtained from interviews of both ill or well individuals. From appropriate calculations and analyses, the illness can be classified, the hypothesis tested as to whether the outbreak was associated with a common source, a vehicle can be determined, and the necessity for further field or laboratory investigation can be decided.

8.3.5.1 - Epidemic Curve

An epidemic curve is a graph which depicts the distribution of onset times for the initial symptoms of all cases that occurred in a disease outbreak. The unit of time used in the construction of the graph depends on the disease, or the period covered by the outbreak. For example, use a scale in days or weeks for Hepatitis A; and a scale in hours for staphylococcal food poisoning.

The epidemic curve assists in determining whether the outbreak originated from a common-source, such as food, or person-to-person propagation. A common-source epidemic curve is characterized by a sharp rise to a peak; with the fall usually being less abrupt. The curve continues for a period approximately equal to the duration of one incubation period of the disease. A person-to-person curve is characterized by a relatively slow, progressive rise. The curve will continue over a period equivalent to the duration of several incubation periods of the disease. (Exhibit 8-9)

8.3.5.2 - Symptoms Determination

Determine predominant symptoms by constructing a table as illustrated below:

Frequency of symptoms

Symptoms	Number of Cases	Percent with Symptoms (N = 20)
Vomiting	17	85
Nausea	12	60
Diarrhea	12	60
Abdominal cramps	6	30
Headache	3	15
Fever	2	10

The percent of ill persons who manifest each symptom is obtained by dividing the number of individuals reporting a given symptom by the number of individuals reporting any symptom (twenty in this example), and multiplying by one-hundred.

This information helps determine whether the outbreak was caused by an agent that produces a neurological, enteric, or generalized illness. Either infections or intoxications will be suggested. Such information can identify suspect foods and indicate appropriate laboratory tests.

8.3.5.3 - Incubation Periods

The incubation period is the interval between ingestion of a food contaminated with enough pathogens to cause illness and the appearance of the initial symptom of the illness. Calculate this interval for each case. Individual incubation periods will vary because of individual resistance to disease, differing amounts of food eaten, uneven distribution of the infectious agent or toxin throughout the food, and other factors.

The shortest and longest incubation periods give a range. Calculate the median incubation period, the mid-value of a list of individual incubation periods when ordered in a series from the shortest to the longest or the average of the two middle values if such series contains an even number of values. The median, rather than the mean, is used because the former is not influenced by exceptionally short or long incubation periods which are sometimes reported in outbreaks of foodborne illness.

The median and range of the incubation period, coupled with information regarding predominant symptoms, form bases upon which to judge whether the disease in question is an infection or intoxication and thereby determine what laboratory tests should be done.

See Exhibit 8-6.

8.3.5.4 - Attack Rate Table

Complete the Food-Specific Attack Rate Table. It provides an easy way to compare the percentage of ill persons who ate each food with the percentage of ill persons who did not eat each food. The attack rate table is useful in identifying the food responsible for an outbreak or illness. This food will usually have the highest attack rate, percent ill, in the column for persons who ate the food and the lowest attack rate in the column for persons who did not eat the food; it will also have the greatest difference between the two rates. See IOM Exhibit 8-8.

8.3.5.5 - Tracebacks of Foods Implicated in Foodborne Outbreaks

Traceback investigations are important epidemiological tools that are used to determine the source of food implicated in foodborne outbreaks. Traceback investigations may prevent further sale and distribution of contaminated food. Commonly, states or local government agencies conduct the initial epidemiological investigation of foodborne outbreaks and identify suspect (interstate) product(s) requiring tracebacks. In some cases FDA may be asked to assist another agency with a traceback investigation.

If a request for an inter-state traceback investigation is received by a District Office, it should be referred to the OCM/OEO 301-796-8240. OCM/OEO, CFSAN and ORA HQ staff will review the epidemiological data and hazard analysis or environmental assessment before initiating a traceback investigation. OCM/OEO will issue traceback assignments to the appropriate district(s). The task of developing and issuing assignments for traceback investigations related to outbreaks may be delegated from OCM/OEO to CFSAN/OC as necessary. OCM/OEO will coordinate inter-district assignments for traceback investigations. The field should use the FDA Guide to Tracebacks of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations, dated April 2001, unless otherwise directed by DDFI or OCM/OEO.

8.3.6 - REPORTING

Your district will follow Field Management Directive FMD-119 for proper reporting of epidemiological investigations. Promptly submit a complete narrative of the investigation in English (IOM 1.1), including references to exhibits, samples, medical records, and laboratory reports. There is no prescribed reporting format, but it should be in a logical order, see IOM Exhibit 5-17. With the inclusion of investigative memos in Turbo EIR, Turbo can be utilized to prepare these memos. See the Turbo EIR Quick Reference Guide for detailed information. See also IOM 8.10.

Submit copies of any written reports and documents for all INJURY or ILLNESS complaints involving all CFSAN products (see section 8.2 and 8.4.5) to:

Food and Drug Administration
CFSAN/OSAS
CAERS Staff (HFS-700)
5100 Paint Branch Pkwy
College Park, MD 20740
Attn: CAERS Monitor

Illness/injury complaints involving special nutritional products (refer to IOM 8.4.5.2) must be accompanied by a completed FACTS Adverse Event Questionnaire (Exhibit 8-1) when forwarded to CFSAN.

If additional follow-up on any complaint involving a CFSAN product is necessary, the Division of Field Program Planning and Evaluation (HFS-635) will issue an assignment.

8.3.7 - REFERENCES

1. "Procedures to Investigate Foodborne Illness" Int'l Assoc. of Milk, Food and Environmental Sanitarians, Inc., Ames, Iowa 50010.
2. "Diseases Transmitted by Foods" CDC, Atlanta, GA. 30333.
3. "Procedures to Investigate Waterborne Illness" Int'l Assoc. of Milk, Food and Environmental Sanitarians, Inc., Ames, Iowa 50010.
4. "Epidemiology Man and Disease" J.P. Fox, M.D., and L.R. Elveback, PhD, MacMillan Publishing Co., N.Y., N.Y. - 1970.
5. FMD 119 - Consumer Product Complaints System.
6. Regulatory Procedures Manual Chapters 5 - 10.
7. "Control of Communicable Diseases Manual," American Public Health Association, Washington, D.C. 20001-3710.

SUBCHAPTER 8.4 - INVESTIGATION - INJURY & ADVERSE REACTION

8.4.1 - INVESTIGATIONS

The purpose for investigating injury and adverse reactions to drugs, devices, biologics, foods, dietary supplements, tobacco products, and cosmetics is to determine the cause of, and to prevent additional injury or adverse reaction to the consuming public.

Injury and adverse reaction complainants should receive a prompt, courteous response, and assurance their complaints will receive appropriate consideration. An immediate follow-up should be made when there is an indication of a serious injury or adverse reaction.

When investigating injuries or adverse reactions, do not make comments or enter into discussions with firms as to the involvement of particular products, unless specifically instructed to do so. Many adverse reactions come to FDA from consumers or health care professionals through the voluntary reporting branch of the MedWatch system. These reports are to be held confidential. Divulging information before the reports are confirmed or denied is inappropriate, and not to be done.

Whenever the press has been informed about a complaint, follow instructions found in Section 1.6.1. When the responsible firm invites the news media to observe the inspectional process, follow instructions found in Section 5.1.4.3.

Personnel routinely receiving complaints should be particularly sensitive to those involving recently approved drugs, devices and biologics. Clinical trials may not have identified all possible adverse reactions, and FDA's approving Center may want to reconsider current labeling, modify directions for use, establish registries for monitoring distribution, or withdraw approval based on the most recent information.

8.4.1.1 - Procedures

When investigating all injuries and adverse reactions:

1. Complete a FACTS Consumer Complaint Report and FACTS Follow-up Report (replaces the FDA 2516 and 2516a) to record and investigate all complaints, unless previously reported through one of FDA's other post marketing surveillance systems such as MedWatch. For special nutritionals, complete the FACTS Adverse Event Questionnaire. For cosmetics, complete the Cosmetics Adverse Event Report. See IOM Exhibits 8-1, 8-2, 8-3, and 8-4.
2. Provide complete details on the product involved, including brand name and identity statement with all qualifiers appearing on the label and code marks. In device cases, obtain a wiring diagram or furnish a complete description. Take photographs, if appropriate.
3. Identify the source of the offending article.
4. Provide details of how the product was used, including frequency, in what amounts, other on-going treatments, any known previous adverse reactions or pre-existing allergies and whether applied by the user or someone else. Determine if label directions were followed. Obtain copies of all labeling/inserts. Also, be alert for medical research or literary reviews the reporting party may have conducted or relied upon, and collect copies of such research or reviews. The device community has various publications of frequency of types of adverse events investigated and findings.
5. Obtain a complete description of the incident (sequence of events) and the nature of the injury or adverse reaction, including date, time, location and symptoms or description of injury.
   a. Include any hospital or physician's records available, and identify pre-existing conditions which may have a bearing on the injury or adverse reaction.
   b. Obtain photographs of the victim's injuries, if significant. See IOM 8.2.6 for the procedures used to obtain medical records.
6. List names of other persons involved, such as beauty salon operators, medical personnel, lawyers, insurance agents. Obtain their views on the injury or adverse reaction. The views of an attending physician are important because they may vary markedly from those of the patient.
7. Ask the consumer if an attempt to report the adverse reaction to the product manufacturer has been made,

and the nature of the manufacturer's response, if known.
8. Any other consumer complaints, injuries or alleged adverse reactions reported to the manufacturer concerning the product.
9. If necessary, obtain distribution information of the implicated lot(s) from the manufacturer.

8.4.2 - DRUGS - INJURY OR REACTIONS

Drug injuries or reactions, either human or veterinary, result from the use of products which may:
1. Vary markedly from declared potency.
2. Contain deleterious substances.
3. Are mislabeled as to identity, warnings, or instructions.
4. Have been mistaken for other drugs despite proper labeling.
5. Have changed composition, or become contaminated after shipment.
6. Are dangerous when used according to directions.
7. Have not been used in accordance with label directions or directions from the prescriber.
8. Have been improperly administered, or administered without the necessary precautions.
9. Have been contaminated with objectionable microorganisms, soaps or cleaning solutions.
10. Have been misidentified.
11. Be labeled as sterile drugs, but are found to be non-sterile.
12. Have adverse effects that were not identified prior to marketing.

8.4.2.1 - Investigative Procedures

The following procedures should be followed for investigating suspected adverse drug reactions, including drug-induced birth defects:
1. If you are interviewing the consumer, conduct the normal complaint investigation and gather all pertinent information regarding the product, patient, adverse event, etc. If the consumer received medical treatment, obtain a medical records release (Exhibit 8-5). Reporting of drug adverse experiences is voluntary and you should encourage and assist complainants and health care providers to complete the FDA 3500 form (see Exhibit 8-10) and submit to MedWatch. Report your findings in FACTS Consumer Complaint Follow-up screens and in a memo of investigation.
2. If you are investigating an adverse reaction at the manufacturer, conduct your investigation in an attempt to determine whether the adverse event was caused by a drug quality defect. Determine if the manufacturer was aware of the complaint, has conducted an investigation and per IOM 5.5.7 Adverse Event Reporting has submitted the reportable event to FDA. Your findings will be reported through FACTS Consumer Complaint Follow-up screens and a memo of investigation or Establishment Inspection Report.
3. You may also be directed to conduct investigations at other establishments, such as pharmacies or distributors. Conduct your normal complaint investigation determining each party's role and involvement. If individuals interviewed are not required to report adverse drug reactions, encourage and assist them to complete and submit the FDA 3500 form to MedWatch.

In all cases of suspect drug-induced adverse reactions, the Center will review the information on the FDA 3500 form, and will issue assignments to the field if additional information is needed.

8.4.3 - DEVICES - INJURY

The cause of medical device injuries may originate with the manufacturer, operator, user, or from other factors including, but not limited to the transportation or installation of the device.

8.4.3.1 - Mechanical, Electrical or Electromechanical Devices

Injuries caused by mechanical, electrical or electromechanical devices may result from devices that:
1. Do not conform to specifications due to:
   a. Mistreatment (e.g., damage in transit), or
   b. Failure to comply with good manufacturing practices.
2. Malfunction because:
   a. Of incorrect installation,
   b. Have not been used in accordance with labeled instructions,
   c. Have been used/installed with accessories or parts which are not compatible,
   d. Have been used under conditions which interfere with their ability to function (e.g., electromagnetic interference (EMI), fluid seepage into electrical circuits, etc.),
   e. Have been damaged during use, or
   f. Random failures.
3. Have not been adequately designed for intended use (e.g., unstable, poor structural integrity, sharp or pointed surfaces, electrical leakage, etc.).
4. Do not contain adequate directions or warnings.
5. Are intended to be sterile but are non-sterile.
6. Fail or deteriorate for any reason.

8.4.3.2 - Devices for Implant

Causes of injuries which may result from implanted devices include those listed in IOM 8.4.3.1. The term installation, as used above, does not include implantation. Injuries also may result because the materials used in the implant are not biocompatible, thereby causing an adverse tissue reaction and/or deterioration of the implant.

8.4.3.3 - In Vitro Diagnostic Devices

Certain In Vitro Diagnostics (IVD) are instruments, such as gas chromatographs and automated blood analyzers, and much of the information under IOM 8.4.3.1 is applicable.

Injuries to patients from IVD products may, in many cases, be considered indirect, because they are due to complications resulting from misdiagnosis or delays in patient treatment due to incorrect test results. Examples of IVD failures include false positives, false negatives and erratic results. Poor performance or failure may be due to poor manufacturing practices or user error.

Manufacturing problems include:
1. Process errors and mix-ups (e.g., varying fill in kit components, improper ingredient addition, etc.).
2. Labeling does not contain adequate directions or warnings, or contains incorrect information.
3. Labeling mix-ups.
4. Contamination, making the product unusable or causing misdiagnosis.

User errors include:
1. Failure to follow label directions
2. Use of unclean or poorly calibrated laboratory equipment.
3. Improper storage of reagents

8.4.3.4 - Investigative Procedures

When investigating incidents implicating a medical device, you must first confirm whether or not the device was a contributing factor. An appropriate follow-up, such as inspection at the manufacturer, may be necessary.

Current agency policy defers regulation to the Department of Transportation (DOT) of automotive adaptive equipment which are medical devices. Consumer complaints or other reports concerning these devices should be referred to DOT.

Copies of EIRs, FACTS Consumer Complaint Report and Follow-Up Report, including documentation and related materials, for all device consumer complaints should be sent to HFZ-343.

Reports received through the Medical Device Reporting system are not considered to be consumer complaints and are tracked through a system maintained by CDRH. A FACTS Consumer Complaint Report should not be completed for any incident that CDRH has requested follow-up on via MDR, unless you originally were advised of the incident by a consumer and initiated a FACTS Consumer Complaint Report at that time. For additional information concerning MDR reports, see the applicable Compliance Program in the CPGM.

Interview the victim, physician(s), and any other individual(s) who witnessed or has knowledge of the incident. When conducting an investigation at a hospital, be sure to contact and inform the administrator of the purpose of the investigation.

8.4.3.4.1 - DEVICES

Obtain the following information for devices:
1. A complete description of the incident (sequence of events) and the injury, including:
   a. Type, model, serial number and manufacturer of the device.
   b. Details of the alleged incident, including: number of people involved; symptoms, onset time and duration and outcome; date and time of occurrence; reports of other investigating agencies and their conclusions, e.g., fire marshal or OSHA reports; similar incidents which may have resulted in injury; all operational SOPs, written or unwritten.
2. Copies of medical records and/or laboratory records. Use an FDA 461, Authorization for Medical Records Disclosure, IOM Exhibit 8-5, signed by the patient or other authorized person, when obtaining these records.
3. Official cause of death, death certificate and/or autopsy report, if indicated.
4. Determine if the device malfunctioned, and the cause.
5. The condition of the device at the time of use. Review its maintenance history, including responsibility for maintenance (past and present), special service calls, repairs, whether component warning or safety systems were functional, maintenance records, changes or corrections accomplished just prior to or immediately after the incident, and who performed the activity. An interview with bio-engineering department personnel may be indicated.
6. Who has access to the device, and if individuals using the device are familiar with its operation?
7. The results of any examination or inspection of the device by the hospital or other party to determine the cause of the incident.
8. Whether there are other devices of the same model number or lot number on the premises.

8.4.3.4.2 - IN VITRO DIAGNOSTICS

For In Vitro Diagnostics, determine:
1. What are the results of the test used for? (Screening, therapeutic drug monitoring, epidemiological information, monitoring the course of disease, susceptibility testing, etc.)
2. The clinical value or worth of the test (is it diagnostic, does it only aid in diagnosis).

The report of the investigation and related documentation is extremely important and must be promptly submitted. The report will be used by CDRH Medical and Scientific Review Staff in their health hazard evaluation.

8.4.3.4.3 - DIALYSIS INJURY OR DEATHS

For Dialysis Injury or Deaths, in addition to the general device investigative procedures,
1. Obtain the following information:
   a. Determine time of incident (i.e., at beginning of procedure, or after several hours of operation).
   b. Actions taken by staff, the number of patients normally treated, medications given, etc.

c. Whether reuse of the dialyzer is practiced (manual or automated).
d. Contact and interview maintenance personnel, where appropriate. Verify there is a maintenance schedule.
e. Verify whether checks on alarm systems were performed prior to each start up and at any other critical stages in the operation, and how often. Determine the last time temperature and/or other alarm systems were calibrated.

2. Verify when the dialysis facility filed a User Facility Report (UFR) in compliance with the Safe Medical Devices Act of 1990.
3. Describe the type of water treatment devices used to make the dialysate. Verify who services and maintains the water treatment system, including off-site regeneration systems. Determine when these services were performed and recorded (name and times), in relationship to the incident. Report, for off-site regeneration systems, whether the resin bed regeneration was "medical use only" or mixed with other uses.
4. Where a dialysis center practices reuse of dialyzers, determine the type of disinfectant method used (manual or automated), type of disinfectant used (i.e., formaldehyde, renalin, glutaraldehyde, etc.) and review the service and maintenance records for proper procedure including names, dates and time.

8.4.4 - BIOLOGICS - INJURY, REACTION OR FATALITY

Reactions or symptoms of illness may occur in association with the administration of vaccines and other biological products. The Center for Biologics Evaluation and Research (CBER) is interested in all unexpected clinical responses to a biological product, as well as any expected responses of unusual frequency or severity. In some cases, a reaction or illness could occur because the product may:

1. Vary from declared potency.
2. Have been contaminated during manufacturing, shipment, or after shipment.
3. Be mislabeled.
4. Not have been given according to directions.
5. Not have been stored under proper conditions.
6. Have been provided to the wrong person.
7. Contain substances innocuous to most people, but which the recipient is unable to tolerate (anti-Kidd, anti-Duffy), or contains substances not usually present in such a product which stimulate an adverse response in the recipient (HLA antibodies).

8.4.4.1 - Professional Reporting System for Vaccine Adverse Reactions

The National Childhood Vaccine Injury Act of 1986, 42 USC 201, was passed to achieve optimal prevention of childhood infectious diseases through immunization. At the same time, it was intended to minimize the number and severity of adverse reactions to vaccines routinely administered to children. This law requires health care providers and vaccine manufacturers to report certain adverse events which occur following the administration of specific vaccines. The vaccines and reportable events are listed in the National Childhood Vaccine Injury Act Vaccine Injury Table. The Department of Health and Human Services (DHHS) has established a Vaccine Adverse Events Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine, in all age groups, including but not limited to those in the table.

The Vaccine Adverse Event Reporting System (VAERS) is administered under a joint FDA/CDC contract. The system utilizes a preaddressed and postage paid form (Form VAERS-1) for reporting adverse events which occur subsequent to vaccine administration. See IOM Exhibit 8-11.

8.4.4.2 - Investigation/Reporting

When a biologics reaction/injury complaint is received by the district office (DO), a preliminary investigation should be conducted. CBER should be consulted before initiating any follow-up which extends beyond the complainant, and in some cases even before the complainant interview.

All complaints initially received by the District Office must be recorded on the FACTS Consumer Complaint Report. When interviewing the complainant about a biologics complaint /injury, obtain:

1. Complete description of the complaint/injury.
2. Onset and duration of the reaction/injury.
3. Name of product administered, include date and time of administration.
4. Manufacturer and lot number of product, if available.

At this point, it is generally unnecessary to conduct interviews beyond the complainant, or obtain records, until a preliminary review has been conducted. It is important to rapidly communicate the basic information about the incident, implicated product, lot, license number, manufacturer, and presence of intact units to the Center and the OCM/OEO contact. Immediately, CBER offices will advise whether reactions are expected or unexpected, and the level of investigation, including sample collection and analysis, necessary. Further follow-up is unnecessary until it has been determined the reaction/injury is not unexpected, or has not already been reported through other channels.

Vaccine Products - If the complaint involves an adverse reaction of any kind, then a Form VAERS-1 (IOM Exhibit 8-11) should be sent to the complainant. The form should be completed by the complainant's physician, if at all possible, or by the complainant, if the physician will not cooperate. The completed VAERS Reporting Form should be mailed directly to the address on the form. When you send a VAERS form to a complainant, note this fact in the Remarks Section of the FACTS Consumer Complaint Report.

If the complaint does not involve an adverse reaction, obtain the necessary information to allow the Center to make an informed decision on follow-up at the manufacturer.

Biological Products - If the complaint is an adverse reaction to a product, an FDA 3500, MedWatch Form (See IOM Exhibit 8-10) must also be completed and forwarded to the complainant for completion by their physician. If the physician will not cooperate by completing the FDA-3500, request the complainant to do it. Assist the complainant in completing the FDA 3500, if necessary. Note in the "Remarks" section of the FACTS Consumer Complaints Report that the FDA 3500 was forwarded to the complainant.

If the complaint does not involve an adverse reaction, obtain information necessary to permit the Center or home district to make an informed decision on follow-up at the manufacturer. If a complainant desires further information, refer them to CBER, Office of Biostatistics and Epidemiology, Division of Epidemiology, at 301-827-3974.

If the complaint is a fatality where blood or a blood component is implicated, notify CBER, Office of Compliance and Biologics Quality, as soon as possible (21 CFR 606.170). This is required of the collecting facility, in the event of a donor reaction, and by the facility which performed the compatibility tests, in the event of a transfusion reaction. An investigation of the incident shall be conducted by either HCFA or FDA, based on the type of facility involved, for example, transfusion service, blood bank, plasma center or hospital.

8.4.5 - FOODS, DIETARY SUPPLEMENTS AND COSMETICS - INJURY OR REACTION

CFSAN regulates a wide variety of products including foods, seafood, wine beverages less than 7% alcohol (including wine coolers), bottled water, food additives, infant formulas, dietary supplements, and cosmetics. Each of these products is used differently and regulated under a different part of the Act and thus has slightly different investigational requirements. Background and common causes for adverse events are provided for selected products below.

Monitoring of complaints on CFSAN products is performed by the CAERS Staff. CFSAN investigations are generally limited to serious adverse events. Therefore, for serious adverse events (previously defined above in IOM 8.2.1.1) follow the specific investigation requirements below, in addition to the general investigation requirements above.

NOTE: Contact the CFSAN Adverse Events Reporting System (CAERS) Staff, HFS-845, 240-402-2405, Fax: 301-436-2452, or email CAERS@fda.hhs.gov, for all questions pertaining to field follow-up requests or medical guidance on investigations of adverse reactions associated with CFSAN monitored products. CAERS will coordinate with the office experts.

8.4.5.1 - Cosmetics

It is important that FDA conducts appropriate investigations and follow-up on adverse events attributed to cosmetic products.

Confusion regarding a product's legal status as a cosmetic, a drug or a combination drug/cosmetic may impede investigational use of complaint system information. For clarification of the distinction between cosmetics and drugs, refer to the document, "Is it a cosmetic, a drug or both? (or is it soap?)" located at http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm. Questions may also be directed to the Office of Cosmetics and Colors at (240) 402-1130.

Injuries or adverse reactions may arise from cosmetics which:

1. Are inherently dangerous or which may prove harmful or injurious to a consumer;
2. Cause primary irritation of skin, eye, or mucous membranes (including the lungs and urinary tract) or which may be due to an individual sensitization reaction or allergic response; or due to ingestion;
3. Have undergone formulation changes, or been chemically or microbiologically contaminated while in the possession of the manufacturer, dealer, distributor, or end user;
4. Are misbranded because they contain unlisted ingredients, lack instructions for safe use for certain high risk products (e.g., depilatories, hair dyes), or lack any required warning statements;
5. Have been misused.

8.4.5.2 - Dietary Supplements

The Dietary Supplement Health and Education Act of 1994 (See DSHEA) defined the term "dietary supplement" to mean a product taken by mouth that contains one or more dietary ingredients (i.e., vitamins, minerals, herbs or other botanicals, amino acids, and dietary substances, as well as a concentrate, metabolite, constituent, extract, or combination of any of the dietary ingredients). The intended use of a dietary supplement is to increase the total dietary substance or to supplement the diet. Under DSHEA, a dietary supplement is a food which must be labeled as a "dietary supplement" and cannot be represented for use as a conventional food or the sole item of a meal or diet.

DSHEA also removes dietary ingredients from coverage under the food additive provisions of the FD&C Act. Rather, DSHEA places the burden on the Agency to prove a dietary supplement or dietary ingredient is adulterated before the product can be removed from the marketplace.

Therefore, a crucial source of information on potentially unsafe products is the Agency's consumer complaint system. It is extremely important that FDA conduct appropriate investigations and follow-up on adverse events attributed to dietary supplement products.

The instruction and guidance provided in IOM 8.4.5.2.1/2 must be followed when conducting follow-up on complaints involving adverse reactions to special nutritional products.

8.4.5.2.1 - CAUSES

Injuries or other adverse reactions may be associated with the use of products which:

1. Vary markedly from the declared potency or concentration.
2. Contain deleterious substances accidentally included in their manufacture.
3. Have changed composition or become contaminated after shipment.
4. Are mislabeled as to identity, warnings or instructions for use.
5. Have not been used according to label instructions or the directions of the manufacturer or prescriber.
6. Are dangerous when used according to directions.

8.4.5.2.2 - PROCEDURES

When investigating adverse events attributed to special nutritional products, direct attention to, and document:

1. Complete details on the product involved, including code marks.
2. The source of the offending article.
3. Details of how the product was used, including frequency, in what amounts, concomitant treatments, and whether administered by the user or someone else. Determine if label directions were followed. Obtain copies of all labeling/inserts.
4. Nature of the injury. Include any hospital or physician's records available, and identify pre-existing conditions which may have a bearing on the injury. Obtain photographs of the victim's injuries, if significant. See IOM 8.2.6 for the procedures used to obtain medical records.
5. Names of other persons involved, such as medical personnel, lawyers, insurance agents, etc. Obtain their views on the injury. The views of attending physician are important because they may vary markedly from those of the patient.
6. A complete description of the incident (sequence of events) and the injury.

Complete the FACTS Adverse Event Questionnaire (See IOM Exhibit 8-1) either during the initial consumer contact (e.g., telephone report of complaint), or soon thereafter. The Adverse Event Questionnaire contains additional information which must be obtained and forwarded to CFSAN. Information already contained in the FACTS Consumer Complaint Report need not be duplicated on the questionnaire.

NOTE: Contact the CFSAN Adverse Events Reporting System (CAERS) Staff, HFS-845, 240-402-2405, Fax: 301-436-2452, or email CAERS@fda.hhs.gov, for questions pertaining to field follow-up requests related to foods, seafood, food additives, dietary supplements, infant formulas and medical foods. CAERS personnel will coordinate field guidance related to these products with CFSAN's experts.

Questions on compliance or other regulatory matters should be directed to the Office of Compliance, Division of Enforcement, HFS-605, 240-402-2417.

8.4.5.3 - Investigation Requirements for Serious Adverse Events of CFSAN Regulated Products

If the suspect product is a Cosmetic, interview the injured person and/or the reporter of the event and complete the FACTS Consumer Complaint Cosmetic Report (IOM Exhibit 8-4).

If the suspect product is not a Cosmetic, interview the injured person and/or the reporter of the event and complete the Adverse Event Questionnaire (IOM Exhibit 8-1).

If suspect product is an Infant Formula or Baby Food, immediately inform OCM/OEO at 301-796-8240 and investigate on a high-priority basis due to the continued sensitivity to these incidents. This will include follow-up with the doctor or hospital, sample collection and analysis of appropriate product. Refer complaints involving baby food regulated by USDA to USDA for appropriate follow-up. See IOM 8.3.1.3 and 3.2.1.2.

Obtain Medical Records Release forms (FDA-461) from the injured person or guardian.

If the adverse event is a death, the following medical records should be considered for collection:

1. Admission History and Physical or Emergency Room/Clinic record of the event if the patient was not admitted
2. Discharge Summary
3. Autopsy Report
4. Death Certificate

Samples - If you believe a suspect product should be sampled, discuss with your Supervisor. See IOM 8.2.7 for guidance.

For all events, a memo of investigation will be completed. Send a complete copy, including copies of all labels and labeling, Medical Records Release (FDA 461) and medical records collected to the CAERS Staff.

8.4.5.4 - Undeclared Allergen/Allergic Reactions

We often receive complaints involving allergic reactions to food products containing suspected undeclared allergens. It is important to obtain specific information unique to these complaints. Suspected undeclared allergen complaints should receive high priority. Undeclared allergens in food products often result in recalls.

The following should be addressed with the consumer and recorded in the “Complaint Description” section of the FACTS consumer complaint report:

1. List all foods the person is allergic to.
2. List all foods consumed within approximately the hour prior to reaction.
3. Indicate how much was consumed of the suspect food(s).
4. Record the on-set time of the reaction.

5. List all symptoms experienced in the order they occurred.
6. Indicate treatment given.
7. Record the ingredient statement from product packaging on the complaint form ("Remarks"-page 1). (Look for hidden allergens within the ingredient statement.)
8. Indicate if the label includes a "may contain" statement and record the statement.
9. Indicate whether the consumer has a documented food allergy. (It may be necessary to collect the medical records as the investigation of the complaint progresses.)

Inspectional follow up at the manufacturing plant may be warranted to determine if suspect allergenic ingredient is added to the product; or if the possibility of cross-contact exists.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) became effective 1/1/2006. See the FDA Website for additional background information related to it.

8.4.6 - VETERINARY PRODUCTS - COMPLAINTS/ADVERSE REACTIONS

Complaints and adverse reactions associated with veterinary products including animal drugs, medicated feeds, and medical devices for animals are handled through the FDA CVM Division of Veterinary Product Safety (HFV - 240). Veterinarians, animal owners, and drug manufacturers may report problems to their local FDA district offices or directly to the Center for Veterinary Medicine. The District should advise the complainant to complete a FDA 1932a, "Veterinary Drug Adverse Experience, Lack of Effectiveness or Product Defect Report" for drug adverse events associated with unapproved animal and approved human drugs and veterinary devices. For approved animal drugs, the complainant should be instructed to call the manufacturer directly to report the event. Detailed instructions and options for different case scenarios are available at http://www.fda.gov/cvm/adetoc.htm.

For 3 day Field Alert Reports (FAR), the drug manufacturer should notify and submit the FAR to their respective District office within 3 days. The District Offices will ask for additional information if necessary and submit the 3 day FAR to the Division of Veterinary Product Safety.

Complaints and adverse reactions associated with animal feeds including pet food products are handled through the Division of Compliance (HFV-230) at the Center for Veterinary Medicine. Veterinarians, animal owners and firms may report pet food problems to consumer complaint coordinators at their FDA District Office or OCM/OEO; the District will complete a FACTS Consumer Complaint Report. Pet food reports may also be made directly to CVM using FDA's Safety Reporting Portal. Instructions for stakeholders to report problems associated with pet food products are available at http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm.

8.4.7 - SAMPLE COLLECTION

Collect a sample of the product which caused the injury and an official sample from the same lot. Collect the same and other lot codes, if available. Check with your supervisor if you have any doubt as to the appropriateness of collecting a particular sample.

See IOM 4.5.5.3 for routing of injury and complaint samples to the laboratory.

8.4.7.1 - Device Samples

Obtain Center concurrence prior to collecting any device samples.

8.4.7.2 - Biological Samples

Do not collect samples of the suspect product until an evaluation of the preliminary information on the injury/reaction has been made by CBER (Licensed products) or the Home District (Unlicensed Products, Plasma and Blood Products).

8.4.7.3 - Cosmetic Samples

Products such as depilatories, permanent hair dyes, home permanents, deodorants, hair straighteners, etc. are known to cause adverse reactions. Samples of these products should not be collected except in cases of alleged severe or unusual injury (e.g., multiple complaints). In cases of obvious allergic type reactions, samples should not be collected. For example, most cosmetic products which get into the eye will cause temporary eye irritation and in such cases, a sample generally should not be collected.

8.4.7.4 - Microbiological Contamination

Collect samples associated with consumer complaints in which microbiological contamination is suspected.

8.4.7.5 - Allergen Samples

Sample if the allergen is visible (i.e., nuts) and is not declared on label (and if deemed necessary by District management). In all other cases, collect a sample only after consultation with OEO (e.g., National Consumer Complaint Coordinator) and CFSAN. See IOM Sample Schedule Chart 13 for guidance on sample size. Note: the sample size may be modified depending on product availability.

8.4.7.6 - Tobacco Products Samples

When collecting tobacco product samples as a result of a product complaint or adverse report investigation, see IOM 4.5.5.3.8, for sample collection guidance and contact CTP's Office of Compliance and Enforcement.

8.4.8 - REPORTING

Prompt reporting is essential. You may save the lives of others with prompt reporting. See IOM 1.1 English language requirement.

8.4.8.1 - Reporting Forms

Field personnel should report all consumer complaints in FACTS. In addition, for adverse reactions or injury associated with drugs, medical devices, cosmetics, tobacco products, and biologics (except vaccines), provide complainants with the MedWatch web address (www.fda.gov/medwatch) or the FDA 3500 MedWatch form (IOM Exhibit 8-10). Prior to sending a MedWatch form to the complainant, enter the FDA FACTS consumer complaint number in the box below the Triage Unit Sequence # in the upper right corner of form FDA 3500.

For complaints with veterinary products including animal drugs, medicated feeds, and medical devices for animals, provide complainants with an FDA 1932a "Veterinary Drug Adverse Experience, Lack of Effectiveness or Product Defect Report".

For adverse reactions to vaccine products, provide complainants with form VAERS-1 (IOM 8.4.4.2, IOM Exhibit 8-11).

8.4.8.2 - Routing Reports

A copy of the FACTS consumer complaint report and your narrative report(s), including any copies of medical or injury reports obtained should be submitted by your district to the appropriate office. Fax transmission may be used.

8.4.8.2.1 - DRUGS

Submit drug complaints and injuries to:

MedWatch
The FDA Medical Products Reporting Program (HFD-410)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Fax Number: 301-827-7241

8.4.8.2.2 - MEDICAL DEVICE AND RADIOLOGICAL PRODUCTS

Submit medical device and radiological product complaints and injuries to:

Food and Drug Administration
Center for Devices and Radiological Health
Division of Surveillance Systems (HFZ-530)
WO66 10903 New Hampshire Avenue
Silver Spring, MD 20993

8.4.8.2.3 - FOODS AND COSMETICS

If the online MedWatch form is not used for reporting adverse events, send both adverse events and product problems for CFSAN regulated products including cosmetics, infant formulas, dietary supplements and all other foods to:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
CAERS Staff (HFS-845)
Attn: CAERS Monitor
5100 Paint Branch Pkwy
College Park, MD 20740

8.4.8.2.4 - VETERINARY PRODUCTS

Submit veterinary injuries or adverse reaction reports to:

Food and Drug Administration
Center for Veterinary Medicine
Division of Surveillance (HFV-210)
7500 Standish Place
Rockville, MD 20857

8.4.8.2.5 - LICENSED BIOLOGICAL PRODUCTS

For licensed biological products (includes vaccines), except for source plasma and blood products, the receiving district will complete the FACTS consumer complaint report and fax a copy to HFM-650 at 301-827-6748, select HFM-650 in the referrals box and then electronically forward to the home district. The home district will select "Surveillance for Next EI" as the final disposition and close the complaint. CBER will issue an assignment if follow-up is needed.

8.4.8.2.6 - UNLICENSED BIOLOGICAL PRODUCTS

For unlicensed biological product, plasma, blood and blood products, the receiving district will complete and electronically forward the FACTS consumer complaint to the home district and send a hard copy to HFM-650. The home district will determine if any follow-up is needed and issue an appropriate assignment. Advice is available from HFM-650 at 301-827-6220.

8.4.8.2.7 - BIOLOGICS INJURY/ADVERSE REACTION REPORTS

Submit biologics injury and adverse reaction narrative reports to:

Food and Drug Administration
Center for Biologic Evaluation and Research
Office of Compliance
1401 Rockville Pike, Suite 400S
Rockville, MD 20852

NOTE: In addition, check the "Notify EO/EMOPS?" box in FACTS for all injury and adverse reaction complaints. For

serious injury/illness reports, please notify the OCM/OEO immediately at 301-796-8240.

8.4.8.2.8 – TOBACCO PRODUCTS INJURY/ADVERSE REACTION REPORTS

If the online MedWatch form is not used for reporting adverse events, send the hardcopy MedWatch form to:

The FDA Safety Information and Adverse Event Reporting Program
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20852

SUBCHAPTER 8.5 - DISASTER PROCEDURES

The objective of FDA investigations in the aftermath of non-attack disasters is to determine whether or not foods, drugs including biologics, cosmetics and devices affected by the catastrophe are safe for human and animal use; and if not, to effectively remove them from commerce.

In disaster operations, FDA will assist state, local and other federal agencies in removing contaminated or unfit merchandise from the market.

8.5.1 - DISASTER TYPES

The types of natural and man-made disasters which affect FDA operations are:

Floods	Earthquakes
Hurricanes	Volcanoes
Tornadoes	Chemical Spills
Wrecks	Riots and Disorders
Fires Explosions	Bioterrorism

8.5.2 - RESPONSIBILITY & COORDINATION

State and local officials usually assume direct responsibility, as their laws and regulations can be immediately invoked, however FDA assistance is often requested. Except in unusual circumstances, FDA responsibilities are to assist the state and local health agencies in removing, destroying, or reconditioning affected merchandise.

In situations involving interstate movement of merchandise; large interstate firms; areas in which state or local political ramifications are anticipated; or when state or local health officials so request; FDA may assume the primary role in the operation.

8.5.3 - PREPARATION

Personal Safety - In a disaster or pending disaster the personal protection of yourself and your family is your primary concern. Provide for your own safety as you perform your FDA duties in a disaster area. Inoculations and protective clothing should be considered. See IOM 1.5.1 and 1.5.1.3.

Disasters produce dangerous situations (e.g.; high water, escaping gases, fallen electrical lines, damaged buildings, falling rubble, etc.), so care and extra safety precautions must be observed. If you become sick or injured, you become another problem to already overworked health officials.

CAUTION: In situations where electrical power has been out for an extended period of time, and firms attempt to salvage frozen or refrigerated products using dry ice; do not enter these areas without first providing for proper ventilation and/or obtaining oxygen breathing apparatus.

Inspectional and Investigational Preparation - After taking care of yourself and family, and being properly equipped and supplied, you are ready to begin disaster operation. Stock your car in the same manner as for any inspectional activities; however, consider the extra amounts of materials needed in the particular situation.

Extra gasoline and oil, drinking water, communication equipment (cellular and satellite phones, email, etc.), battery powered radios, lighting equipment (battery flashlights, propane or gasoline lanterns, etc), extra film, medical supplies and materials of an emergency nature must be provided if power facilities and normal distribution channels are disrupted. Consideration must also be given to your own sleeping and eating needs.

Review the Model Food Salvage Code, 1984 Recommendation of the Association of Food and Drug Officials and the U.S. Department of Health and Human Services for guidance.

8.5.4 - PRELIMINARY INVESTIGATION

Initial Information - FDA usually learns of disasters, or impending disasters from weather agencies, news media, public health agencies, civil defense units, or law enforcement organizations. Initially, there is little anyone can do, other than monitor the course and severity of a disaster, until the situation becomes sufficiently stabilized for personnel to move into the area to survey damage.

Initial Procedures - FDA's initial course of action is to contact state and local officials, offer assistance, and begin to coordinate the mobilization of personnel and resources necessary to handle the emergency.

If you are in an area when a disaster strikes or is imminent, advise your supervisor on the situation by the fastest means possible. In the initial stage of the operation you may be the only FDA representative on the scene. If this is the case, contact the state or local officials and offer your services, advising them you have alerted or will alert your district as soon as possible. Keep your supervisor informed.

Each district has a disaster plan which will be implemented in applicable situations. As the situation develops, you will receive instructions from your supervisor.

8.5.5 - FIELD OPERATIONS

Inspectional and investigational activities will normally be conducted with other FDA personnel and state or local counterparts.

Once personnel are mobilized and assignments issued, your operational procedures will be similar, regardless of the type of disaster. You will be searching out, identifying and investigating foods, drugs, devices, and cosmetics for actual or possible contamination and taking the necessary steps to preclude their use until they are released, reconditioned, or destroyed.

A rapid physical survey must first be made of the disaster area to determine the extent of damage, and the amounts and kinds of merchandise involved.

CAUTION: Although procedures in this subchapter do not cover disasters resulting from nuclear attack, it is possible you may discover products suspected of contamination by radioactive materials in the disaster area. If you suspect the presence of radioactive materials, take no action on the materials yourself, but have the area cordoned off at once. Notify the command official and immediately contact your supervisor to alert the regional radiological health representative and the state radiation control agency. Follow their instructions.

When in doubt as to the condition of any materials affected, request holds or embargoes pending final outcome of further examinations. See IOM 8.5.5.2.

8.5.5.1 - Embargoes

See IOM 3.3.1 and 2.7.1.

FDA has no embargo powers except as specified in:
1. The Federal Meat Inspection Act
2. The Poultry Products Inspection Act
3. The Egg Products Inspection Act
4. Certain parts of the FD&C Act, namely Section 304(g) [21 U.S.C. 334(g)]

In emergency situations, state and local embargoes are an effective tool. Embargoes can be employed immediately and, the merchandise held, destroyed, or reconditioned without time consuming delays. Some state and local embargo powers are limited as to time and/or amounts. In these cases, the use of federal injunction and seizure action must not be overlooked. State or local agencies may also confer their embargo authority to FDA personnel for the duration of the emergency.

8.5.5.2 - Field Examination & Samples

During all your investigational activities, examine the lots affected for obvious adulteration, decomposition, contamination, or physical damage. Use your camera extensively, and collect samples whenever indicated. Judge the extent of field examination and sample collections necessary, based on the nature and magnitude of the disaster.

In major catastrophes, large numbers of samples may not be necessary because of obvious visible contamination and the emergency disposition powers invoked by state and local officials. In minor local disasters, such as fires, riots, train, truck, or shipwrecks, lots may be held pending outcome of examinations, so extensive sampling may be required.

Examine cans or jars for physical damage (rusty, burst seams, holes, ripped, etc.), and for visible adulteration from filth, oil, or chemicals, and damage to the product's labels (defaced labels). In addition, examine jars and bottles for sediment or other visible filth under cap crimps and cap lugs. When a lid is removed, sediment or microcontamination may be drawn into the container by internal vacuum. Discard any jars you open for examination. Visible contamination under lids may be photographed or lids may be used as exhibits as conditions permit.

Plastic, paper, cloth bags, and cardboard containers must be examined for physical damage and contamination.

Stocks of devices must be examined for contamination and water, heat, mechanical, physical, electrical, or chemical damage. If any doubt exists as to whether or not devices have been affected, experts should be consulted or utilized.

Examine bulk containers and their contents, including underground storage tanks. Examine material in rail cars, truck trailers, and storage silos. Be especially alert for rail car and trailer movement. These quickly disappear, as clean-up crews arrive.

8.5.5.3 - Flooding

All flood water, regardless of its source, must be considered a polluting medium because of overflowing sewers, outhouses, decomposing livestock, street run-off water, etc.

Depending on the extent of the flood, first determine the locations of the major stocks of regulated products. Food and drugs will normally receive first priority. As stocks of goods are located, rapidly survey the extent of damage, then concentrate on affected materials. Use your camera extensively. Examine the walls of buildings and storage areas and the top and sides of stacked or tiered goods for flood water residue, debris, and the usually well defined high-water mark. Finished products, ingredients, and containers stacked above this line are still of concern because other problems probably exist (e.g. vermin defilement, failure of refrigeration, thawing of frozen items, etc.).

Make arrangements to have any suspect material embargoed by local officials, or held pending final disposition. Management is usually cooperative and willing to do things it may not normally do to get back to normal operations as quickly as possible. Cooperate with management, but avoid hasty decisions.

Many products are quickly rendered unsuitable for human consumption by water action. Items such as bread, cakes, cookies, candies, bulk flour, sugar, bulk liquids, and similar items not in jars or hermetically sealed containers can often be immediately hauled to disposable areas and destroyed.

Determine areas which have lost power. In facilities such as frozen food firms, frozen or refrigerated warehouses, etc., check the sites for length of down-power and condition of the products. If power is restored in time to avoid thawing, or prevent spoilage of refrigerated items, and products were not inundated, or otherwise affected, there is no need for further examination.

Even though flood waters may not have inundated the firm, the situation may have caused sewer and waste lines to back-flush into basements and immediately drain out again. Debris or sewage particles along walls and on low floor surfaces or presence of sewage odors are evidence of backflushing.

Grain, cottonseed, soybeans, dried bean products, peanuts, and similar products may become flood damaged in terminal elevators, on farms, and in flat storage facilities. In addition to flood water contamination, molding products may develop mycotoxin contamination. Examine susceptible products and facilities for damage, inundation, and mold.

Rodent activity may increase in flooded areas as the vermin seek food and shelter. Be alert to rodent defilement on products.

As lots of products are checked, embargoed, or released and the immediate situation returns to normal, firms will want to start operating. Prior to their beginning operations, examine equipment and processing facilities for pollution, and its aftermath. Plant operation must not be permitted unless proper cleanup and sanitizing is performed.

8.5.5.4 - Hurricanes & Tornadoes

Investigate following the guidance in IOM 8.5.5.3. In addition, examine products for evidence of physical damage caused by flying particles and crushing by debris. Physical damage to product containers may be extensive. Broken or leaking containers of materials such as chemicals, oils, fertilizers, etc., may have contaminated materials subject to FDA coverage. Also see IOM 8.5.5.6 on chemical contamination from various sources.

8.5.5.5 - Fires, Explosions, Riots

FDA operations following these disasters are usually localized and do not normally involve a large number of personnel or extended resources.

Examine products for exposure to excessive heat, physical damage from flying particles and falling debris, and lack of refrigeration in down-power areas. Examine for water damage from fire fighting activities and handle these as a flooding situation. Also, be alert for possible pollution from using non-potable water in fire fighting.

Fire fighting often involves use of chemicals, so examine products for residues from possible toxic fire extinguishing materials, and question fire authorities regarding this issue.

In addition, chemical contamination in fire disasters can also be present from other sources, including:

1. Stored chemicals rupturing from heat or from impact of falling debris;
2. Spraying or leaking chemicals (liquid, powder, dust, granules) as damaged containers are being removed or salvaged from the fire area;
3. Tracking of chemical material from contaminated areas to other areas by fire crews or others;
4. Burning or melting plastic containers, insulation, and other building materials;
5. Leaking fuels, storage batteries, anti-freeze, etc., from burning, damaged or overheated equipment;
6. Chemicals from melting or vaporizing electrical insulation and, in particular, cooling chemicals from leaking or exploding electrical transformers. Large commercial transformers are often directly involved in the fire area and may leak or explode from the heat, spreading toxic liquid chemicals (some transformer oils contain concentrations of PCB) over a large area, even contaminating products in non-fire areas.

8.5.5.6 - Chemical Spills, Hazardous Waste Sites, Wrecks

See IOM 3.2.11 for information.

Chemical spills occurring on land or water can pose a serious threat to the environment and contaminate FDA regulated products both directly and indirectly.

In wrecks, the physical impact usually causes most damage. Toxic items in the same load may rupture and add to the contamination. In train wrecks, other railcars loaded with chemicals, oils or other contaminating materials may rupture and contaminate food and drug products in otherwise undamaged cars. Removal of the wreckage may cause further physical damage or chemical contamination. Exposure to weather may also adversely affect the products.

Do not overlook the possibility that runoff of toxic chemicals from wrecked and ruptured cars may contaminate adjacent or nearby streams supplying water to downstream firms under FDA jurisdiction.

Hazardous waste sites also pose a hazard to the immediate environment, as well as off-site, if runoff contaminates nearby surface waters or if leachate contaminates ground water supplies.

8.5.5.7 - Earthquakes

Extreme care must be exercised when working in earthquake areas. Do not enter severely damaged buildings.

Most damage from an earthquake comes from the after shocks, falling debris, and resulting fires and flooding. Items under FDA jurisdiction are most likely to suffer physical damage, spoilage from lack of refrigeration, and/or fire and flood damage.

8.5.6 - BIOTERRORISM

Guidance to the Field on Bioterrorism (10/17/2001)

When a District is notified of a suspected bioterrorism event (including anthrax events) involving an FDA regulated product, they will notify Office of Crisis Management/Office of Emergency Operations (OCM/OEO) (301-796-8240) and the local OCI office immediately. OCM/OEO will then notify the appropriate FDA Center, the HHS Office of Emergency Preparedness (OEP) and OCI headquarters. OCI will then notify FBI and/or local law enforcement. If OCM/OEO or any other FDA office gets a report, OCM/OEO will notify the offices above as well as the District Office involved. Notification of the state officials will occur at the direction of OCM/OEO or OCI.

It is vital that the person taking the initial report obtain complainant contact information as well as detailed information about the event. This is the same information that is regularly collected for consumer complaints and used to record the complaint in FACTS. Complainants should be instructed to call local police (911) and follow police instructions.

If a bioterrorism act is suspected, FDA staff should not collect or accept samples from any local, state, or law enforcement agency as such actions will be coordinated by OCI and the FBI, as appropriate. If an FDA product is suspected in a tampering, please call OCM/OEO immediately. In the event that FBI/OCI determines the product is not suspect, OCM/OEO will issue further guidance to the District Office.

8.5.7 - PRODUCT DISPOSITION

In every disaster situation orderly disposition of affected merchandise poses problems. Lots under embargo, or voluntarily held pending examination or analysis, must be secured until the examination or analysis is completed, and a decision to release is made. If the material can be released, it is returned to the owner. If contamination is obvious and state or local officials condemn the lots, arrangements must be made for disposition. Mixed adulterated and non-adulterated materials must be held for segregation and disposition.

Depending on the circumstances and the magnitude of the disaster, segregation, destruction, or reconditioning of affected goods may be accomplished in the immediate area. However, the materials may be moved to distant locations for further manipulation.

FDA normally opposes movement of affected goods since control of the lots is difficult. However, in cases of wide spread disasters, reconditioning centers established in non-disaster areas may be the most efficient way to handle the problem. Decisions of this nature will be made by command or headquarters officials. Should the materials be moved, arrangements must be made for their control. Short moves might necessitate guards on the vehicles to prevent diversion, while longer ones may be by regular carriers with control by shipping records, sealed railroad cars, bonded truckers, etc.

A situation not usually encountered during our normal operations is the problem of scavengers. Handling scavengers and preventing their activity is a police matter. Nevertheless, it ties in closely with your operations in disasters, and plans must be formulated for the protection of products detained, released, or awaiting disposition at the disposition site.

In disasters, local police forces are usually augmented by State and County Police, National Guard, State Militia, or private security forces. Arrangements should be made by the disaster command officials for guarding of affected products. If this has not been done, you should make the recommendation.

8.5.7.1 - Segregation

The condition of certain products may be difficult to ascertain since one often has no way of determining how excessive heat, humidity, or disaster conditions affected packaged contents. Smoke damaged containers of one material may not be of concern, while for other materials; it may be cause for condemnation. Rules for each product in each situation are impossible. Your decisions in disaster areas should be based on experience, review of the laboratory results if possible, and input from your state/local counterparts and superiors.

The segregation process often creates a multitude of problems, especially when insurance claims-agents and salvage firms become involved. You are not to segregate materials yourself. This is the responsibility of the owner or his agent. You should advise them what constitutes releasable conditions. After segregation, you may be instructed to advise them what can and cannot be released based on your examination and/or laboratory results.

8.5.7.2 - Destruction

It is not your responsibility to say how condemned products are to be destroyed. This is a concern of the owner and the state or local health agencies that condemned the products. Many times, however, FDA will be asked to aid in or recommend destruction methods. The most common destruction method is crushing and dumping in a land fill in approved areas. See IOM 2.6.1. Destruction methods usually are worked out with state or local officials. The final decision in major operations may be required of the command officials or higher headquarters, especially if the environmental impact is significant.

Control products to be destroyed and protect them from pilfering at destruction sites.

8.5.7.3 - Reconditioning

Often, products affected may be reconditioned depending on the condition of the product, it's container, type of product, intended use, and extent and type of contamination.

Any reconditioning must be closely supervised, with proper safeguards for product accountability. Procedures must be such that control is maintained over the complete operation, with proper disposition of the rejected portion and the reconditioning of the acceptable portion performed to the satisfaction of all health officials.

Certain products which cannot be salvaged for human or animal use might be of use in non-food or non-feed industries. Examples of such products include:
1. Butter for soap stock
2. Meat and Poultry products for technical oil production
3. Oils and nuts for technical oil production
4. Flour for glue or wall board construction
5. Grains and fruits (especially dried) for industrial alcohol
6. Fish for fertilizer
7. Eggs for tannery use

However, these must be denatured to render them unfit for food or feed use. Firms must account for the amounts of product denatured, to whom it was sold, and the final use of the product. Examination of the product at its final destination and/or a spot check may be required to assure it is utilized in non-food or non-feed products.

8.5.7.4 - Relabeling

Relabeling will be permitted, if all the following conditions are met:
1. The new label contains all mandatory information, is not misleading in any way, and conforms with the Act in all other aspects;
2. Label codes are carried over to the new label;
3. The product is not contaminated; and
4. The container has its original integrity.

8.5.7.5 - Ammonia Leaks

Refer to IOM 1.5.4.2.3 for guidance prior to entering any area where an ammonia leak has occurred.

If products involved in an ammonia leak are to be salvaged or reconditioned, cover the following points:
1. Cases of food should be removed from ammonia spill rooms as soon as possible;
2. Food packages should be removed from master corrugated cases as soon as possible. Ammonia appears to be absorbed by the corrugated cases;
3. Food products should be repacked into unaffected cases and moved to storage areas free of ammonia and other products;
4. When sampling ammonia contaminated products use IOM Sample Schedule Chart 3 for guidance.

The following barrier characteristics of packaging materials exposed to ammonia will help in deciding if food products may be salvaged or reconditioned:
1. Kraft and other types of paper are very permeable;
2. Plastic films (polyethylene, saran, cryovac, etc.) are relatively good barriers;
3. Water glaze (ice) on food will absorb ammonia and the washing action by melting ice may eliminate ammonia;
4. Waxed paper overwrap and waxed cardboard boxes are very permeable;
5. Loose packed Individually Quick Frozen (I.Q.F.) Foods are more susceptible than block frozen foods;
6. Glass, metal and heavy aluminum foil packages are excellent barriers.

8.5.7.6 - Perishable Products

Milk is extremely perishable, and is highly susceptible to bacterial contamination. Any attempts at salvaging milk are risky. Retail cartons of milk are not to be salvaged. Storage vats or sealed tanks of milk in processing plants must be closely examined and tested before release. If milk has been affected by flood waters, it should be condemned.

Fresh fruits and vegetables which have been inundated by flood waters cannot be adequately cleaned. Most are subject to rapid spoilage.

Products which require refrigeration or freezing and that have been immersed in flood waters cannot be reconditioned. The same applies to meats or poultry which have been without refrigeration and may be in a state of decomposition.

The following is general guidance in determining when frozen or refrigerated products cannot be reconditioned:
1. Products that are contaminated;
2. Products that have thawed and there is evidence of decomposition;
3. Products that have thawed and represent a potential public health hazard;
4. Products that have not been maintained at temperatures appropriate to individual product requirements;
5. Products meeting criteria in the proceeding sections regarding types of containers.

8.5.7.7 - Reconditioning Plastic, Paper, Cardboard, Cloth and Similar Containers

Products packed in plastic, paper, cardboard, cloth and similar containers that have been water damaged usually cannot be reconditioned. (In some instances, sugar has been permitted to be returned to a refinery for reprocessing, but each case must be decided individually). Fire and/or smoke damaged pre-packaged products may be permitted to be relabeled if the contents have not been affected.

General rules for reconditioning of products in these types of containers are the following:

1. The product is not contaminated and the product is not highly susceptible to bacteriological contamination;
2. If the external container is torn, the interior liner must be intact, and the external container must be repaired or replaced to eliminate possible contamination of the product;
3. Soiled containers may be cleaned, if the product is not damaged and the container can be cleaned;
4. Foods from torn packages, where the product has been exposed but not obviously subjected to contamination, may be repackaged;
5. Water, chemical or other liquid damage, where the exterior package may be replaced, providing the internal containers were not affected and the external containers can be replaced without contaminating the product;
6. Fire damaged products (e.g. wet, burned, heavy smoke or toxic fume contamination), are generally not reconditionable.

NOTE: Foods for infants, the aged or infirm, and drug products must be strictly controlled to assure the product is acceptable.

8.5.7.8 - Reconditioning Screw-top, Crimped-cap, and Similar Containers

Products in containers with screw-caps, snap-lids, crimped-caps (soda pop bottles), twist-caps, flip-top, snap-open, and similar type closures must not be reconditioned. Sediment and debris from flood water becomes lodged under the cap lips, threads, lugs, crimps, snap-rings, etc. and is impossible to remove, especially after it has dried. If these container/closure systems are affected only by fire or smoke, but the contents are not affected by the heat, they may be relabeled.

General rules for reconditioning are:

1. Product is not contaminated, or rendered unfit for food.
2. Soiled containers may be reconditioned if soil can be removed, and it does not involve the closure or contents.
3. Rust on closure: No rust allowed; surface rust may be removed by buffing or other suitable means.
4. Cap or crown dents: slight indentations obviously not affecting the rim seal would be reconditionable.
5. If there is evidence of exposure to extreme temperatures or pressures (hurricanes-tornadoes), products are not reconditionable.
6. If there is soil around the closure, products are not reconditionable.
7. If submerged in water, chemicals, or other liquids, products are not reconditionable.
8. If container/closure is defective or not properly sealed, products are not reconditionable.

8.5.7.9 - Reconditioning Hermetically Sealed (Top & Bottom Double Seam) Cans

Products in this type container which have been exposed to fire and smoke, and which are not damaged by the heat or exposed to water contamination, may be relabeled.

This type container, having been immersed in water, may be reconditioned and relabeled under controlled conditions and supervision as follows:

1. Inspect cans;
2. Remove labels;
3. Wash containers in soap or detergent solution, brushing as necessary;
4. Rinse in potable water;
5. Buff to remove rust. Heavily rusted cans are to be discarded;
6. Disinfect by:
   a. Immersion in a solution of sodium hypochlorite containing not less than 100 ppm available chlorine or other equivalent disinfectant, or
   b. If product will stand it, immerse in 212°F water, bring the temperature of the water back to 212°F and maintain the temperature at 212°F for at least five minutes, then remove and cool to 95°F;
7. Dry thoroughly; and
8. Re-label.

General Rules for reconditioning canned foods are:

1. The product is not contaminated.
2. No rust is allowed. Surface rust may be removed, by buffing, electrolysis, or other suitable means.
3. Cans soiled by dirt, smoke, etc., may be reconditioned if the product is not contaminated and the container can be cleaned by an acceptable method.
4. Water contaminated cans may be reconditioned if subjected to an approved bactericidal treatment and dried promptly.
5. If can dents consist of insignificant paneling or slight dents not affecting the double seam, or cracking the can corrugation, and not causing the can end to bulge, reconditioning is possible.
6. Leaking cans, cans with open seams, severely damaged seams, cans which are abnormal (i.e., swollen or flipper) and cans with defective closures are not reconditionable.
7. Cans exposed to extreme temperatures are not reconditionable.
8. Cans crushed to the point that the can body is extensively creased, paneled or dented on the seams can not be reconditioned.

8.5.7.10 - Reconditioning Devices

Radiation Type Devices - Radiation producing products such as x-ray equipment, TV sets, and microwave ovens are relatively complex, expensive, sensitive devices. Any of these type devices which have been inundated by flood waters, exposed to fire, heat, mechanical or physical damage such as falling debris, chemically corroded, or electrically damaged must be checked by expert personnel. They will decide whether the device can be repaired

or reconditioned by the manufacturer and/or re-tested for compliance.

Do not release any of these type devices, but report the situation to your supervisor so arrangements can be made for appraisal. The regional radiological health representative will normally be the individual contacted by your district in this type situation.

Medical Devices and Diagnostic Products - Do not attempt any reconditioning of these type products.

Any medical devices or diagnostic products which have been affected by disaster forces should not be released. Advise your supervisor of the facts so the district officials can obtain any necessary advice and guidance from the Center for Devices and Radiological Health.

8.5.8 - REPORTING

See IOM 1.1 English language requirement. There is no prescribed format for narrative reporting of disaster operations. Consult with your supervisor as to your district's preference. The report should briefly describe the onset of the disaster, its magnitude, and your activities. Include cooperation with officials, planning operations, and the logical sequence of your activities.

Your report must contain exhibits consisting of photographs, diagrams, records, references to samples, and any other items necessary for proper presentation of the operation. Refer to RPM Chapter 8 “Emergency Procedures,” for guidance on reporting natural disasters and civil disorders. Attach copies of any FDA forms issued, especially the use of FDA-2809 (exhibit 8-12), Natural Disaster Report, listing amounts of materials destroyed and the method of destruction. See IOM 2.6.4. Prepare charts and lists as necessary to provide documentation of all affected lots destroyed, reconditioned, or released. Include kinds and amounts of materials segregated, released, reconditioned, and destroyed and method of reconditioning and/or destruction.

Record operation and time in FACTS.

SUBCHAPTER 8.6 - SURVEILLANCE

8.6.1 - SURVEILLANCE PROCEDURES

Instructions for planned surveillance activities are found in your Compliance Program Guidance Manual. During your inspectional, investigational, and other activities, be alert to anything which may be new or unusual or interesting from FDA's viewpoint such as:

1. New firms;
2. New products;
3. New production and distribution practices;
4. New equipment and industrial processes;
5. Seasonal practices;
6. Industry trends;
7. Recent or on-going construction and plans for future expansion;
8. Proposed products;
9. New ideas the firm is contemplating;
10. New products in the development stage;
11. Activities about a firm's competitor;
12. Plans for consolidation, mergers, diversification, etc.;
13. Equipment failures or malfunction possibly affecting other firms, faulty design of equipment, incompatibility of ingredients, faulty process design, equipment manufacturers' recommendations which violate proper manufacturing precautions, health fraud (quackery), etc.;
14. Health Fraud (Quackery) is defined as "the deceptive promotion, advertisement, distribution or sale of articles, intended for human or animal use, which are represented as effective to diagnose, prevent, cure, treat or mitigate disease, or provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes." See CPG: Chapter 1.

Use the FDA-457, Product/Establishment Surveillance Report, to report any of the items listed above. Include any other ideas/observations you may consider worthy of reporting. FDA must keep abreast of new ideas, trends, or contemplated changes in the industries we regulate as well as problems with possible broad impact.

8.6.2 - FDA 457 PREPARATION

Report product or establishment surveillance on the FDA 457, Product/Establishment Surveillance Report, and submit it to your supervisor. See IOM Exhibit 8-13. Prospective new establishments must be verified for appropriateness before inclusion in the active FEI. See Field Management Directive (FMD) 130

Complete blocks 1 through 18 and 22 through 26 of the FDA 457 for product surveillance or blocks 1, 6, 8 through 10, and 18 through 26 of the FDA 457 for establishment surveillance. Your supervisor or reviewing official will complete blocks 27 through 30. For a human drug firm or product which has not actually entered the market, enter the information in the REMARKS Section.

The following number designations correspond to identically numbered blocks on the FDA 457.

1. "HOME DISTRICT" - Enter the name of the home district of the new firm or firm producing the product reported. See IOM 2.2.5.6 for definition of home district.
2. "REPORTING UNIT SYMBOL" - Enter your district symbol here (e.g., "ATL-DO", "BLT-DO", "LOS-DO", etc.). If units other than field units report on the form, their mailing symbol goes here.
3. "CENTRAL FILE NO." - Enter the central file number (CFN) or firm establishment indicator (FEI), if readily available. Otherwise, leave blank.
4. "J.D./T.A." - Leave blank.
5. "COUNTY" - Leave blank.
6. "DATE" - Enter date you prepare the FDA 457.
7. "PRODUCT CODE" - Enter the 7-character Product Code from the Data Codes Manual.
8. "OPERATION" - Enter operation code from the Data Codes Manual. For surveillance it is 13.

9. "PROGRAM ASSIGNMENT CODE" - Enter the Program/Assignment Code (PAC) from the Data Codes Manual.
10. "HOURS" - Enter the time spent on this operation, including time for preparing the report, into FACTS. Report time to the nearest 1/4 hour in fractions, not decimals. Do not report travel time.
11. "IDENTIFICATION" - Enter the generic name of the product and quote enough of the label to properly identify the item, including the firm name and address.
12. "MANUFACTURER CONTROL CODES" - Enter all codes, lot numbers, batch codes, etc., found on the containers, labels, wrappers, packages, cases, etc. and indicate whether the number is located on the label, containers, case, etc.
13. "AMOUNT ON HAND" - List lot size (amount of the products) on hand or available. If count cannot be made, make an estimate and so indicate.
14. "DATE LOT RECEIVED" - Determine and enter the date the dealer received the lot(s).
15. "ESTIMATED VALUE" - This is the invoice value of the amount on hand at the time you observed it. Estimate, if not readily available.
16. "SAMPLE NO(s)" - Enter sample number(s) of any relevant samples collected. If no samples are collected, enter "None".
17. "DEALER" - List name and complete address including the ZIP code of dealer who owns or has custody of the product.
18. "DISTRIBUTOR MANUFACTURER SHIPPER OTHER" - Check applicable box or boxes and list name, complete address, ZIP code and telephone number, including area code.
19. "ESTABLISHMENT TYPES/INDUSTRY CODES" - Enter up to three establishment types with up to six industry codes each for the establishment.
20. "ESTABLISHMENT SIZE" - Enter gross dollar value of the annual production of all FDA regulated products made or manipulated in the establishment.
21. "INFORMATION OBTAINED BY" - Check the applicable box to indicate how the FEI information was obtained.
22. "REMARKS" - Enter explanatory information here.
23. "REPORT PREPARED BY" - Type or print your name and title.
24. "EMPL NO." - Enter your employee number.
25. "PC" - Enter your Position Classification code.
26. "SIGNATURE" - Enter usual signature.
27. "REPORTING UNIT ACTION" - Your supervisor or reviewing official completes this section by checking the applicable box.
28. "NAME OF REVIEWING OFFICIAL" - Typed or printed name of person reviewing the report.
29. "TITLE" - Title of reviewing official.
30. "DATE REVIEWED" - The reviewing official enters date report was reviewed.

Complete reverse side of the FDA 457 by checking the appropriate box(s).

8.6.3 - FDA 457 ROUTING

Submit all FDA 457's to your supervisor for review, assignment, or routing as indicated:

1. Human Drug Surveillance - Submit a copy of the FDA 457 to the Center for Drug Evaluation and Research (HFD-323).
2. Veterinary Drug Surveillance - Submit a copy of the FDA 457 to the Center for Veterinary Medicine, (HFV-236).
3. Device Surveillance - Submit a copy of the FDA 457 to the Office of Medical Devices (HFZ-331).
4. Foods Surveillance - Submit a copy of the FDA 457 to the home district.
5. Tobacco Product Surveillance – Submit a copy of FDA 457 to the Center for Tobacco Products, Office of Compliance and Enforcement
6. Other Products - Submit a copy of the FDA 457 to the home district.

SUBCHAPTER 8.7 - INVESTIGATIONAL RESEARCH

8.7.1 - RESEARCH ASSIGNMENTS

"Investigational Research" is investigation to discover and interpret facts, or to revise accepted theories and practices in the light of new facts, to improve investigational operations.

Investigational Research may be proposed by you, or assigned by your supervisor, and must be submitted for approval on the FDA 1609, Research Project Record. To formally propose research, complete this form and submit the original and two copies to your supervisor. After branch approval, the original is retained by the branch research coordinator; one copy by the researcher; and one copy by HFC-132. Approval authority, except for research under the Science Advisor Research Associate Program (SARAP), is at the branch director level. SARAP projects are considered on a competitive basis and approved at headquarters. Investigational personnel are eligible to compete for SARAP approvals. Instructions and conditions for SARAP proposals are provided in the "ORO Research Programs" booklet.

Numerical and alpha listings of active laboratory and investigational research projects will be computer generated at headquarters and supplied to the districts on a semi-annual basis. To prevent duplications, check these listings (in possession of the science branch research coordinator) prior to proposing projects.

8.7.2 - JOINT RESEARCH PROJECTS

Project proposals involving significant analytical requirements must be approved in advance by the appropriate laboratory. Whenever investigational research requires analysis of samples, consider submitting a joint investigational/laboratory project proposal and final report. In these instances, request your supervisor to assist in arranging

such joint projects.

When proposed research projects involve engineering assistance beyond that which is available within the district, request this through your supervisor from the Domestic Operations Branch/Division of Domestic Field Investigations (HFC-130). DDFI Engineers may be available to assist on a specific short term basis, and to work with field investigators on joint projects, or may initiate investigational research independently.

8.7.3 - RESEARCH PROJECT IDENTIFICATION CODE

Project Codes are assigned by the district investigations branch research coordinator after project approval. You should assure a correct code has been assigned before beginning work under the approved project. The project code will reveal the district, the research category, and sequential project number (1 through 99) within the category for the district.

8.7.4 - RESEARCH PROJECT PROGRESS REPORTS

You must submit semi-annual progress reports for each ongoing research project. Each researcher shall initiate this form for each active project in April and October to reach DDFI (HFC-130) by April 15th and October 15th, respectively.

8.7.5 - TERMINATION OF RESEARCH PROJECTS

Report project termination on FDA 1609 and FDA 1609a. Enter a summary of the completed project on the FDA 1609, including actions taken and publication, if any. If a paper has been prepared for publication, include the abstract.

The complete project report, with supporting data, may be on plain-paper continuation sheets to the FDA 1609, or may be a separate memorandum attached to the FDA 1609. Submit a Form FDA 1609a to accompany a termination FDA 1609, to summarize the concluding semi-annual period of work on the project and to report final time expenditures. The minimum number of termination forms and project report copies is original plus two. After branch action, the original is retained by the branch research coordinator; one copy by researcher; and one copy by HFC-130.

8.7.6 - PRIORITY

Investigational research, after project approval, will be considered in relative priority to other assignments. Always keep your supervisor apprised when you are working on research projects. Whenever possible, such work should be done with other assignments for efficient operations. When research projects are urgently needed or of substantial scope and duration, you may request supervisory approval of appropriate continuous periods for uninterrupted work. The "Research Priority" entered in block # 9 of the FDA-1609a indicates relative priority to other research, not the priority relative to regulatory and compliance assignments. You should complete regulatory and compliance work while avoiding, as best you can, delays in completing approved research projects. See your supervisor to help determine priorities.

8.7.7 - DATA REPORTING

Investigational research time is reported in FACTS under the Miscellaneous Operations Accomplishment Hours screen (available under navigate on the tool bar), using a distinctive Program/Assignment Code (PAC), reporting as Operation 01, Research.

If laboratory personnel are working on investigational research projects, follow laboratory procedures for reporting time, while using the Investigational Research Project Identification Code.

SUBCHAPTER 8.8 - COUNTERFEITING/TAMPERING

8.8.1 - REPORTING CONTACTS

All reports of counterfeiting, tampering or tampering threats must be immediately reported to the Office of Criminal Investigations (OCI) Headquarters' Office, SAIC-IOD (Special Agent in Charge- Investigative Operations Division) (301-276-9500) and the Office of Crisis Management (OCM)/Office of Emergency Operations (OEO), HFA-615, (301-796-8240).

If the complaint or report involves a USDA (United States Department of Agriculture) regulated product, the District office should report it directly to the USDA and notify OCI, SAIC-IOD and OCM/OEO immediately.

8.8.1.1 - OCM / OEO RESPONSIBILITY

OCM/OEO is the focal point for communications; especially in those counterfeiting/tampering cases where regional/national coverage is necessary. Alert the OEO immediately to all suspected or confirmed counterfeiting/tampering incidents, whether or not there is an injury/illness involved, especially if media attention will be initiated by any source.

8.8.2 - COORDINATION WITH OTHER GOVERNMENT AGENCIES

Federal - The Federal Bureau of Investigations (FBI) and the USDA share enforcement of the Federal Anti-Tampering Act (FATA) with FDA as described below:

1. FBI Responsibility - The FBI has concurrent jurisdiction under the FATA over products regulated by FDA. The FDA understands the FBI's primary interest in the FATA matters will be to investigate; particularly, those cases which involve a serious threat to human life or a

death. SAIC-IOD or the local OCI Field Office will coordinate all referrals to the FBI in accordance with agency policy.
2. USDA Responsibility - The USDA will investigate and interact with the FBI on counterfeiting/tampering of products regulated by USDA. If a counterfeiting/tampering complaint or report is made to an FDA District office and involves a USDA regulated product, the District office should report it directly to the USDA and notify OCI, SAIC-IOD and OCM/OEO immediately.

State and Local - Isolated incidents of counterfeiting/ tampering not investigated by OCI and not meeting the criteria for FBI or USDA follow-up, may be referred to the appropriate state or local investigative agencies, as outlined in IOM 8.8.3. Assistance should be provided to cooperating officials as necessary or where requested.

8.8.3 - AUTHORITY & RESPONSIBILITY

FDA is authorized to investigate reported counterfeiting/tampering of FDA regulated consumer products under the FATA, Title 18, USC, Section 1365 and Title 18, USC, Section 2320. See IOM Exhibit 8-14. In most cases, the authority for such investigations is also found in the FD&C Act.

OCI has the primary responsibility for all criminal investigations of counterfeiting/tampering/threat incidents of FDA regulated products. Given that responsibility, OCI Field Offices will coordinate responses to counterfeiting/tampering reports with the District Offices they deem appropriate, to ensure initial investigative steps are taken in a timely and efficient manner.

In those incidents where OCI does not, or cannot, initiate a criminal investigation, they will inform the District Offices of their decision and the District Offices will determine the proper follow-up, which could include further investigation by the Districts or referral to local or state authorities. The District Offices will keep OCI informed of their follow-up activities and any relevant changes in its status. Prior to initiation of any tampering investigation, you and your supervisor should evaluate the situation from a personal safety perspective. You and your District management may also need to determine if a situational plan is warranted. Refer to IOM 5.2.1.2 - Personal Safety, and IOM 5.2.1.4 Situational Plan, for more information.

8.8.4 - RELEASE OF INFORMATION

Information on matters under investigation by OCI should not be released without prior discussion and concurrence of the OCI Field Office.

Information regarding open regulatory investigations should not be released without prior discussion and concurrence of the OCM/OEO office.

See IOM 1.6.1 and 8.8.1.1 for additional information concerning dealing with the media in investigative matters.

8.8.5 - INVESTIGATION

The purpose of these investigations is to determine if counterfeiting/tampering has occurred; the seriousness of the problem; the quantity of affected products on the market; the source of the counterfeiting/tampering; and quick removal from consumers or commerce of any contaminated product. OCI will seek to identify and initiate criminal prosecution of those persons responsible for criminal activity associated with counterfeiting/tampering/threat incidents.

FDA will investigate reports of counterfeiting/tampering associated with FDA regulated products. Priority will be given to reports of death, illness, injury, or a potential health hazard. Adhere to existing procedures and instructions as outlined in the IOM and RPM when conducting counterfeiting/tampering investigations, inspections, sample collections, special investigations, and related activities including interviews, record examination, direct observation, affidavits, etc. Additional guidance on investigational authority under FATA can be found in IOM 8.8.3.

8.8.5.1 - General Procedures

Counterfeiting/Tampering incidents historically have occurred in unpredictable forms and products. Standard operating procedures (SOPS), in most cases, will suffice for these investigations. As events take place, specific instructions for some investigations may be provided by OCI headquarters and/or your District office. Expeditious resolution is important, especially when a health hazard may be involved.

Attempt to answer the following questions as rapidly as possible:
1. Has counterfeiting/tampering occurred, or can the condition of the product be explained by other means?;
2. Is death, injury, or illness associated with the report and, if so, does it appear to be caused by the product counterfeiting/tampering?;
3. Does the incident appear to be isolated, or widespread?;
4. Is it likely other, similarly affected FDA regulated products remain in distribution, and if so, what is the extent and magnitude of distribution?;
5. If not isolated, could the product counterfeiting/tampering have occurred at the production facility or in the distribution chain?; and
6. Can specific persons or points in the distribution chain be identified as possibly causing the problem?

When counterfeiting/tampering, threat or false reports are evident, or highly suspect, use the concepts listed below which are appropriate for the situation. **Be sure to coordinate your efforts with OCI SAIC/IOD and OCM/OEO.**

8.8.5.2 - Interviews

It is often advantageous to work in pairs during interviews with complainants. Conduct interviews in a location which reduces unnecessary interruptions or distractions.

Establish rapport with the person or persons being interviewed to put them at ease. Listen to the person. Let them first tell the story in their own way. Listen carefully to each facet. Be genuine and at ease. After hearing the entire story, ask them for more information to fill in details. Ask for clarification of key points.

Obtaining details and requesting clarification of key points allows you to obtain an idea of the validity of the person's story through comparison of the accuracy of the details with previous information supplied.

Note-taking may put the person being interviewed on edge. If this appears to be the case, do not take notes until you request clarification of key points. For cases of counterfeiting/tampering, ask who was with the person, what happened in the store, any problems noted with the product at the store, and other questions which will provide you with more information on when, where, or why events took place, who was present, etc. If two investigators are involved in the interview, one should take notes while the other asks the questions.

During interviews, watch for changes in attitudes, body language, hesitation in speech, etc., as you observe and listen to the person being interviewed. Describe your observations of body language and personal characteristics in your report.

In most counterfeiting cases, ORA investigators and OCI agents conduct joint inspections/investigations at the distributors. It is the purpose of the ORA investigators to document receipt and distribution of counterfeit products and to discuss voluntary recall of those products by the wholesalers. OCI agents will at the same time conduct their investigation into the knowledge and source of the counterfeit products. It is NOT the purpose of the investigator to simply accompany the OCI agent during his/her investigation.

8.8.5.3 - Sampling

Tampering Cases: Follow these procedures:

Whenever a sample is collected for suspected tampering, you must collect an authentic sample of the same product. It should be from the same lot and code, if at all possible. The sample size for the authentic portion is at least 6 intact units.

Collect any containers a suspect may have handled as they placed the tampered product on the shelf. Preparation of the sample and the shipping method should be carefully selected to insure the integrity and security of the samples. Coordinate with the OCI and the Forensic Chemistry Center (FCC) on correct sample packaging.

When handling product containers or other evidence associated with tampering, take care to avoid adding or smearing fingerprints by wearing cotton gloves, using tongs, forceps, or by picking the container up by opposing corners. Identify product containers carefully and in as small an area as possible. Do not open outer containers to identify inner containers or inserts.

When sampling or handling product, be alert for traces of evidence such as hair, dust, paint chips, glass fragments, etc. Secure such evidence in a separate container such as a glass vial, small manila envelope or plastic bag.

Samples should be packed to avoid movement of the product container within the bag. Individual dosage units from previously opened containers can be protected by removing them from their container utilizing a spoon or forceps. Secure them in separate containers so they do not rub or smear possible evidence. Further guidance can be found in the FBI "HANDBOOK OF FORENSIC SERVICES" (http://www.fbi.gov/about-us/lab/handbook-of-forensic-services-pdf) and was supplied to each district. As a precaution, rubber gloves may be worn inside of cotton gloves as protection against toxic or caustic substances.

Ship samples with extreme care to insure their integrity. Thoroughly describe your sample and its characteristics on the collection report (C/R) to facilitate the analysis. Include any descriptive terms used by individuals associated with the complaint. If special instructions to preserve fingerprints or for further handling are indicated, they should be noted on the C/R and FDA-525. If speed is imperative consider hand delivery to the lab.

Counterfeiting Cases: Follow these procedures:

The District office may be asked to pick up suspect counterfeit products. Normal procedures for handling suspected products and the preservation of evidence should be followed as outlined in the tampering section for sampling above. In most counterfeiting cases, investigators do not usually collect an authentic sample of the same product. Authentic samples should only be collected when requested by OCI in consultation with FCC.

8.8.5.4 - Complainants

When visiting the complainant, use the standard consumer complaint procedures set forth in the IOM. Plan and think through the reasons for and goals for your visit before approaching the complainant. Listen carefully to the complainant. Review background of the complainant for history of complaints or lawsuits filed. Background checks are appropriate when district management has strong suspicions concerning the validity of the complaint or the potential for the complaint being used to defraud. It is often advantageous to work in pairs while interviewing complainants.

When collecting samples from the complainant, document them as official samples, including an affidavit describing the circumstances involved in the purchase and use of the product.

When investigating at a complainant's residence, obtain permission from the occupant to examine trash containers for discarded product labeling and/or containers which can be utilized to further investigations. Be alert to sources of contamination in the residence which are similar to the

contaminants found in the product. Be sure to examine other containers of the same product in the residence with the owner's permission and sample them if suspect. Obtain permission to examine medicine cabinets if a drug dosage form is involved.

It is possible individuals you contact may not be aware of the provisions of the FATA. A general discussion of the FATA, its provisions for investigation, filing of false reports, and counterfeiting/tampering can be useful and informative to those individuals. Prior to concluding your interview of the complainant, obtain a signed affidavit attesting to the circumstances of the complaint, as directed by IOM 4.4.8. Include a statement in the affidavit similar to the following, "I have been informed of the provisions of the Federal Anti-Tampering Act and also that the providing of false information to the federal government is illegal." It is permissible to pre-type this statement at the bottom of an Affidavit, FDA 463a, and photocopy it before use if you have a large number of counterfeiting/tampering complaints to investigate.

8.8.5.5 - Retail Stores

When investigating a counterfeiting/tampering report at a retail store or other source of product, the local police department can be of assistance and provide advice. Before instituting any activities at the scene, protect the area to preserve any evidence on the store shelves, floor or adjacent areas and products. Discuss with the firm's management, and/or the personnel doing the stocking of the shelves, how material is received and handled prior to being placed on shelves.

Document the area using photographs of the product shelves, surrounding area, and any shots which would provide information on the product, its location and store layout. Samples of materials in the area that may be applicable to the investigation are to be collected. Because suspects are thought to handle multiple product containers when placing a tampered product on a store shelf, a diagram of the container relationships to each other should be prepared and individual containers given subsample numbers.

Be observant of persons present in the store, as guilty parties are thought often to return to such location, especially when the agency or news media are present. Be alert to statements of store personnel about activities they have observed. Obtain descriptions of the actions, dress and physical characteristics of persons the employees have noted exhibiting unusual/notable behavior in the store. Ascertain if the firm has a closed circuit TV monitoring system and if they maintain tapes, if so, these may be a source of leads. Obtain information about employees terminated in past year, employee problems, or shoplifters who may wish to cause problems in the store.

8.8.5.6 - Manufacturer and Distribution System Follow-up

The key to a successful investigation or inspection is to clearly define the objectives of the operation and to examine each facet of the establishment in light of the objective(s). Aspects of the production/distribution system to inspect for leads may include, but not be limited to the following:

8.8.5.6.1 - MANUFACTURING SITES

Document the following:

1. Age of facility, and date when production of the first batch of the product under investigation was initiated;
2. List of other facilities which produce the product under investigation;
3. For drugs, list by strength, size of container, name, dosage form, and number of packages per shipping case, all products manufactured or processed at the facility. If products handled are repackaged at this facility, give the name and address and method of receipt from the product source;
4. Obtain the names, titles, addresses, office and residence telephone numbers of representatives of the company, including that of the Chief Executive Officer (CEO), who are specified as contacts for various aspects of the event under investigation. State whether these representatives are members of an established management team to deal with such events, or have they been identified for the particular instance at hand;
5. Contract packagers, if any, should be described by name, location and products handled;
6. For the suspect lot, document the lot number, the size of the lot, size and type of containers in which it was packaged, its history of production and distribution beginning with the date of weighing of the raw material, and the dates and description of steps in processing;
7. Describe any locations within the facility where an employee could have access to the contaminant being investigated;
8. Describe the characteristics of the suspected contaminant within the facility, its container type, its brand and generic name, its lot number, size of container, whether the container is full, or partially full and the approximate amount remaining;
9. Describe security for the suspected contaminant including limitations of access, where it is stored, and responsibility for controlling access to the material.
10. Describe what legitimate use, if any, the facility has for the suspected contaminant in each of the locations found;
11. Determine how often the material is used and whether or not a log of its use is maintained;
12. If a log is maintained, obtain a copy showing its use and discuss with plant management the legitimacy of each such use;
13. Determine whether the firm verifies use and use rates and has a method of determining explanations for any discrepancies noted;
14. Have samples of the suspect contaminant been obtained by the FDA or other agencies, and if so, what are the results of analysis?;
15. Does the firm test for the contaminant under investigation?;
16. What method is utilized for such testing, and at what frequency?;

17. List the facility's sources of raw materials for the suspect lot/product;
18. Evaluate the raw material storage conditions to determine the potential for manipulation of materials;
19. Describe the lot numbering system, any plant identification numbers, and expiration dates placed on retail products and cases;
20. If any product for export is processed at this plant, describe any differences from domestic products;
21. If the product under investigation has tamper resistant packaging (TRP), determine the type of system utilized, and if the system utilized has been evaluated to determine if breaching is possible. If breaching is possible, describe. Describe lot numbers or code numbers placed on TRP and security measures taken for TRP materials on hand and those sent to contract packagers. Determine whether TRP materials are accountable;
22. If the plant process includes collection of samples for examination on the production line or by laboratory facilities, discuss where the samples are maintained, who has access to them, and their disposition;
23. Report dates and description of each step in processing, including identification of storage locations between steps. Obtain estimates of flow rates and volume of materials in hoppers and drums at key stages. Determine distances between production areas or between processing equipment at critical points. This information can be useful for statistical evaluation of the likelihood of contamination at various points in the process;
24. Include a description of the in-process lot numbering systems for each phase of manufacturing, security for each process and/or product while in storage and during processing;
25. In some types of processes, there are provisions for an individual to ensure sufficient product is placed in each container being filled. If this is the case in the plant under inspection, describe the circumstances and security for this process;
26. Determine whether the facility hires part-time employees, or transfers employees from one location to another on a temporary basis. Were any were present during production of the suspect lot?;
27. Describe provisions for determining reliability of employees;
28. Determine if employees can move from area to area within the facility. Describe any restrictions on their movements and if enforced;
29. Describe laboratory control tests and in-process tests performed on the finished packaged product and in-process materials. Determine if reserve samples are retained of all lots;
30. Determine how rejects and reworked materials are handled;
31. Describe any unusual events which may have taken place during the period when the suspect material was in the facility; and
32. Determine if the firm has a plan to safeguard against counterfeiting/tampering as part of its quality assurance (Q.A.) program. If so, determine the implementation date of this plan and review any periodic assessment reports for potential problem areas.

8.8.5.6.2 - DISTRIBUTION FACILITIES

It may be necessary to obtain the following information at each level in the distribution chain:

1. Amount of suspect lot on hand at time of inspection;
2. Obtain the turnover rate for the product under investigation;
3. Amount of suspect lot received, and any variations from amount consigned to the facility;
4. Date received;
5. How received;
6. Name and type of carrier which delivered the product. Determine security of the vehicle or container while in-transit;
7. Obtain distribution history of the suspect lots;
8. Describe the distribution area covered by the facility being inspected and the number of accounts served, whether they are retail or wholesale;
9. Determine if the facility handles any cash and carry orders;
10. Determine if the facility will accept returns and how are they handled;
11. Describe stock rotation practices and how they can be assured;
12. Determine if lot numbers of products distributed can be traced;
13. Describe the method of packing of shipments; for example, plastic tote bins sealed with nylon tape, intact cartons only, cases are split, etc.;
14. Describe the methods of shipment utilized by the warehouse; and/or
15. Describe personnel practices, problems and other information on visitors, contractors, etc.

It is often advantageous to chart a pictograph or a time line chart of the distribution system which shows basic information on each level in the distribution chain and distances between each link in the chain. It is also often worthwhile to prepare a time-line chart showing the progression of the suspect lot through the manufacturing process to the source of the complaint, including the significant steps in the manufacture and distribution of the suspect product.

8.8.5.6.3 - SECURITY

Obtain the following information. However, when preparing the EIR, do not report the details of the security system, since an inadvertent release could compromise a facilities security system. Discuss with your supervisor how to report this information.

1. General security arrangements, including the number of guards, their shifts, locations, and whether or not they patrol the facility;
2. Describe any closed circuit TV systems, their locations, and any physical barriers to prevent access to the plant grounds and its facility;
3. Describe who is logged in and out of the facility and whether or not employees must display identification badges upon entry. If plant employees are issued uniforms by color or design, which designate their work station locations, also describe;

4. Determine whether visitors, contractor representatives, cleaning crews, etc., are subject to movement tracking or control, and if any were present during production of the suspect product;
5. If the suspect product was particularly vulnerable to in-plant tampering during certain stages of handling, identify particular employees who had access to product during these stages and interview them individually. There may be occasions when line employees may be able to remember suspicious activities on the part of co-workers or others working in the area when suspect lots were being produced;
6. Describe the security measures taken for the processing area after hours, during work breaks, and at meal times. Be alert to those periods when in-process containers are left unattended on a packing/production line; and
7. Describe any employee relations problems such as layoffs, firings, probations, adverse actions, etc.

8.8.6 - RECORD REQUESTS

Occasionally, your investigation may require you to obtain information not specifically authorized under the FD&C Act, e.g., distribution records of food products, production records for cosmetics or foods, etc. Seek to obtain such records if the following criteria have been met, or if, in the opinion of your supervisor, district, or headquarters, it is necessary to do so:

1. The apparent counterfeiting/tampering incident may be serious and is assigned a high priority by your supervisor, district and/or agency, and;
2. The data sought is normally of the type FDA is trained to evaluate and have access to in other areas of routine FD&C Act activities, e.g., production records, formulas, distribution records, etc., and;
3. The requested data is likely to be necessary to the successful resolution of the investigation, and;
4. Other alternatives to obtain the information are not as readily available.

If a request for data is made, you should direct it to the most responsible individual at the location. Explain clearly and concisely your need for the data. Do not issue a written request unless you have specific supervisory/district concurrence to do so.

8.8.7 - REFUSALS

All refusals encountered during counterfeiting/tampering investigations should be documented using existing procedures. Refusals of requests should include documentation the criteria in IOM 8.8.6 were met and the firm was aware of the non-routine nature of the request. The lack of precedent in this area suggests thorough documentation to allow appropriate compliance review and follow-up. A search warrant, subpoena or other court order may be appropriate in some circumstances. The feasibility and necessity of these actions should be discussed with the OCI before such action is initiated.

8.8.8 - REPORTING

See IOM 1.1 English language requirement. Complete the FACTS Consumer Complaint Report and the FACTS Complaint Follow-up Report for all counterfeiting/tampering complaints received. See IOM Exhibits 8-2 and 8-3.

All completed and/or resolved reports of counterfeiting/tampering incidents should be provided to the OCM/OEO (HFA-615) to develop background information for agency use. If the investigation is of a continuing nature, OCM/OEO may require interim reports on a case by case basis.

Note: Time reporting should occur through FACTS.

Counterfeiting/Tampering reports should be reported in FACTS using the following guidelines:

Counterfeiting: Use the Problem Keyword "**OR**" (for "Other") and "**counterfeit**" in the Problem Keyword Detail field when recording complaints about counterfeiting in FACTS."

Tampering: Use the Problem Keyword "**TM**." It should be followed by a brief description of the problem such as "**tamper evident seal missing**" or "**foreign capsules in bottle**".

SUBCHAPTER 8.9 - OFFICE OF CRIMINAL INVESTIGATIONS (OCI)

8.9.1 - OCI PROCEDURES

The Office of Criminal Investigations (OCI) has the primary responsibility for all criminal investigations conducted by the FDA, including suspected tampering incidents and suspected counterfeit products. Similarly, OCI has primary responsibility and is the primary point of contact for all law enforcement and intelligence issues pertaining to threats or perceived threats against FDA regulated products. OCI participates in numerous law enforcement and intelligence task forces both nationally and internationally to include a full time representative to Interpol.

8.9.1.1 - Reports of Criminal Activity

All reports of suspected or confirmed criminal activity, including suspected tampering or counterfeiting incidents, must be reported to the appropriate OCI field office or resident office without delay. Additionally, all threats or perceived threats against FDA regulated products are to be referred immediately to the local OCI Field Office or to OCI Headquarters. In those instances where OCI does not, or cannot, initiate a criminal investigation in a timely manner, the District Offices will determine, in consultation with OCI, the proper follow-up.

8.9.1.2 - Liaison with Law Enforcement / Intelligence Community

OCI is the FDA's liaison component with the law enforcement community for criminal investigations and related matters. In addition OCI serves as the primary point of contact between the FDA and the Intelligence Community on all matters of mutual interest. All contacts regarding requests or questions received from federal, state, or local law enforcement agencies or intelligence agencies are to be referred without delay to the local OCI Field Office. Similarly, contacts to FDA Headquarters or Centers should be referred to OCI Headquarters. When FDA personnel receive information or requests from law enforcement or other agencies, they should obtain the caller's name, organization, and request and then refer the caller to the appropriate OCI component. After referring the caller to OCI, contact the affected OCI unit to provide them with the caller's information. This will ensure OCI is not caught by surprise. FDA personnel should not respond to inquiries concerning criminal investigations, including questions seeking confirmation of whether FDA is or is not conducting a criminal investigation.

8.9.1.3 - Consensual Electronic Surveillance

OCI has been designated the authority to administer the consensual electronic surveillance program for the FDA. To comply with FDA Policy and Department of Justice requirements, all FDA personnel must contact the appropriate OCI Field Office SAIC to request approval before any electronic surveillance; this includes recording consensual telephone conversations. FDA Headquarters and Center personnel should contact OCI Headquarters, AD IOD for approval requests.

8.9.1.4 - Postal Mail Cover

OCI is also the point of contact for any request for a mail cover through the U.S. Postal Inspection Service. A mail cover provides a written record of all data appearing on the outside of any class of mail to obtain information for:

1. Protecting national security;
2. Locating a fugitive; and
3. Obtaining evidence of the commission or attempted commission of a crime punishable by more than one year in prison. A mail cover may not be used in non-criminal investigations, except in those cases involving a civil forfeiture of assets related to violations of criminal laws.

SUBCHAPTER 8.10 - GENERAL INVESTIGATION REPORTING

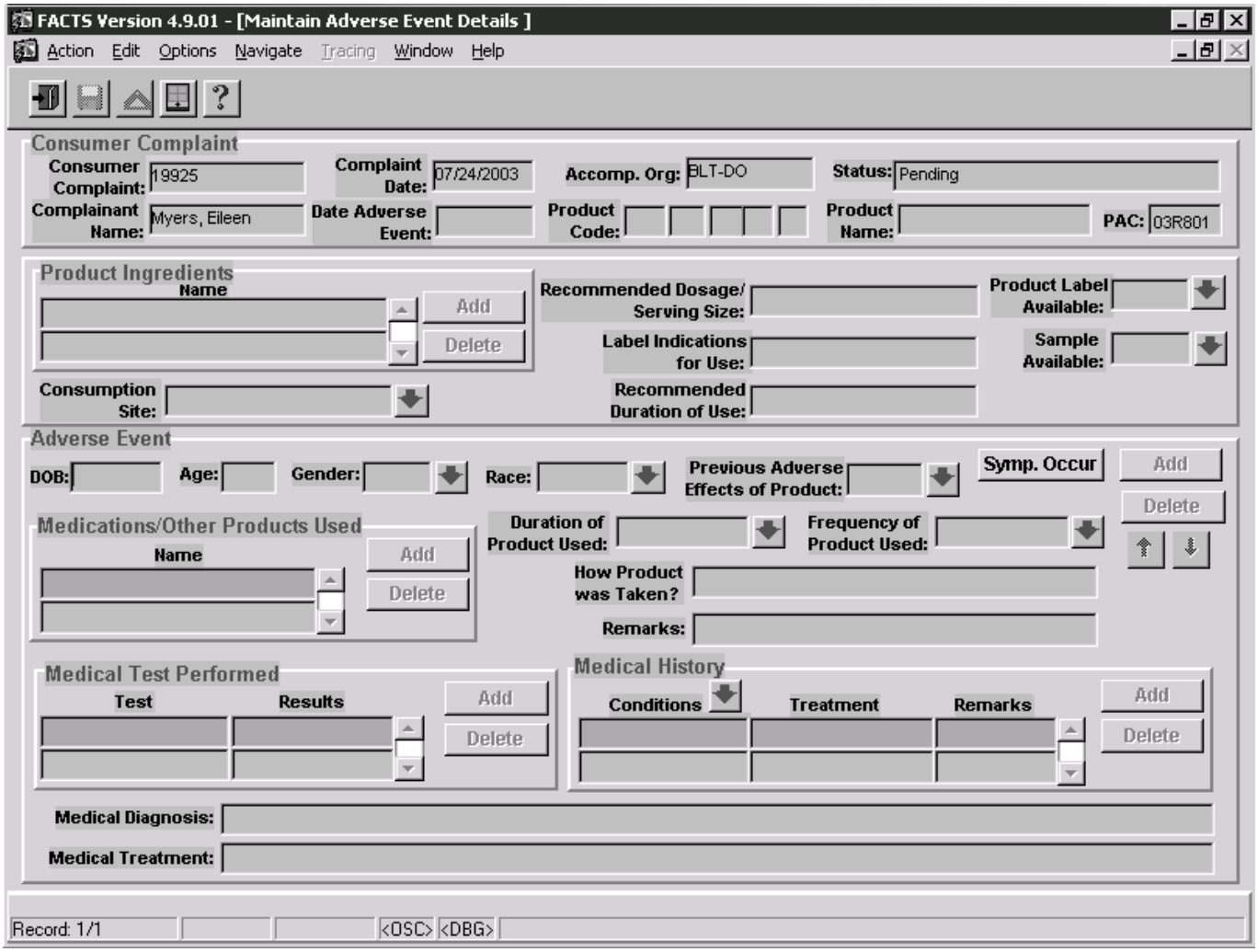
The current Field Accomplishment and Compliance Tracking System (FACTS) Investigation (Operation 13) is used to capture the findings, endorsement and accomplishment time for investigations. FACTS does not provide for the generation of a hard copy memorandum. Limitations on data input also inhibit your ability to produce an investigative memo describing all relevant facts of your investigation. Therefore, in each case where a hard copy is required, use the reporting method described below. The FACTS Summary and Endorsement should be annotated to indicate the location of the actual report and endorsement (i.e., "see KAN-DO files," "see FACTS Consumer Complaint #," etc.), along with minimal narrative text describing the findings of the investigation.

Following the completion of an investigation, you will prepare a written report in English (See IOM 1.1) of the investigation as directed by your supervisor, which documents all pertinent data, including referencing of firms and attachments/exhibits, samples collected, etc. Use memorandum format, with appropriate supervisory endorsement and routing. For consumer complaints complete the FACTS Complaint Follow-Up Report. See IOM 8.2, 8.2.8 and 8.4.5. For surveillance activities, use Surveillance Report form (FDA 457). See IOM 8.6.2. In other situations, use methods directed by your District.

In those instances where FACTS is used for simple data/time entry under the Investigation Operation, and when you may not need a written report (examples: OEI improvement or pesticide surveillance), then enter sufficient information in the appropriate FACTS fields. The fields are those necessary for your supervisor to endorse the entry.

FACTS Operation 13, Investigation, will be used for inspections where the firm is Out of Business (OOB), Not Official Establishment Inventory (NOEI), or where no inspection was made (i.e., when lack of FDA jurisdiction has been established). Currently, this requires a written, hard copy memorandum and supervisory endorsement for inclusion in your District's files. In the case of OOB and NOEI, this is required for the appropriate filing personnel to know to remove the active files and send to the record center or storage per District procedure. For "no inspection made" the information in the file, especially the reason, may be helpful to future investigators. When you have a FACTS assignment to conduct an inspection and you determine the firm is OOB or that there is no FDA jurisdiction (i.e., when no clinical research has been conducted by a clinical investigator), follow FACTS procedures for converting the operation 12 to an operation 13.

(For investigations involving the Import Process, see Chapter 6.1.2)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Consumer Complaint
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Complaint Date: 07/24/2003
Accomp. Org: BLT-DO
Status: Pending
Complainant Name: Myers, Eileen
Date Adverse Event:
Product Code:
Product Name:
PAC: 03R801
Product Ingredients
Name
Add
Delete
Recommended Dosage/ Serving Size:
Product Label Available:
Label Indications for Use:
Sample Available:
Consumption Site:
Recommended Duration of Use:
Adverse Event
DOB:
Age:
Gender:
Race:
Previous Adverse Effects of Product:
Symp. Occur
Add
Delete
Medications/Other Products Used
Name
Add
Delete
Duration of Product Used:
Frequency of Product Used:
How Product was Taken?
Remarks:
Medical Test Performed
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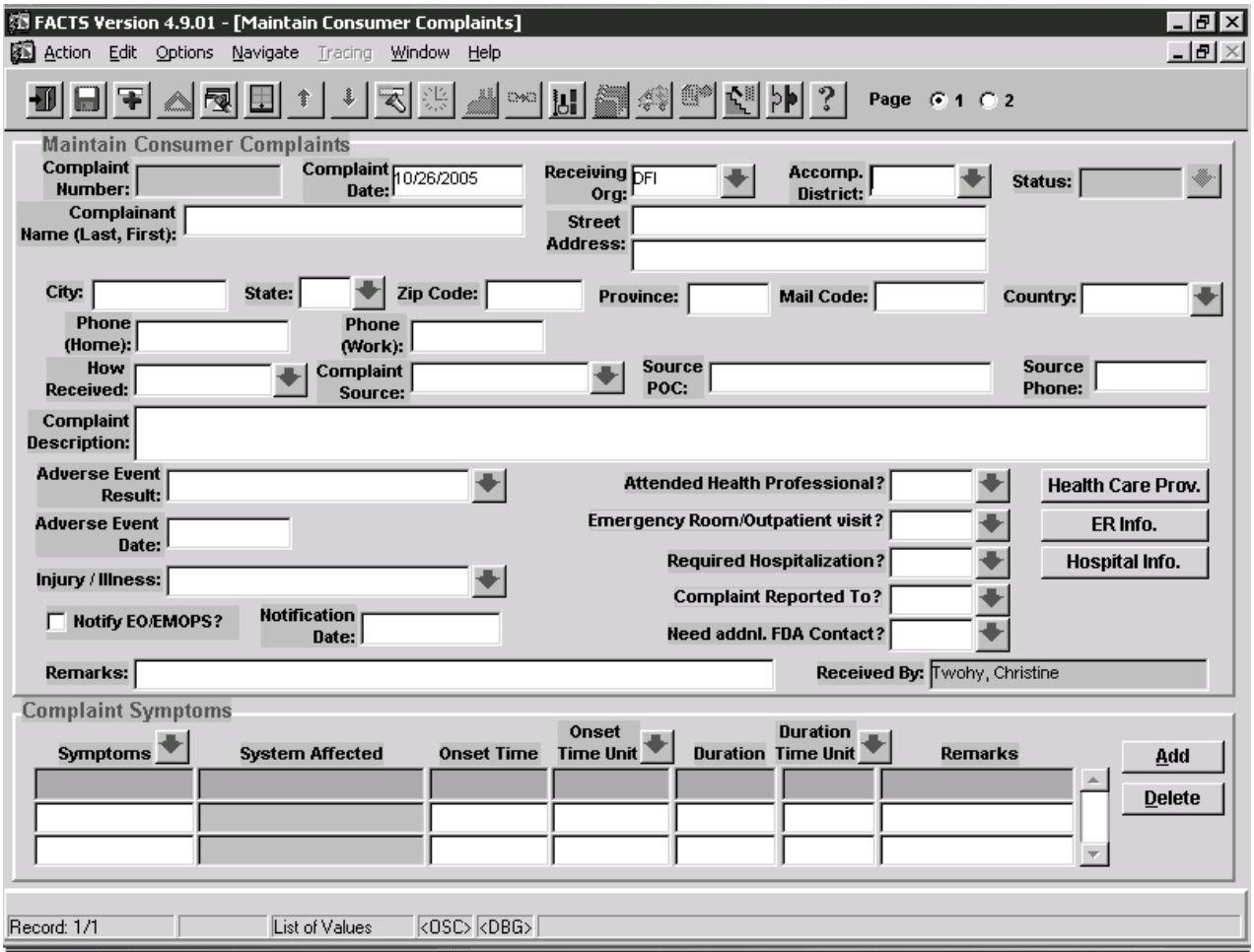
FACTS Version 4.9.01 - [Maintain Consumer Complaints]
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Page 1 2
Maintain Consumer Complaints
Complaint Number:
Complaint Date: 10/26/2005
Receiving Org: DFI
Accomp. District:
Status:
Complainant Name (Last, First):
Street Address:
City:
State:
Zip Code:
Province:
Mail Code:
Country:
Phone (Home):
Phone (Work):
How Received:
Complaint Source:
Source POC:
Source Phone:
Complaint Description:
Adverse Event Result:
Attended Health Professional?
Health Care Prov.
Adverse Event Date:
Emergency Room/Outpatient visit?
ER Info.
Required Hospitalization?
Hospital Info.
Injury / Illness:
Complaint Reported To?
Notify EO/EMOPS?
Notification Date:
Need addnl. FDA Contact?
Remarks:
Received By: Twohy, Christine
Complaint Symptoms
Symptoms
System Affected
Onset Time
Onset Time Unit
Duration
Duration Time Unit
Remarks
Add
Delete
Record: 1/1
List of Values
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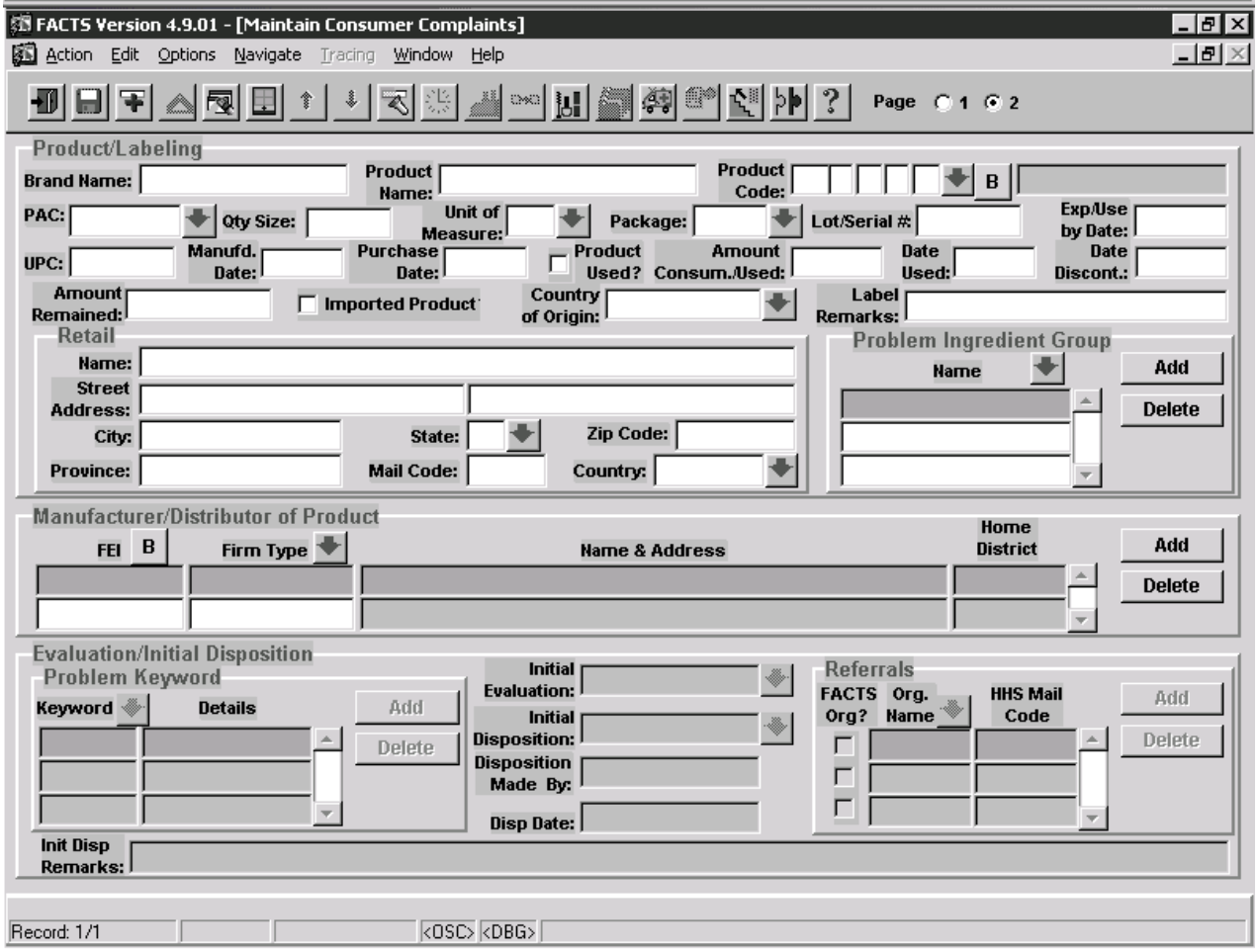
FACTS Version 4.9.01 - [Maintain Consumer Complaints]
Action Edit Options Navigate Tracing Window Help
Page 1 2
Product/Labeling
Brand Name:
Product Name:
Product Code:
B
PAC:
Qty Size:
Unit of Measure:
Package:
Lot/Serial #:
Exp/Use by Date:
UPC:
Manufd. Date:
Purchase Date:
Product Used?
Amount Consum./Used:
Date Used:
Date Discont.:
Amount Remained:
Imported Product
Country of Origin:
Label Remarks:
Retail
Name:
Street Address:
City:
State:
Zip Code:
Province:
Mail Code:
Country:
Problem Ingredient Group
Name
Add
Delete
Manufacturer/Distributor of Product
FEI
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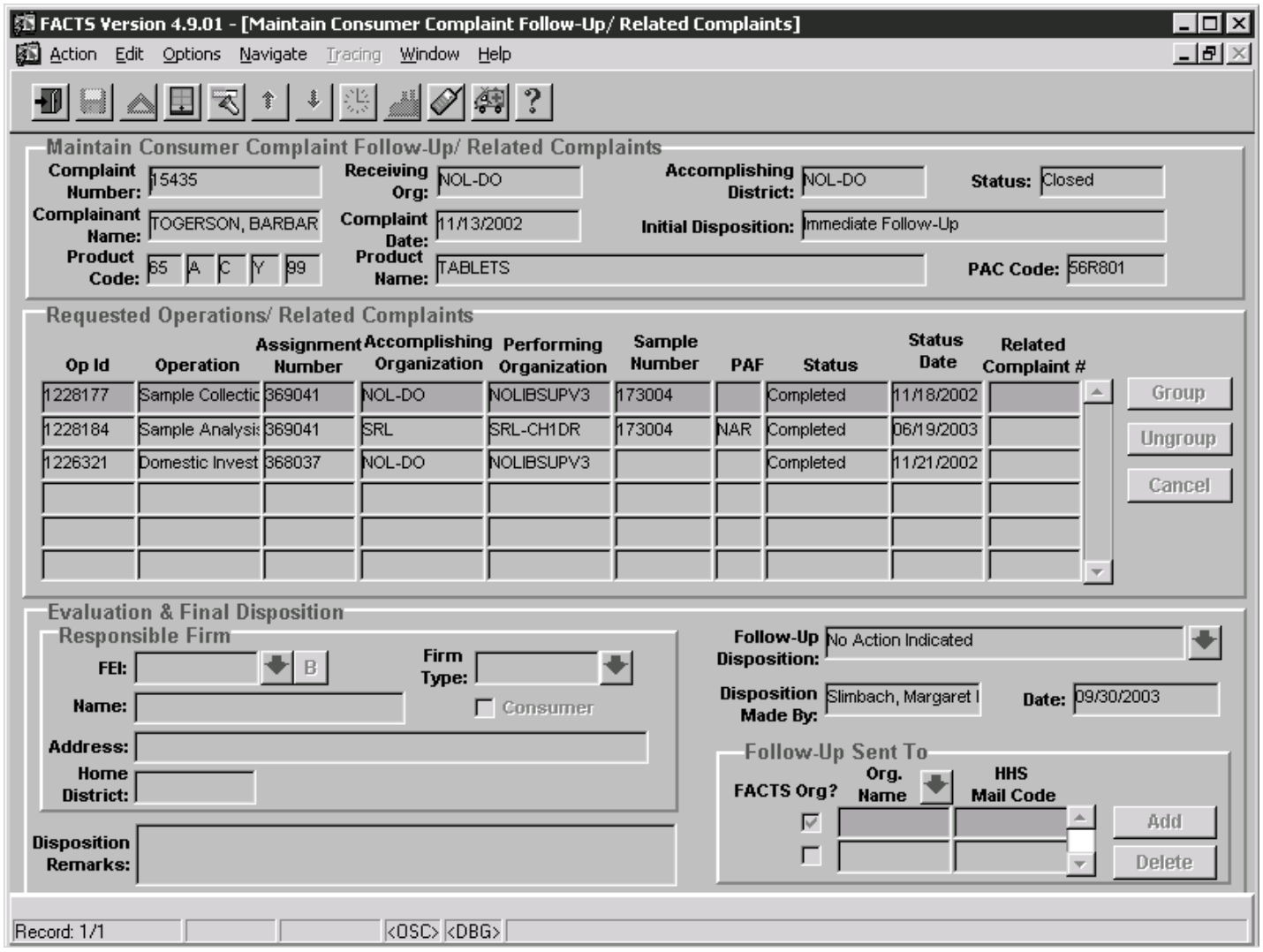
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Receiving Org: NOL-DO
Accomplishing District: NOL-DO
Status: Closed
Complainant Name: TOGERSON, BARBAR
Complaint Date: 11/13/2002
Initial Disposition: Immediate Follow-Up
Product Code: 65 A C Y 99
Product Name: TABLETS
PAC Code: 56R801
Requested Operations/ Related Complaints
Op Id | Operation | Assignment Number | Accomplishing Organization | Performing Organization | Sample Number | PAF | Status | Status Date | Related Complaint #
1228177 | Sample Collectic | 369041 | NOL-DO | NOLIBSUPV3 | 173004 | | Completed | 11/18/2002 |
1228184 | Sample Analysi | 369041 | SRL | SRL-CH1DR | 173004 | NAR | Completed | 06/19/2003 |
1226321 | Domestic Invest | 368037 | NOL-DO | NOLIBSUPV3 | | | Completed | 11/21/2002 |
Group
Ungroup
Cancel
Evaluation & Final Disposition
Responsible Firm
FEI:
B
Firm Type:
Name:
Consumer
Address:
Home District:
Disposition Remarks:
Follow-Up Disposition: No Action Indicated
Disposition Made By: Slimbach, Margaret I
Date: 09/30/2003
Follow-Up Sent To
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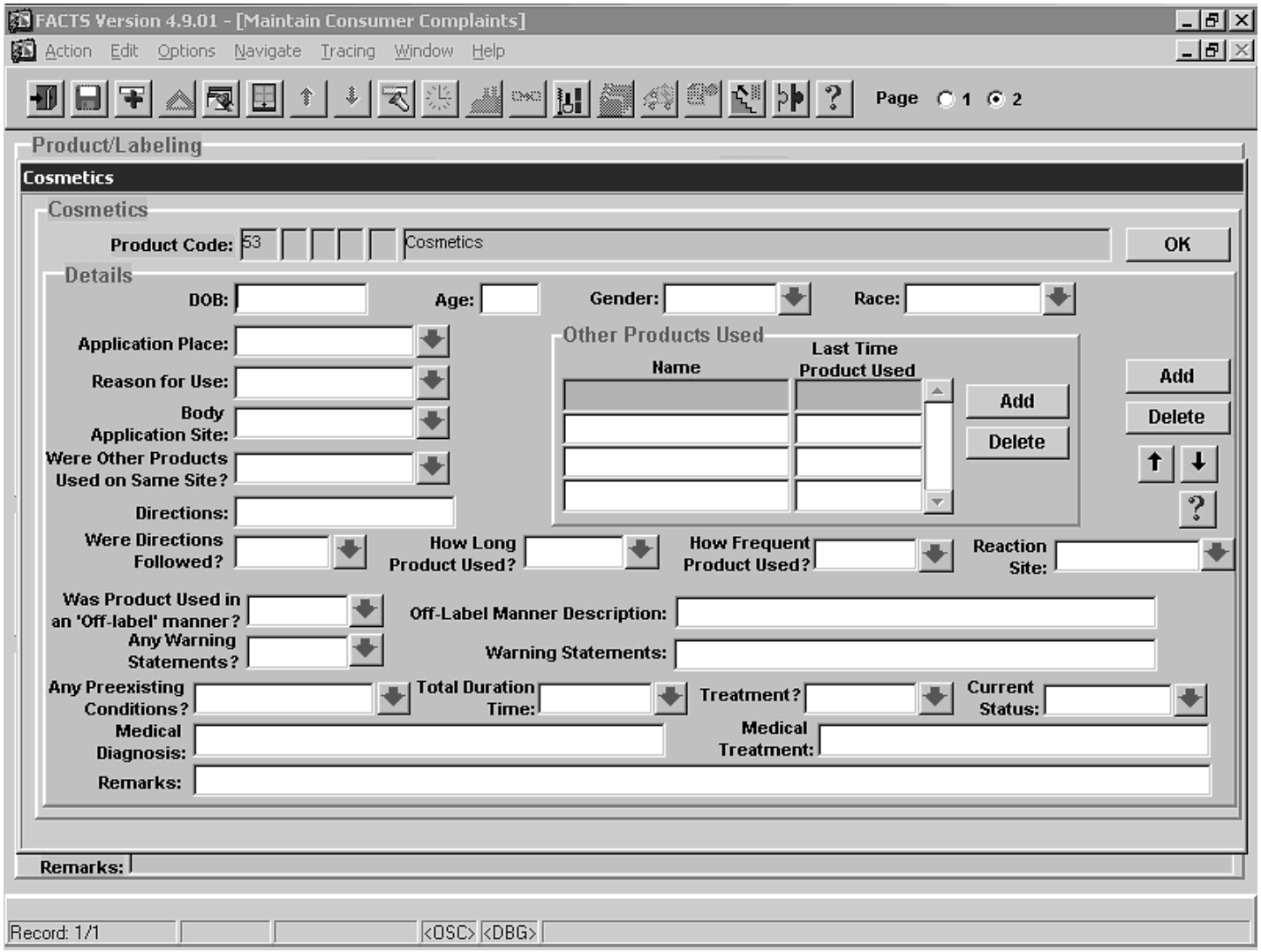
FACTS Version 4.9.01 - [Maintain Consumer Complaints]
Action Edit Options Navigate Tracing Window Help
Page 1 2
Product/Labeling
Cosmetics
Cosmetics
Product Code: 53 Cosmetics
OK
Details
DOB:
Age:
Gender:
Race:
Application Place:
Reason for Use:
Body Application Site:
Were Other Products Used on Same Site?
Directions:
Other Products Used
Name
Last Time Product Used
Add
Delete
Add
Delete
Were Directions Followed?
How Long Product Used?
How Frequent Product Used?
Reaction Site:
Was Product Used in an 'Off-label' manner?
Off-Label Manner Description:
Any Warning Statements?
Warning Statements:
Any Preexisting Conditions?
Total Duration Time:
Treatment?
Current Status:
Medical Diagnosis:
Medical Treatment:
Remarks:
Remarks:
Record: 1/1
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

158-15 Liberty Ave.
Jamaica, NY 11433

AUTHORIZATION FOR MEDICAL RECORDS DISCLOSURE

Authorización Para Revelar Expediente Medico

TO WHOM IT MAY CONCERN:

You are hereby authorized to furnish the United States Food and Drug Administration all information and copies of any and all records you may have pertaining to ~~(my case)~~ (the case of

Miss Mary Ellen Pertillo
(Name)

Daughter),
(Relationship to you)

including, but not limited to, medical history, physical reports, laboratory reports and pathological slides, and X-ray reports and films. FDA may provide the public access to the content of the information obtained through this form, except to the extent that the information relating to personal privacy is protected from disclosure by law.

A Quien Pueda Interesar:

Por la presente se le authoriza proveer a la Administracion de Drogas y Alimentos de Estados Unidos toda información y copias de cualquira y todos los documentos que usted pueda tener con relacción a ~~(mi caso)~~ (el caso de

_____
(Nombre)

_____),
(Parentesco)

incluyendo, pero no limitado a, historial medico, examenes fisicos, informes de laboratorio, laminillas de patologia, placas e informes de radiologia. La Administración de Drogas y Alimentos puede proveer acceso público al contenido de la información obtenida mediante este formulario, a excepción de información relacionada a la privacidad persona, la cual esta protegida y no puede ser divulgada por ley.

Anthony Oliver Pertillo — 10-26-05
(Signature) (Firma) *(Date) (Fecha)*

Sidney H. Rogers — 10-26-05
(Witness) (Testiso) *(Date) (Fecha)*

CLASSIFICATION OF ILLNESSES ATTRIBUTABLE TO FOODS
(A CLASSIFICATION BY SYMPTOMS, INCUBATION PERIODS, AND TYPES OF AGENTS[1, 2])

DISEASE	ETIOLOGIC AGENT AND	INCUBATION OR LATENCY	SIGNS & SYMPTOMS	FOODS INVOLVED3	SPECIMENS TO COLLECT	FACTORS THAT CONTRIBUTE OUTBREAKS
UPPER GASTROINTESTINAL TRACT SIGNS AND SYMPTOMS (NAUSEA, VOMITING) OCCUR FIRST OR PREDOMINATE						
INCUBATION (LATENCY) PERIOD USUALLY LESS THAN ONE HOUR						
FUNGAL AGENTS						
Gastrointes-tinal irritating group mush-room poisoning	Possibly resin-like substances in some mushrooms (mushroom species are different than those cited on pp. -- & --.)	30 minutes to 2 hours	Nausea, vomiting, retching, diarrhea, abdominal cramps	Many varieties of wild mushrooms	Vomitus	Eating unknown varieties of mushrooms, mistaking toxic mushrooms for edible varieties
CHEMICAL AGENTS						
Antimony Poisoning	Antimony in gray enamelware	Few minutes to 1 hour	Vomiting, abdominal pain, diarrhea	High-acid foods and beverages	Vomitus, stools, urine	Using/buying antimony-containing utensils, storing high-acid foods in gray enamelware
Cadmium Poisoning	Cadmium in plated utensils	15 to 30 minutes	Nausea, vomiting, abdominal cramps, diarrhea, shock	High-acid foods & beverages, candy love beads or cake decorations	Vomitus, stools, urine, blood	Using/buying cadmium-containing utensils, storing high-acid foods in cadmium-containers, ingesting cadmium-containing foods
Copper Poisoning	Copper in pipes and utensils, old dairy white metal	Few minutes to few hours	Metallic taste, nausea, vomiting (green vomitus), abdominal pain, diarrhea	High-acid foods and beverages, ice cream (ices) and beverages.	Vomitus, gastric washings, urine, blood	Storing high-acid foods in copper utensils or using copper pipes for dispensing high-acid beverages, faulty back-flow prevention valves in vending machines
Fluoride poisoning	Sodium fluoride in insecticides	Few minutes to two hours	Salty or soapy taste, numbness of mouth, vomiting, diarrhea, abdominal pain, pallor, cyanosis dilated pupils, spasms, collapse, shock	Any accidentally contaminated food, particularly dry foods, such as dry milk, flour, baking powder & cake mixes	Vomitus, gastric washings	Storing insecticides in same area as foods, mistaking pesticides for powdered foods
Lead poisoning	Lead in earthenware pesticides, putty, plaster, cans with lead solder seams	30 minutes or longer	Mouth and abdominal pain, milky vomitus, black or bloody stools, foul breath, shock blue gum line	Beverages stored in lead containing vessels, any accidentally conta-minated food	Washings, stools, blood, urine	Storing high-acid foods in lead-con-taining vessels, storing pesticides in same area as food, imported canned high-acid foods with faulty seams
Tin poisoning	Tin in tinned cans	30 minutes to two hours	Bloating, nausea, vomiting, abdominal cramps, diarrhea, headache	High-acid foods and beverages	Vomitus, stools, urine, blood	Using uncoated tin containers for storing acidic foods. Very high tin concentrations are required to cause illness.
Zinc poisoning	Zinc in galvanized containers	Few minutes to few hours	Mouth and abdominal pain, nausea, vomiting, dizziness	High-acid foods and beverages	Vomitus, gastric washings, urine, blood, stools	storing high-acid foods in galvanized cans
INCUBATION (LATENCY) PERIOD 1 TO 6 HOURS						
BACTERIAL AGENTS						
Bacillus cereus Gastroenteritis (emetic form, mimics staphylococcal intoxication)	Exotoxin of B. cereus organism in soil (strains differ from diarrheal form)	0.5 to 5 hours	Nausea, vomiting, occasionally diarrhea	Boiled or fried rice, pasta, cooked corn-meal dishes, porridge	Vomitus, stool	Storing cooked foods at room temp-erature, storing cooked foods in large containers in refrigerators, preparing foods several hours before serving
Staphylococcal intoxication	Exo-enterotoxins A, B, C, D & E of Staphylococcus aureus, staphylococci from skin, nose & lesions of infected humans and animals and from udders of cows	1 to 8 hours, mean 2 to 4 hours	Nausea, vomiting, retching, abdominal pain, diarrhea, prostration	Lower water activity foods (aw), e.g. cheese, whipped butter, ham, meat & poultry products, cream filled pastry, food mixtures, leftovers, dry milk	Vomitus, stools, rectal swabs, carriers nasal swabs, swabs of lesions, anal swab	Inadequate refrigeration, workers touching cooked food, preparing food several hours before serving, workers with infections containing pus, holding foods at warm (bacterial incubating) temperatures, fermentation of abnormally low-acid foods

CHEMICAL AGENTS

Nitrite poisoning4	Nitrites or nitrates used as meat curing compounds or ground water from shallow wells	1 to 2 hours	Nausea, vomiting, cyanosis, headache, dizziness, weakness, loss of consciousness, chocolate brown colored blood4	Cured meats, any accidentally contaminated food exposed to excessive nitrification	Blood	Using excessive amounts of nitrites or nitrates in foods for curing or for covering up spoilage, mistaking nitrites for common salt and other condiments, improper refrigeration of fresh foods.

TOXIC ANIMALS

Diarrhetic shellfish poisoning (DSP)	Okadaic acid and other toxins produced by dinoflagellates, Dinophysis acuminata and other species	0.5 to 12 hours commonly < 3 hrs	Diarrhea, nausea, vomiting, abdominal cramps, chills, fever, headache	Mussels, clams, scallops	Gastric washings	Harvesting shellfish from waters with high concentration of Dinophysis

INCUBATION (LATENCY) PERIOD USUALLY 7 TO 12 HOURS
FUNGAL AGENTS

Cyclopeptide and Gyromitrin groups of mushroom poisoning	Cyclopeptides and Gyromitrin in some mushrooms	6 to 24 hours average 6 - 15 h	Abdominal pain, feeling of fullness, vomiting, protracted diarrhea, loss of strength, thirst, muscle cramps, feeble rapid pulse, collapse, jaundice, drowsiness, dilated pupils, coma, death	Amanita phalloides A. verna, Galerina antumnalis, Gyromitra esculenta (false morels) and similar species of mushrooms	Urine, blood, vomitus	Eating certain species of Amanita, Galerina, and Gyromitra mushrooms, eating unknown varieties of mushrooms, mistaking toxic mushrooms for edible varieties

BURNING MOUTH, SORE THROAT AND RESPIRATORY SIGNS AND SYMPTOMS OCCUR

INCUBATION (LATENCY) PERIOD LESS THAN 1 HOUR
CHEMICAL AGENTS

Calcium chloride Poisoning	Calcium chloride freezing mixture for Frozen dessert bars	Few minutes	Burning lips, mouth, throat, vomiting	Frozen dessert bar	Vomitus	Splashing of freezing mixture onto popsicles while freezing; cracks in molds allowing CaCl2 to penetrate popsicle syrup
Sodium hydroxide poisoning	Sodium hydroxide in bottle washing compounds, detergents, drain cleaners or hair straighteners	Few minutes	Burning of lips, mouth, and throat; vomiting, diarrhea, abdominal pain	Bottled beverages	Vomitus	Inadequate rinsing of bottles cleaned with caustic

INCUBATION (LATENCY) PERIOD 12 TO 72 HOURS
BACTERIAL AGENTS

Beta-hemolytic streptococcal infections	Streptococcus pyrogenes from throat and lesions of infected humans	1 to 3 days	Sore throat, fever, nausea, vomiting, rhinorrhea, sometimes a rash	Raw milk, foods containing eggs	Throat swabs, vomitus	Workers touching cooked foods, workers with infections containing pus, inadequate refrigeration, inadequate cooking or reheating, preparing foods several hours before serving

LOWER GASTROINTESTINAL TRACT SIGNS AND SYMPTOMS (ABDOMINAL CRAMPS, DIARRHEA) OCCUR FIRST OR PREDOMINATE

INCUBATION (LATENCY) PERIOD USUALLY 7 TO 12 HOURS
BACTERIAL AGENTS

Bacillus cereus enteritis (diarrheal form, mimics C. perfringens)	Enterotoxin of B. cereus. soil organism (strain differs from emetic form)	6 to 16 hours	Nausea, abdominal pain, diarrhea, some reports of vomiting	Cereal products, custards, sauces, starchy foods, e.g. pasta, potatoes, and meatloaf	Stools, vomitus	Inadequate refrigeration, holding of foods at warm (bacterial incubation) temperatures, preparing foods several hours before serving, inadequate reheating of leftovers
Clostridium perfringens gastroenteritis	Endo-enterotoxin formed during sporulation of C. perfringens in intestines, organism in feces of infected humans, other animals, and in soil	8 to 22 hours, mean 10 hours	Abdominal pain, diarrhea	Cooked meat, poultry, gravy, sauces and soups	Stools	Inadequate refrigeration, holding foods at warm (bacterial incubation) temperatures, preparing foods several hours before serving, inadequate reheating of leftovers

INCUBATION (LATENCY) PERIOD USUALLY 12 TO 72 HOURS
BACTERIAL AGENTS

Aeromonas diarrhea	Aeromonas hydrophila	1 to 2 days	Water diarrhea, abdominal pain, nausea, chills, headache	Fish, shellfish, snails, water	Stools	Contamination of foods by sea or surface water
Campylobacteriosis	Campylobacter jejuni	2 to 7 days, mean 3 to 5 days	Diarrhea, (often bloody), severe abdominal pain, fever anorexia, malaise, headache, vomiting	Raw milk, raw clams and shellfish, water poultry and meat	Stools, rectal swab, blood	Drinking raw milk, eating raw or undercooked shellfish, inadequate cooking or pasteurization
Cholera	Endemic in temperate U.S. coastal sea water. V.cholerae serogroup 01 classical and El Tor biotypes; serogroup O139	1 to 5 days, usually 2 - 3 days	Profuse, watery diarrhea (rice-water stools), vomiting abdominal pain, dehydration, thirst, collapse, reduced skin turgor, wrinkled fingers, sunken eyes, acidosis	Raw fish & shellfish foods washed or prepared with contaminated water	Stools, rectal swabs	Obtaining fish & shellfish from sewage contaminated waters in endemic areas, poor personal hygiene, infected workers touching foods, inadequate cooking, using contaminated water to wash or freshen foods, inadequate sewage disposal, using night soil as fertilizer
Cholera-like vibrio gastroenteritis	Non 01/O139 V. cholerae ,& related species, eg, V. mimicus, V. fluviallis, V. hollisae	2 to 3 days	Watery diarrhea (varies from loose stools to cholera-like diarrhea)	Raw shellfish, raw fish	Stools, rectal swabs	Eating raw shellfish or raw fish, inadequate cooking, cross contamination
Pathogenic Escherichia coli Diarrhea (THREE FORMS):						
Enterotoxigenic E. coli (ETEC) Gastroenteritis	Enterotoxigenic strains E. coli	10 to 72 hours, usually 24 to 72 hrs	Watery diarrhea, abdominal cramps, nausea, malaise, low grade fever	Water, semi-soft cheeses, foods requiring no further heating	Stools, rectal swab	Infected workers touching foods, inadequate refrigeration, inadequate cleaning and disinfection of equipment
Enterohemorrhagic E. coli (EHEC) Gastroenteritis	O157:H7 E. coli Verotoxins	3 to 9 days, mean 4 days	Bloody diarrhea, severe abdominal cramping, complications- Hemolytic Uremic Syndrome (HUS), kidney failure	Raw ground beef, raw milk, cheese	Stools, rectal swabs	Infected workers touching foods, inadequate refrigeration, inadequate cooking, inadequate cleaning and disinfection of equipment
Enteroinvasive E. coli (EIEC) Gastroenteritis	Enteroinvasive strains of E. coli	10 to 72 hours	Severe abdominal cramps, watery diarrhea, vomiting malaise, complications – HUS, kidney failure	Raw milk, raw ground beef, cheese	Stools, rectal swabs	Infected workers touching foods, inadequate refrigeration, inadequate cooking, inadequate cleaning and disinfection of equipment
Salmonellosis	Various serotypes of Salmonella from feces of infected humans and other animals	6 to 72 hours, mean 18 to 36 hours	Abdominal pain, diarrhea, chills, fever, nausea, vomiting, malaise	Poultry, meat and their products, egg products, other foods contaminated by salmonellae	Stools, rectal swabs	Inadequate refrigeration, holding foods at warm (bacterial incubation) temperatures, inadequate cooking and reheating, preparing foods several hours before serving, cross contamination, inadequate cleaning of equipment, infected workers touching cooked foods, obtaining foods from contaminated sources
Shigellosis	Shigella flexneri, S. dysenteriae, S. sonnei, & S. boydii from feces of infected humans	24 to 72 hours	Abdominal pain, diarrhea, bloody & mucoid stools, fever	Any contaminated foods, frequently salads, water	Stools & rectal swab	Infected workers touching foods, inadequate refrigeration, inadequate cooking and reheating
Vibrio parahaemolyticus Gastroenteritis	V. parahaemolyticus from sea water or seafoods	2 to 48 hours, mean 12 hours	Abdominal pain, diarrhea, nausea, vomiting, fever, chills, headache	Raw seafoods, shellfish	Stools, rectal swabs	Inadequate cooking, inadequate refrigeration, cross contamination, inadequate cleaning of equipment, using seawater in food preparation
Yersiniosis	Yersinia enterocolitica, Y. psuedotuberculosis	24 to 36 hours	Severe abdominal pain, fever, headache malaise, sore throat may mimic appendicitis	Milk, tofu, water, pork	Stools, blood	Inadequate cooking, contamination after pasteurization, contamination of foods by water, rodents, other animals

VIRAL AGENTS

Astrovirus gastro-enteritis	Astroviruses from human feces	1 to 2 days	Diarrhea, some-times accompanied by one or more en-teric signs or symp-toms	Ready-to-eat foods	Stools, acute and convalescent blood	Failure to wash hands after defecation, infected person touching ready-to-eat foods, inadequate cooking or reheating
Acute viral Gastroenteritis (Small round structured virus)	Norwalk-like viruses, Calici-viruses	1 to 3 days (Norwalk-like virus mean 36 hours)	Nausea, vomiting, abdominal pain, diarrhea, low grade fever, chills, malaise, anorexia, headache	Clams, oysters cockles, green salad pastry, frostings, ice, cut fruit salads	Stools, acute and convalescent blood sera	Polluted shellfish growing waters, poor personal hygiene, infected persons touching prepared foods, foods not requiring further cooking, contamin-ated waters

PARASITIC AGENTS

Amebic Dysentery (Amebiasis)	Entamoeba histolytica from feces of infected humans	5 days to several months; mean 3 to 4 weeks	Abdominal pain, constipation or diarrhea	Raw vegetables and fruit	Stools	Poor personal hygiene, infected workers touching food, inadequate cooking
Anisakiasis	Anisakis simplex Pseudoterranova decipiens	4 to 6 hours	Stomach pain, nausea, vomiting, abdominal pain, diarrhea, fever	Rock fish, herring, cod, squid	Stools	Ingestion of raw fish, inadequate cooking
Beef tapeworm infection (Taeniasis)	Taenia saginata from flesh of infected cattle	3 to 6 months	Vague discomfort, hunger pain, loss of weight, abdominal pain	Raw or insufficiently cooked beef	Stools	Lack of meat inspection, inadequate cooking, inadequate sewage disposal, sewage contaminated pastures
Cryptosporidiosis	Cryptosporidium parvum	1 – 12 days, usually 7 days	Profuse watery dia-rrhea, abdominal pain, anorexia, low grade fever, vomiting	Apple cider, water	Stools, intestinal biopsy	Inadequate sewage or animal waste dis-posal, contamination by animal manure, contaminated water, inadequate filtration of water
Cyclosporiasis	Cyclopsora cayetanensis	1 – 11 days, typically 7 days	Prolonged watery diarrhea, weight loss, fatigue, nau-sea, anorexia, ab-dominal cramps	Raspberries, lettuce, basil, water	Stools	Sewage contaminated irrigation or spraying water suspected; washing fruits with contaminated water; possibly handling foods that are not subsequently heated
Fish tapeworm infection (Diphyllobothriasis)	Diphyllobothrium latum from flesh of infected fish	5 to 6 weeks	Vague gastrointest-inal discomfort anemia may occur	Raw or insufficiently cooked fresh water fish	Stools	Inadequate cooking, inadequate sewage disposal, sewage contamin-ated lakes
Giardiasis	Giardia lamblia from feces of humans	1 to 6 weeks	Abdominal pain, mucoid diarrhea, fatty stools	Raw vegetables and fruits, water	Stools	Poor personal hygiene, infected workers touching foods, inadequate sewage disposal
Pork tapeworm infection (Taeniasis)	Taenia solium from flesh of infected swine	3 to 6 months	Vague discomfort, hunger pains, loss of weight	Raw or insufficiently cooked pork	Stools	Lack of meat inspection, inadequate cooking, inadequate sewage disposal, sewage contaminated pastures

NEUROLOGICAL SIGNS & SYMPTOMS (VISUAL DISTURBANCES, TINGLING, PARALYSIS) OCCUR

INCUBATION (LATENCY) PERIOD USUALLY LESS THAN 1 HOUR
FUNGAL AGENTS

Ibotenic acid group of mush-room poisoning	Ibotenic acid and and muscinol in some mushrooms	0.5 to 2 hours	Drowsiness and dizziness, state of intoxication, confu-sion, muscular spasms, delirium, visual disturbances	Amanita muscaria, A. pantherina and related species of mushrooms	Vomitus	Eating Amantia muscaria and related species of mushrooms, eating unknown varieties of mushrooms, mistaking toxic mushrooms for edible varieties
Muscarine group of mushroom poisoning	Muscarine in some mushrooms	15 minutes to 2	Excessive salivation, perspiration, tearing, reduced blood pres-sure, irregular pulse, pupils constricted, blurred vision, asth-matic breathing	Clitocybe dealbata, C. rivulosa, and many other species of Inocybe and Boletus mushrooms	Vomitus	Eating muscarine group of mush-rooms, eating unknown varieties of mushrooms, mistaking toxic mush-rooms for edible varieties
Organophos-phorous poisoning	Organic phosphorous insecticides such Parathion, TEPP, Diazinon, Malathion	Few minutes to few hours	Nausea, vomiting, abdominal cramps, diarrhea, headache, nervousness, blurred vision, chest pain, cyanosis, confusion, twitching, convulsions	Any accidentally contaminated food	Blood, urine, fat biopsy	Spraying foods just before harvesting, storing insecticides in same area as foods, mistaking pesticides for powdered foods

TOXIC ANIMALS

Paralytic shellfish Poisoning (PSP)	Saxitoxin and similar toxins from plankton Alexandrium species which are consumed by shellfish	Few minutes to 30 minutes on average, may take up to 2 hrs	Tingling, burning, numbness around lips and finger tips, giddiness, incoherent speech, respiratory paralysis, sometimes fatal	Bivalve molluscan shellfish, e.g., clams mussels, viscera of crabs and lobsters	N/A	Harvesting shellfish from waters with a high concentration of Alexandrium
Tetradon poisoning Aka Fugu (puffer Fish) poisoning	Tetrodotoxin from intestines and gonads of puffer type fish	10 minutes to 3 hrs	Tingling sensation of fingers & toes, dizziness, pallor, numbness of mouth and extremities, gastrointestinal symptoms hemorrage and desquamation of skin, eyes fixed, twitching, paralysis, cyanosis sometimes fatal	Puffer-type fish	N/A	Eating puffer-type fish, failure to effectively remove intestines and gonads from puffer-type fish if they are to be eaten
Neurotoxic shellfish Poisoning (NSP)	Brevetoxins from from Gymnodinium species	few minutes to few hours	Paresthesia, reversal of hot and cold temperature sensations, nausea, vomiting, diarrhea	Shellfish (mussels, clams) from S.E.. coastal waters	Gastric washings	Harvesting shellfish from waters with high concentration of Gymnodinium species of dinoflagellates
Amnesic Shellfish Poisoning (ASP) or Domoic Acid	Domoic acid from diatoms (Toxin is heat stable)	30 min. to 24 hrs for gastrointestinal symptoms, neurolog-Ical symptoms within 48 hrs	Initially nausea, vomiting, abdominal pain, diarrhea, neurological signs include: confusion, memory loss, disorientation, seizure, coma, death may occur	Shellfish (mussels, clams), finfish (anchovies), viscera of crabs and lobsters	N.A.	Harvesting shellfish, crabs and finfish from waters which experience plankton blooms releasing domoic acid in the harvesting area
Diarrhetic shellfish Poisoning (DSP)	LISTED PREVIOUSLY					THIS IS NOT A NEUROLOGICAL ILLNESS, BUT IS INCLUDED HERE FOR EASE OF REFERENCE WITH ALL SHELLFISH POISONINGS.

PLANT TOXICANTS

Jimson weed	Tropane alkaloids in Jimson weed	Less than 1 hour	Abnormal thirst, photophobia, distorted sight, difficulty in speaking, flushing, delirium, coma, rapid heart beat	Any part of a plant, tomatoes grafted to Jimson weed stock	Urine	Eating any part of Jimson weed or eating tomatoes from tomato plant grafted to Jimson weed stock
Water hemlock Poisoning	Resin and cicutoxin in hemlock root	15 to 60 minutes	Excessive salivation, nausea, vomiting, Stomach pain, frothing at mouth, irregular breathing, convulsions, respiratory paralysis	Root of water hemlock Cicuta virosa and C. masculate	Urine	Eating water hemlock, mistaking water hemlock root for wild parsnip, sweet potato or carrot

INCUBATION (LATENCY) PERIOD 1-6 HOURS
CHEMICAL AGENTS

Chlorinated hydrocarbon poisoning	Chlorinated hydrocarbon insecticides such as aldrin, chlordane, ddt, endrin, lindane, & toxaphene	30 minutes to 6 hrs	Nausea, vomiting, paresthesis, dizziness muscular weakness, anorexia, weight loss, confusion	Any accidentally contaminated food	Blood, urine, stools gastric washings	Storing insecticides in same area as food, mistaking insecticides for powdered food

TOXIC ANIMALS

Ciguatera Poisoning	Ciguatoxin in intestines, roe, gonads & flesh of tropical marine fish	3 to 5 hours, sometimes longer	Tingling & numbness about mouth, metallic taste, dry mouth, gastrointestinal symptoms, watery stools, muscular pain, dizziness, dilated eyes, blurred vision, prostration, paralysis, reversal of hot and cold temperature sensations sometimes fatal	Numerous species of tropical fish		Eating liver, intestines, roe, gonads, or flesh of barracuda, large jacks & amberjacks, grouper and other species of tropical reef fish; usually large reef fish are more commonly toxic

INCUBATION (LATENCY) PERIOD USUALLY 12 TO 72 HOURS
BACTERIAL AGENTS

Botulism	Neurotoxins A, B, E & F of Clostridium botulinum spores found in soil & animal intestines	2 hours to 8 days, mean 18 to 36 hrs	Vertigo, double or blurred vision, dryness of mouth, difficulty in swallowing, speaking and breathing, descending muscular weakness, constipation, pupils dilated or fixed, respiratory paralysis, gastrointestinal symptoms may precede neurological symptoms. frequently fatal	Home canned low acid foods, vacuum packed fish; fermented fish eggs, fish and marine mammals	Blood, stool	Inadequate heat processing of canned foods and smoked fish, uncontrolled fermentation

INCUBATION (LATENCY) PERIOD GREATER THAN 72 HOURS
CHEMICAL AGENTS

Mercury poisoning	Methyl & ethyl mercury compounds from industrial waste and organic mercury in fungicides	1 week or longer	Numbness, weakness of legs, spastic paralysis, impairment of vision, blindness, coma	Grains treated with mercury containing fungicide; pork, fish, & shellfish exposed to mercury compounds	Urine, blood, hair	Streams polluted with mercury compounds, feeding animals grains treated with mercury fungicides, eating mercury treated grains or animals fed such grains
Triorthocresyl Phosphate Poisoning	Triorthocresyl phosphate used as extracts or as substitute cooking oil	5 to 21 days, mean 10 days	Gastrointestinal symptoms, leg pain, ungainly high stepping gait, foot and wrist drop	Cooking oils, extracts and other foods contaminated with triorthocresyl phosphate	N/A	Using compound as food extractant or as cooking or salad oil

GENERALIZED INFECTION SIGNS AND SYMPTOMS (FEVER, CHILL, MALAISE, ACHES) OCCUR

INCUBATION (LATENCY) PERIOD GREATER THAN 72 HOURS
BACTERIAL AGENTS

Brucellosis	Brucella abortus, B. melitensis, and B. suis from tissues & milk of infected animals	7 to 21 days	Fever, chills, sweats, weakness, malaise, headache, muscle and joint pain, loss of weight	Raw milk, goat cheese	Blood	Failure to pasteurize milk, livestock infected with brucellae
Typhoid fever	Salmonella Typhi from feces of infected humans	7 to 28 days, mean 14 days	Malaise, headache, fever, cough, nausea, vomiting, constipation, abdominal pain, chills, rose spots, bloody stools	Shellfish, foods contaminated by workers, raw milk, cheese, watercress, water	Stools, rectal swabs blood	Infected workers touching foods, poor personal hygiene, inadequate cooking, inadequate refrigeration, inadequate sewage disposal, obtaining foods from unsafe sources, harvesting shellfish from sewage contaminated areas
Listeriosis	Listeria monocytogenes from soil, manure, silage and environment	3 to 21 days, maybe longer	Low grade fever, flu-like illness, stillbirths, meningitis, encephalitis, sepsis, fatalities occur	Cole slaw, milk, cheese, animal products	Blood, urine, cerebrospinal fluid	Inadequate cooking, failure to properly pasteurize milk, prolonged refrigeration, immunosuppressed, pregnant, aged persons, and neonates are at high risk
Vibrio vulnificus Septicemia	Vibrio vulnificus from sea water	16 hr mean < 24 hr	Malaise, chills, fever, prostration, cutaneous lesions, fatalities occur	Raw shellfish and crabs	Blood	Eating raw shellfish, inadequate cooking, persons with liver damage are at high risk

VIRAL AGENTS

Hepatitis A (Infectious hepatitis)	Hepatitis A virus from feces, urine, blood of infected humans and other primates	10 to 50 days, mean 25 days	Fever, malaise, lassitude, anorexia, nausea, abdominal pain, jaundice	Shellfish, any food contaminated by hepatitis viruses, water	Urine, blood	Infected workers touching foods, poor personal hygiene, inadequate cooking, harvesting shellfish from sewage contaminated waters, inadequate sewage disposal

(Note: Hepatits E is an emerging viral pathogen. It has similar incubation periods and symptoms as Hepatitis A and can be transmitted in foods.)

PARASITIC AGENTS

Angiostrongylaisis (eosinophilic meningoencehplalitis)	Angiostrongylus cantonensis (rat lung worm) from rodent feces and soil	14 to 16 days	Gastroenteritis, headache, stiff neck and back, low-grade fever	Raw crabs, prawns, slugs, shrimp & snails	Blood	Inadequate cooking, ingesting raw food
Toxoplasmosis	Toxoplasma gondii from tissue and flesh of infected animals	10 to 13 days	Fever, headache, myalgia, rash	Raw or insufficiently cooked meat (rare)	Biopsy of lymph nodes, blood	Inadequate cooking of meat of sheep, swine and cattle
Trichinosis	Trichinella spiralis (roundworm) from flesh of infected	4 to 28 days, mean 9 days	Gastroenteritis, fever, edema about eyes, muscular pain, chills,	Pork, bear meat, walrus flesh	Muscle biopsy	Eating raw or inadequately cooked pork or bear meat, inadequate cooking or heat processing, feeding

	swine or bear		prostration, labored breathing			uncooked or inadequately heat processed garbage to swine

ALLERGIC TYPE SYMPTOMS (FACIAL FLUSHING, ITCHING) OCCUR

INCUBATION (LATENCY) PERIOD LESS THAN 1 HOUR
BACTERIAL (AND ANIMAL) AGENTS

Scombroid Poisoning or Histaminosis	Histamine-like substance produced by proteus sp. or other bacteria from histidine in fish flesh	Few minutes to 1 hr	Headache, dizziness, nausea, vomiting, peppery taste, burning throat, facial swelling and flushing, stomach pain, itching of skin	Tuna, mackerel, Pacific dolphin (known as the mahi on the Pacific coast of the U.S.), jack, anchovy, marlin, swordfish, bluefish, sometimes from ripened cheese	Vomitus	Inadequate refrigeration of scombroid fish and improper curing of cheese

CHEMICALS

Monosodium glutamate (MSG) poisoning	Excessive amounts of monosodium glutamate (MSG)	Few minutes to 1 hr	Burning sensation in back of neck, forearms chest, feeling of tightness, tingling, flushing, dizziness, headache, nausea	Foods seasoned with MSG	N/A	Using excessive amounts of MSG as flavor intensifier.
Nicotinic acid (niacin) poisoning	Sodium nicotinate used as a color preservative	Few minutes to 1 hr	Flushing, sensation of warmth, itching abdominal pain, puffiness of face and knees	Meat or other food in which sodium nicotinate has been added	N/A	Using sodium nicotinate as color preservative
	Dietary supplements of niacin used chronically	A few days to a few a few months	Impairment of liver function (elevated transaminases), can result in fulminant liver failure	High potency dietary supplements, especially when used in multiples (500mg or more per day)	N/A	Dietary supplements of niacin can cause similar acute symptoms as niacin, but seldom does because of infrequent use at high doses

INCUBATION (LATENCY) PERIOD 1 TO 6 HOURS
TOXIC ANIMALS

Hypervitaminosis A	Vitamin A containing foods or dietary supplements	Acute: 1 to 6 hours	Headache, gastrointestinal symptoms, dizziness, collapse, convulsions, desquamation of skin	Liver & kidney of arctic mammals	Blood	Eating liver & kidney from cold region animals
		Chronic: days to months or years	Chronic use can cause liver disease, including cirrhosis	High potency dietary supplements, especially with chronic use	N/A or Blood?	Chronic usage of dietary supplements containing 25,000 IU vitamin A or more per day

1. Symptoms and incubation periods will vary with the individual and group exposed because of resistance, age, and nutritional status of individuals, number of organism or concentration of poison in ingested foods, amount of food ingested, pathogenicity and virulence of strains of microorganisms or toxicity of chemical involved. Several of the illnesses are manifested by symptoms in more than one category and have an incubation range that overlaps the generalized categories.
2. A more detailed review can be found in:
   A. Bryan, F.L. 1982, Diseases Transmitted by Foods (A classification and summary), second edition, Centers for Disease Control, Atlanta, GA.
   B. Rhodehamel, E.J., Editor, 1992, "Foodborne Pathogenic Microorganisms and Natural Toxins", Third Edition, Food and Drug Administration, Washington, D.C.
   C. Bryan, F.L., Chairman, Committee on Communicable Diseases Affecting Man, 1999, "Procedures to Investigate Foodborne Illness" Fifth edition, International Association of Milk, Food, and Environmental Sanitarians, Inc., Ames, IA
3. Samples of any of the listed foods that have been ingested during the incubation period of the disease should be collected.
4. Carbon monoxide poisoning may simulate some of the diseases listed in this category. Patients who have been in closed care with motors running or have been in rooms with improperly vented heaters are subject to exposure to carbon monoxide.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

FOOD ILLNESS INVESTIGATION

1. NAME OF PERSON	3. OCCUPATION
Jon R. Roe	Teacher - High School

2. ADDRESS a. STREET	4. TELEPHONE NO.	5. AGE	6. SEX
321 Main St. N.W.	515-557-2145	35	M

2. ADDRESS b. CITY, STATE, & ZIP CODE	7. DID THE PERSON EAT ANY OF THE SUSPECT MEAL?	8. DID THE PERSON BECOME ILL?
Centerville, IA 52411	☒ YES ☐ NO	☒ YES ☐ NO

9. FOOD INJESTED *(Names and types, Trade names, frozen, canned, dried, etc.)*	10. METHOD OF FOOD PREPARATION	11. QUANTITY INJESTED	12. INJESTED a. DATE	12. INJESTED b. TIME	13. CODES OF SUSPECT CONTAINER
"Yummy Brand"	Consumed as purchased	2 oz.	11-8-05	6:30 am	XYZ-74
Cream-filled Donut					
"Better Brand" canned	" " "	4 oz.	11-8-05	6:30 am	3-2-3-A
Orange Juice					
"ABC" Corn Flakes	" " "		11-8-05	6:30 am	None
"Best" Dairy Grade A Milk	" " "		11-8-05	6:30 am	None

(Continue on additional forms if necessary)

14. SYMPTONS

a. SYMPTOMS *(check)*	b. DATE BEGAN	C. TIME BEGAN	d. HOURS DURATION
☐ NAUSEA			
☐ VOMITING			
☒ DIARRHEA	11-8-05	2:30 pm	6
☒ FEVER	11-8-05	2:30 pm	6
☒ PROSTRATION	11-8-05	2:30 pm	6
☐ PARALYSIS			
☒ OTHER *(See Remarks)*	11-8-05	2:30 pm	6

15. PHYSICIAN

a. NAME		
Thomas Meedic, M.D.		
b. STREET ADDRESS		
323 Broad St. N.W.		
c. CITY		d. STATE
Centerville		IA
e. ZIP CODE	f. TELEPHONE NO.	
52412	515-532-3334	

16. HOSPITAL

a. NAME		
N/A		
b. STREET ADDRESS		
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c. CITY		d. STATE
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e. ZIP CODE	f. TELEPHONE NO.	
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17. REMARKS *(Use reverse side if necessary)*

Only product available for sampling was the cream filled donuts which sampled as INV 361245

14. cramps

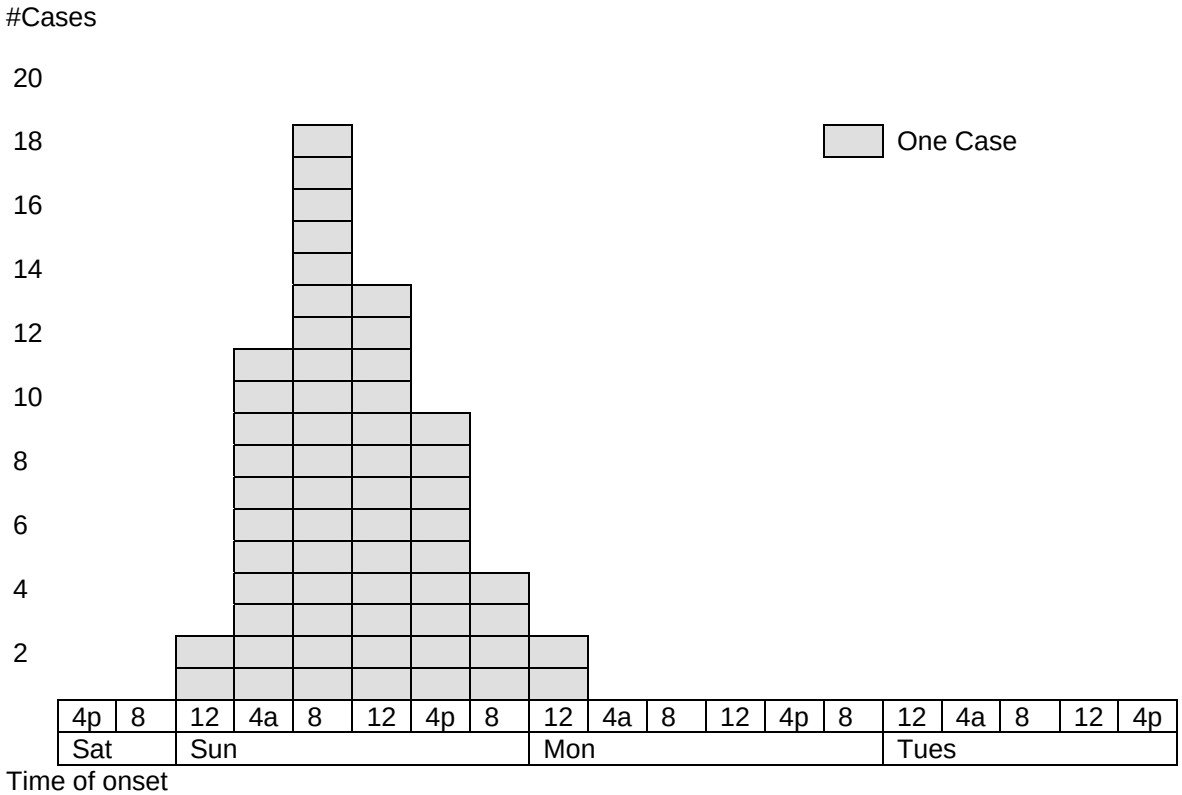
18. DATE OF INVESTIGATION	19. OFFICE	20. EMPLOYEE(S) NAME	21. TITLE
11-9-05	KAN-DO	Sidney H. Rogers	Investigator

FORM FDA 3042 (10/05) PREVIOUS EDITION MAY BE USED

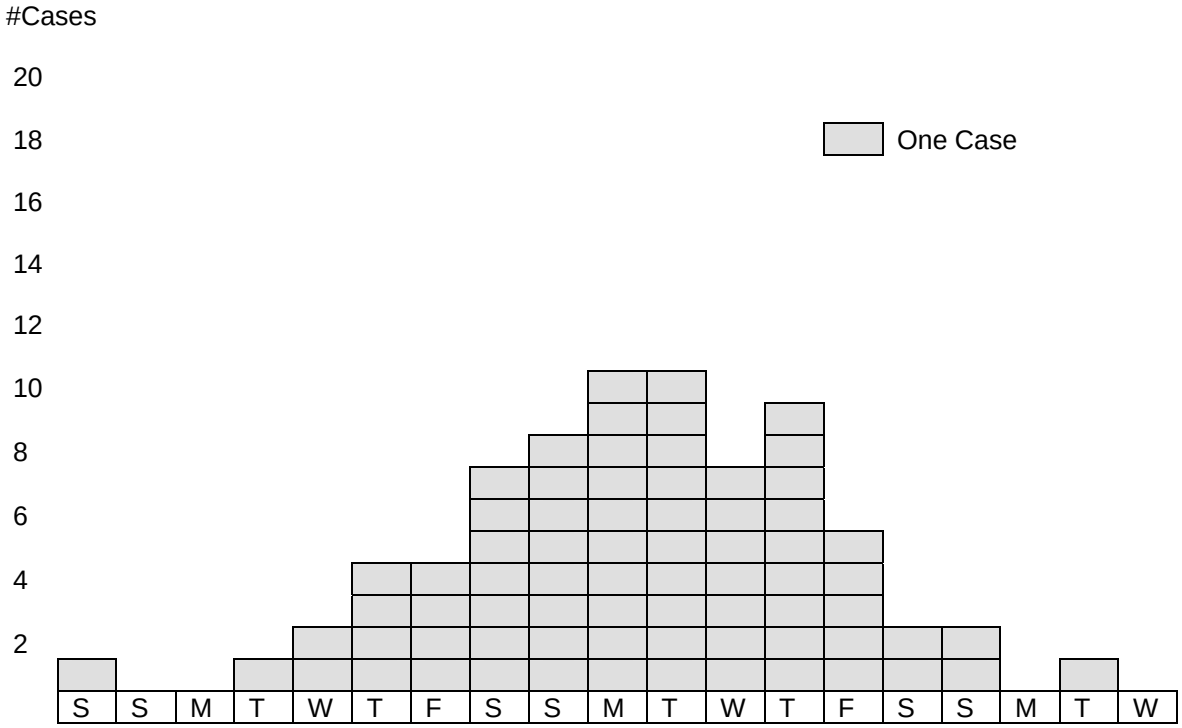
ATTACK RATE TABLE

Food or Beverage	Group A Persons Who Ate Specified Foods				Group B Persons Who Did Note Eat Specified Foods			
	Ill	Not Ill	Total	Attack Rate %	Ill	Not Ill	Total	Attack Rate %
Baked ham.....	29	17	46	63	17	12	29	59
Spinach.....	26	17	43	60	20	12	32	62
Mashed potato.....	23	14	37	62	23	14	37	62
Cabbage salad.....	18	10	28	64	28	19	47	60
Jell-O.....	16	7	23	70	30	22	52	58
Rolls	21	16	37	57	25	13	38	66
Brown bread.....	18	9	27	67	28	20	48	58
Milk.....	2	2	4	50	44	27	71	62
Coffee.....	19	12	31	61	27	17	44	61
Water.....	13	11	24	54	33	18	51	65
Cakes.....	27	13	40	67	19	16	35	54
Ice cream (van.)....	43	11	54	(80)	3	18	21	(14)
Ice cream (choc.)..	25	22	47	53	20	7	27	74
Fruit salad.....	4	2	6	67	42	27	69	61

To compute the attack rate in per cent, divide the number who became ill by the number who ate the food item and multiply by 100. (In the above example, baked ham 29 ÷ 46 x 100 = 63%). The offending food will show the greatest difference between the two attack rate percentages. The offending food should have a higher attack rate in “Group A” and a lower attack rate in “Group B”. For example, in the table above, the attack rate for persons who ate vanilla ice cream (the offending food in the outbreak cited) was 80% while the attack rate for persons who did not eat vanilla ice cream was 14%. The disparity between the persons in “Group A” and “Group B” is the important point.



Epidemic curve of a common-source outbreak



Epidemic curve of a person-to-person transmitted outbreak

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page ____ of ____

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. **Patient Identifier** In confidence
2. **Age at Time of Event, or Date of Birth:**
3. **Sex** ☐ Female ☐ Male
4. **Weight** _____ lb or _____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*
4. **Date of this Report** *(mm/dd/yyyy)*

5. **Describe Event, Problem or Product Use Error**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
#1
#2

2. **Dose or Amount** / **Frequency** / **Route**
#1
#2

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Expiration Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**
2. **Common Device Name**
3. **Manufacturer Name, City and State**
4. **Model #** / **Lot #**
Catalog # / **Expiration Date** *(mm/dd/yyyy)*
Serial # / **Other #**
5. **Operator of Device**
☐ Health Professional
☐ Lay User/Patient
☐ Other: _____
6. **If Implanted, Give Date** *(mm/dd/yyyy)*
7. **If Explanted, Give Date** *(mm/dd/yyyy)*
8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No
9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
Phone # / **E-mail**
2. **Health Professional?** ☐ Yes ☐ No
3. **Occupation**
4. **Also Reported to:**
☐ Manufacturer
☐ User Facility
☐ Distributor/Importer
5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

FORM FDA 3500 (10/05) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: http://www.fda.gov/medwatch/report/consumer/instruct.htm

Report adverse events, product problems or product use errors with:

- Medications *(drugs or biologics)*
- Medical devices *(including in-vitro diagnostics)*
- Combination products *(medication & medical devices)*
- Human cells, tissues, and cellular and tissue-based products
- Special nutritional products *(dietary supplements, medical foods, infant formulas)*
- Cosmetics

Report product problems - quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

-Fold Here-

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization - initial or prolonged
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Just fill in the sections that apply to your report
- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer *(or both)*

Other methods of reporting:

- 1-800-FDA-0178 -- To FAX report
- 1-800-FDA-1088 -- To report by phone
- www.fda.gov/medwatch/report.htm -- To report online

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

-Fold Here-

If your report involves a serious adverse event with a vaccine call 1-800-822-7967 to report.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The public reporting burden for this collection of information has been estimated to average 36 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FORM FDA 3500 (10/05) (Back) **Please Use Address Provided Below -- Fold in Thirds, Tape and Mail**

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

WEBSITE: www.vaers.org E-MAIL: info@vaers.org FAX: 1-877-721-0366

VACCINE ADVERSE EVENT REPORTING SYSTEM

VAERS

24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number _____
Date Received _____

Patient Name:
Last First M.I.
Address
City State Zip
Telephone no. (____) _____

Vaccine administered by (Name):
Responsible Physician _____
Facility Name/Address
City State Zip
Telephone no. (____) _____

Form completed by (Name):
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)*
City State Zip
Telephone no. (____) _____

1. State | 2. County where administered | 3. Date of birth mm / dd / yy | 4. Patient age | 5. Sex ☐ M ☐ F | 6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm / dd / yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm / dd / yy
Time _____ AM PM

11. Adverse event onset mm / dd / yy
Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under

22. *Birth weight* _____ lb. _____ oz.

23. *No. of brothers and sisters*

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project

24. *Mfr./imm. proj. report no.*

25. *Date received by mfr./imm.proj.*

26. *15 day report?* ☐ Yes ☐ No

27. *Report type* ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1(FDA)

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL

FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10: and 11: Give dates and times as specifically as you can remember. If you do not know the exact time, please indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.

NATURAL DISASTER REPORT

ESTABLISHMENT *(Name and Address)*	DATE OF VISIT KIND OF DISASTER *(Fire, flood, etc. If hurricane give name)*
TYPE OF BUSINESS *(Warehouse, coldstorage, candy manufacturer, etc.)*	DISPOSITION CODE *A – State or local seizure* *B – Destruction* *C – Converted to animal feed* *D – Converted to industrial use* *E – Further follow-up needed (Give date)*

PRODUCTS REQUIRING DESTRUCTION, CONVERSION, OR SEGREGATION

	DESCRIPTION *(E.g. 20, 100 lb. cloth bags flour)*	APPROXIMATE VALUE	DISPOSITION CODE *(More than one letter may be used where necessary)*
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			

SAMPLE NOS. *(If any)*	SUMMARY	
	DESTROYED	CONVERTED TO NON-HUMAN USE
REMARKS *(Include comments on method of destruction, denaturing, etc.)*	Food *(Lbs.)*	
	Drug	
	Cosmetic	
	Device	
	Sundry	
INSPECTOR	AGENCY	
INSPECTOR	AGENCY	

FORM FDA 2809 (9/05)

1. HOME DISTRICT	2. REPORTING UNIT SYMBOL	3. CENTRAL FILE NO.	4. J.D./T.A.	5. COUNTY	6. DATE
NWE	NOL	1234567	----	----	8-2-99

7. PRODUCT CODE	8. OPERATION	9. PROGRAM ASSIGNMENT CODE	10. HOURS
45AF-19	13	09001	1/2

11. IDENTIFICATION *(Quote pertinent labeling including Establishment name and address)*

"NO CLUMP" BRAND ANTI-CAKING AGENT
CLUMPLESS CORP. 3214 WHARF AVE.
WALTHAM, MA 02154

12. MANUFACTURER CONTROL CODES *(Labels, packaging and shipping containers)*	13. AMOUNT ON HAND	14. DATE LOT RECEIVED
BAGS CODED: "AC 123171"	1200/100# BAGS	7-15-99
	15. ESTIMATED VALUE: $ 24,000.00	16. SAMPLE NO(s).: NONE

17. DEALER *(Name, street address, city, state, and ZIP code)*

CREOLE INDUSTRIES
239 CANAL ST.
NEW ORLEANS, LA 70130

18. ☐ DISTRIBUTOR ☐ SHIPPER ☒ MANUFACTURER ☐ OTHER

(Name, street address, city, state, ZIP code, and telephone)

CLUMPLESS CORP.
3214 WHARF AVE.
WALTHAM, MA 02154
(617) 765-4321

19. ESTABLISHMENT TYPE(S)	INDUSTRY CODE 1	2	3	4	5	6	20. ESTABLISHMENT SIZE *($ VOLUME)*	21. INFORMATION OBTAINED BY *(Check one)*	
a. Manufacturer	4 5								MAIL
b.									TELEPHONE
c.								XXX	VISIT

22. REMARKS

23. REPORT PREPARED BY *(Type or print name and title)*	24. EMPLOYEE NO.	25. PC	26. SIGNATURE
Sidney H. Rogers, Investigator	075	2	*Sidney H. Rogers*

27. REPORTING UNIT ACTION

☒ REFERRED TO HOME DISTRICT ☒ ADD TO ACTIVE OEI
☐ COLLECT OFFICIAL SAMPLE ☐ ROUTINE FOLLOW-UP
☐ REFERRED TO STATE OR OTHER FEDERAL AUTHORITIES ☐ INSPECT
☐ REINSPECT ☐ MAKE INVESTIGATION ☐ NO ACTION
☐ REFERRED TO HDQTRS _____ (Routing Symbol)

28. NAME OF REVIEWING OFFICIAL *(Type or print)*

Harry Abelman

29. TITLE	30. DATE REVIEWED
Supervisory Investigator	9-2-99

FORM FDA 457 (5/90) PREVIOUS EDITION MAY BE USED **PRODUCT/ESTABLISHMENT SURVEILLANCE REPORT**

SUSPECTED VIOLATIONS *(Check appropriate box)*

DRUGS – DEVICES

HEALTH

	Dangerous under any condition of use: 502(j).		Inadequate directions for use: 502(f)(1).
	Dangerous when sold indiscriminately: 502(f).		Failure to bear list of active ingredients: 502(e).
	Dangerous on account of excessive dosage: 502(j).		Possible variation from professed standard: 501(b), (c), (d).
	Dangerous because of inadequate warnings: 502(f)(2).		Vitamin preparations – possible variation from professed standard: 501(b), (c), (d).
	Drugs dangerous on account of impurities: 501(a)(2), (3), 502(j).		Extravagant therapeutic claims: 502(a)1

[1] If descriptive or promotional material employed in sale of product bears or contains extravagant therapeutic claims, indicate (in REMARKS on front or in separate memo) source, how received, and how employed in sale of product. See Section 201(m), Labeling: 301(b), 301(k), Prohibited Acts.

☐ HYGIENIC

ECONOMIC

	Deceptive packaged: 502(I).		Suspect short weight or volume: 502(b)

☐ NEW DRUG

FOODS

HEALTH

	Presence of poisons: 402(a)(1), (2).		Therapeutic claims for food: Subject to 502.
	Dangerous and non-nutritive substances (confectionery): 402(d)		Vitamin claims: 403(a), (j). May also be subject to 502.
	Poisonous containers: 402(a)(6).		Special dietary foods: 403(j)

HYGIENIC

	Stored under insanitary conditions: 402(a)(4).		Suspected filth or decomposition: 402(a)(3).

ECONOMIC

	Deceptive packaging: 403(d).		Failure to declare mandatory statements: nonstandardized foods: 403(e), (f), (I), (k).
	Short weight or volume: 403(e)(2).		Standardized foods, misbranding or nonconformity: 403(g), (h).
	Misrepresentation in labeling: 403(a). See 201(m).	X	New Product, New Manufacturer

COSMETICS

	Dangerous cosmetics: 601(a).		Adulteration: 601.
	Misbranding: 602		

OTHER

EXPLAIN

FORM FDA 457 (5/90) (BACK)

Federal Anti-Tampering Act

Public Law 98-127 - OCT. 13, 1983
98th Congress
An Act
To amend title 18 of the United States Code to prohibit certain tampering with consumer products, and for other purposes. (Oct. 13, 1983, [S. 216])
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Anti-Tampering Act". (Federal Anti-Tampering Act. 18 USC 1365 note.)

SEC. 2 Chapter 65 of title 18 of the United States Code is amended by adding at the end thereof the following new section:

"§ 1365. Tampering with consumer products
"(a) Whoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, or attempts to do so, shall-
"(1) in the case of an attempt, be fined not more than $25,000 or imprisoned not more than ten years, or both;
"(2) if death of an individual results, be fined not more than $100,000 or imprisoned for any term of years or for life, or both;
"(3) if serious bodily injury to any individual results, be fined not more than $100,000 or imprisoned not more than twenty years, or both; and
"(4) in any other case, be fined not more than $50,000 or imprisoned not more than ten years, or both.
"(b) Whoever, with intent to cause serious injury to the business of any person, taints any consumer product or renders materially false or misleading the labeling of, or container for, a consumer product, if such consumer product affects interstate of foreign commerce, shall be fined not more than $10,000 or imprisoned not more than three years, or both.
"(c)(1) Whoever knowingly communicates false information that a consumer product has been tainted, if such product or the results of such communication affect interstate or foreign commerce, and if such tainting, had it occurred, would create a risk of death or bodily injury to another person, shall be fined not more than $25,000 or imprisoned not more than five years, or both.
"(2) As used in paragraph (1) of this subsection, the term 'communicates false information' means communicates information that is false and that the communicator knows is false, under circumstances in which the information may reasonably be expected to be believed.
"(d) Whoever knowingly threatens, under circumstances in which the threat may reasonably be expected to be believed, that conduct that, if it occurred, would violate subsection (a) of this section will occur, shall be fined not more than $25,000 or imprisoned not more than five years, or both.
"(e) Whoever is a party to a conspiracy of two or more persons to commit an offense under subsection (a) of this section, if any of the parties intentionally engages in any conduct in furtherance of such offense, shall be fined not more than $25,000 or imprisoned not more than ten years, or both.
"(f) In addition to any other agency which has authority to investigate violations of this section, the Food and Drug Administration and the Department of Agriculture, respectively, have authority to investigate violations of this section involving a consumer product that is regulated by a provision of law such Administration or Department, as the case may be, administers.
"(g) As used in this section-
"(1) the term 'consumer product' means-
"(A) any 'food', 'drug', 'device', or 'cosmetic', as those terms are respectively defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or
"(B) any article, product, or commodity which is customarily produced or distributed for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which is designed to be consumed or expended in the course of such consumption or use;
"(2) the term 'labeling' has the meaning given such term in section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m));
"(3) the term 'serious bodily injury' means bodily injury which involves-
"(A) a substantial risk of death;
"(B) extreme physical pain;
"(C) protracted and obvious disfigurement; or
"(D) protracted loss or impairment of the function of a bodily member, organ, or mental faculty; and
"(4) the term 'bodily injury' means-
"(A) a cut, abrasion, bruise, burn, or disfigurement;
"(B) physical pain;
"(C) illness;
"(D) impairment of the function of a bodily member, organ, or mental faculty; or
"(E) any other injury to the body, no matter how temporary".
SEC. 3. The table of sections at the beginning of chapter 65 of title 18 of the United States Code is amended by adding at the end thereof the following new item:
"1365. Tampering with consumer products."