# DEPARTMENT of HEALTH and HUMAN SERVICES

Food and Drug Administration

***FY 2011 Online Performance Appendix***

## Introduction

The FY 2011 Online Performance Appendix is one of several documents that fulfill the Department of Health and Human Services's (HHS) performance planning and reporting requirements. HHS achieves full compliance with the Government Performance and Results Act of 1993 and Office of Management and Budget Circulars A-11 and A-136 through the HHS agencies' FY 2011 Congressional Justifications and Online Performance Appendices, the Agency Financial Report, and the HHS Summary of Performance and Financial Information. These documents are available at http://www.hhs.gov/budget/.

The FY 2011 Congressional Justifications and accompanying Online Performance Appendices contain the updated FY 2009 Annual Performance Report and FY 2011 Annual Performance Plan. The Agency Financial Report provides fiscal and high-level performance results. The HHS Summary of Performance and Financial Information summarizes key past and planned performance and financial information.

I am pleased to present the FY 2011 Online Performance Appendix for the Food and Drug Administration (FDA), which includes the initial report on our FY 2009 Performance Goals.

At FDA, we manage our programs to achieve measurable results and outcomes that protect and advance the public health. This Performance Report reflects the goals and objectives in the Department of Health and Human Services Strategic Plan and the FDA Strategic Action Plan~~s~~.

In FY 2009, FDA met or exceeded 97% of our performance goals that have been reported on so far. In fact, each year since 2002, FDA has met or exceeded at least 92% of our performance goals for each year. This is an excellent record of achievement, and reflects well on the efforts and professionalism of FDA's employees.

In accordance with the requirements of the Reports Consolidation Act of 2000, I, as the Agency Head, assert that the performance information in this report is accurate, complete and reliable, based on available data in FDA's performance information systems. The FY 2009 Performance Report includes descriptions of the means by which HHS requires us to verify and validate performance data and related data issues, including the completeness and reliability of the data. Where required, the programs have included discussions of the actions planned and completed to improve the completeness and reliability of the data.

At FDA, we pledge to continue to speed innovations that make our food and cosmetics supply safer and make medical products effective, safer, and more affordable for both human and animal consumption. We also pledge to continue to ensure that the public receives accurate and timely science-based information so they can use medical products and foods to improve their health. We will continue to be good stewards of the resources that Congress provides and build a healthier America for generations to come.

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

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# FDA Summary of Targets and Results Table

The Summary of Targets and Results Table provides an overview of all targets established for each corresponding fiscal year.

| Fiscal Year | Total Targets | Targets with Results Reported | Percent of Targets with Results Reported | Total Targets Met | Percent of Targets Met |
|---|---|---|---|---|---|
| 2006 | 46 | 46 | 100% | 45 | 98% |
| 2007 | 51 | 51 | 100% | 49 | 96% |
| 2008 | 45 | 45 | 100% | 42 | 93% |
| 2009 | 47 | 34 | 72% | 33 | 97% |
| 2010 | 77 | | | | |
| 2011 | 78 | | | | |

# Foods Performance Detail

**Long Term Objective:** Increase access to safe and nutritious new food products.

| Measure | FY | Target | Result |
|---|---|---|---|
| 213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. *(Output)* | *2011* | 80% | October, 2012 |
| | *2010* | 70% | October, 2011 |
| | *2009* | 60% | October, 2010 |
| | *2008* | 60% | 100% (Target Exceeded) |
| | *2007* | 50% | 100% (Target Exceeded) |
| | *2006* | 70% | 87% (Target Exceeded) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 213301 | CFSAN's electronic workflow system | The Food Application Regulatory Management (FARM) System is a comprehensive image-based electronic document management, workflow, and reporting automation system. FARM supports electronic processing, review, maintenance, and reporting for food ingredient submissions, including management of food and color additive petitions, Food Contact Notifications (FCNs) (until FY 2008), Generally Recognized as Safe Notices (GRNs) and Biotechnology Consultations. FARM expedites the ingredient review process and subsequent safety decisions. It also helps FDA perform associated activities such as responding and managing Freedom of Information requests and correspondence. FARM also supports industry electronic submission of food ingredient submissions and correspondence in a consistent/standard electronic format, further improving efficiencies for industry and FDA. The CFSAN electronic workflow system within FARM provides real-time tracking information on the progress, status, and timeliness of premarket submissions as well as the capability to generate ad-hoc reports including information and statistics on all significant events during the review process. |

**Long Term Objective:** Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

| Measure | FY | Target | Result |
|---|---|---|---|
| 214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. *(Outcome)* | *2011* | 362 enrolled | December, 2011 |
| | *2010* | 347 enrolled | December, 2010 |
| | *2009* | 332 enrolled | 333 enrolled (Target Exceeded) |
| | *2008* | 317 enrolled | 320 enrolled (Target Exceeded) |
| | *2007* | 240 enrolled | 302 enrolled (Target Exceeded) |
| | *2006* | N/A | 259 enrolled (Historical Actual) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 214101 | Listing of Jurisdictions Enrolled in the draft Voluntary National Retail Food Regulatory Program Standards: http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm121796.htm. | Food Code adoption is tracked through the contract with the Association of Food and Drug Officials (AFDO) and measured as a percent of the U.S. Population. A listing of jurisdictions enrolled in the draft voluntary national retail food regulatory program standards can be found on the CFSAN web page at http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm121796.htm. This listing identifies regulatory agencies that have enrolled in the draft Voluntary National Retail Food Regulatory Program Standards and have agreed to publish their status as they perform their self assessments, and to develop and implement strategic plans to meet all the Standards. Information is self-reported by the jurisdictions to FDA staff that compiles the information and maintains the listing. |

**Long Term Objective:** Detect safety problems earlier and better target interventions to prevent harm to consumers.

| Measure | FY | Target | Result |
|---|---|---|---|
| 214306: The average number of days to subtype priority pathogens in food (Screening Only). *(Output)* | *2011* | 5-8 working days | December, 2011 |
| | *2010* | N/A | N/A |
| | *2009* | N/A | 10-14 working days (Baseline) |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 214306 | Bioplex and ibis Biosensor systems | CFSAN scientists are developing the means to evaluate and adapt commercially available instruments to develop and validate more rapid, accurate, and transportable tests to stop the spread of foodborne illness and cases of chemical contamination. CFSAN scientists are using one such system, known as Bioplex, to rapidly serotype pathogens such as *Salmonella*. The Bioplex system can serotype 48 different samples in 3 to 4 hours, vastly improving response time in foodborne illness outbreaks. CFSAN scientists also are using the ibis Biosensor system to speed the identification of *Salmonella*, *E. coli*, and other pathogens, toxins, and chemical contaminants. When fully deployed, this technology holds the promise of reducing the time to conduct these analyses from 5-10 days to 1-2 days. |

| Measure | FY | Target | Result |
|---|---|---|---|
| 214207: The number of completed administrative assessments of regulatory food safety systems in a mix of economically developed and developing countries to determine comparability of their food safety systems. *(Output)* | *2011* | 5 | December, 2011 |
| | *2010* | N/A | N/A |
| | *2009* | N/A | N/A |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 214207 | FDA Surveillance Systems (e.g., FoodNet, PulseNet, eLEXNET) | FDA will conduct administrative assessments of regulatory food safety systems in developed and developing countries to measure their performance against FDA program standards. These assessments will include reviews of inspections, investigations, sample collections and analyses, and enforcement, response, recovery, and outreach activities. The data generated by these assessments will be linked to FDA food safety monitoring activities, and the data will be recorded and analyzed so that the results can be used to enhance the safety of the U.S. food supply. |

| Measure | FY | Target | Result |
|---|---|---|---|
| 214208: Number of consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. *(Outcome)* | *2011* | +10% | December, 2011 |
| | *2010* | Set Baseline | December, 2010 |
| | *2009* | N/A | N/A |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 214208 | Consumer Focus Group | FDA will use data collected from focus group research to develop FY 2010 baseline. FDA will increase consumer awareness by 10% through research-based and targeted education and outreach campaigns followed by repeat survey/focus groups to determine increase in awareness of FDA's Adverse Event Reporting System for Cosmetics. |

| Measure | FY | Target | Result |
|---|---|---|---|
| 214201: Number of prior notice import security reviews. *(Output)* | *2011* | 80,000 | December, 2011 |
| | *2010* | 80,000 | December, 2010 |
| | *2009* | 80,000 | 81,157 (Target Exceeded) |
| | *2008* | 80,000 | 80,543 (Target Exceeded) |
| | *2007* | 60,000 | 84,088 (Target Exceeded) |
| | *2006* | 45,000 | 89,034 (Target Exceeded) |
| 214202: Number of import food field exams. *(Output)* | *2011* | 160,000 | December, 2011 |
| | *2010* | 140,000 | December, 2010 |
| | *2009* | 120,000 | 138,916 (Target Exceeded) |
| | *2008* | 85,000 | 100,718 (Target Exceeded) |
| | *2007* | 71,000 | 94,743 (Target Exceeded) |
| | *2006* | 73,376 | 94,545 (Target Exceeded) |
| 214203: Number of Filer Evaluations. *(Output)* | *2011* | 1,000 | December, 2011 |
| | *2010* | 1,000 | December, 2010 |
| | *2009* | 1,000 | 1,208 (Target Exceeded) |
| | *2008* | 1,000 | 1,356 (Target Exceeded) |
| | *2007* | 1,000 | 1,355 (Target Exceeded) |
| | *2006* | 1,000 | 1,441 (Target Exceeded) |
| 214204: Number of examinations of FDA refused entries. *(Output)* | *2011* | 7,000 | December, 2011 |
| | *2010* | 7,000 | December, 2010 |
| | *2009* | 5,000 | 7,201 (Target Exceeded) |
| | *2008* | 4,000 | 5,926 (Target Exceeded) |
| | *2007* | 3,000 | 5,510 (Target Exceeded) |
| | *2006* | 3,000 | 5,846 (Target Exceeded) |

| Measure | *FY* | Target | Result |
|---|---|---|---|
| 214205: Number of high risk food inspections. *(Output)* | *2011* | 7,800 | December, 2011 |
| | *2010* | 6,750 | December, 2010 |
| | *2009* | 6,100 | 6,182 (Target Exceeded) |
| | *2008* | 5,700 | 6,230 (Target Exceeded) |
| | *2007* | 5,625 | 6,421 (Target Exceeded) |
| | *2006* | 5,963 | 6,795 (Target Exceeded) |
| 214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. *(Outcome)* | *2011* | 5 data exchange additions/conversions | December, 2011 |
| | *2010* | 5 data exchange additions/conversions | December, 2010 |
| | *2009* | 5 data exchange additions/conversions | 5 data entry labs (Target Met) |
| | *2008* | 5 data entry labs | 11 data entry labs (Target Exceeded) |
| 214206: Maintain accreditation for ORA labs. *(Outcome)* | *2011* | 13 labs | December, 2011 |
| | *2010* | 13 labs | December, 2010 |
| | *2009* | 13 labs | 13 labs (Target Met) |
| | *2008* | 13 labs | 13 labs (Target Met) |
| | *2007* | 13 labs | 13 labs (Target Met) |
| | *2006* | 13 labs | 13 labs (Target Met) |
| 214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)* | *2011* | 2,500 rad & 2,100 chem | December, 2011 |
| | *2010* | 2,500 rad & 2,100 chem | December, 2010 |
| | *2009* | 2,500 rad & 1,650 chem | 2,500 rad & 1,650 chem (Target Met) |
| | *2008* | 2,500 rad & 1,200 chem | 2,500 rad & 1,200 chem (Target Met) |
| | *2007* | 1,000 rad & 1,200 chem | 1,000 rad & 1,200 chem (Target Met) |
| | *2006* | 1,200 chem | 1,200 chem (Target Met) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 214201<br>214202<br>214203<br>214204<br>214205<br>214303<br>214206<br>214305 | Field Data Systems | ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality. |

| Measure | FY | Target | Result |
|---|---|---|---|
| 212404: Reduce the incidence of infection with key foodborne pathogens: *Campylobacter* species. *(Outcome)* | *2011* | 12.6 cases/100,000 (New Baselines)* | December, 2012 |
| | *2010* | 12.3 cases/100,000 | December, 2011 |
| | *2009* | N/A | December, 2010 |
| | *2008* | N/A | 12.8 cases/100,000 (Historical Actual) |
| | *2007* | N/A | 12.8 cases/100,000 (Historical Actual) |
| | *2006* | N/A | 12.7 cases/100,000 (Historical Actual) |
| 212405: Reduce the incidence of infection with key foodborne pathogens: *Escherichia coli* O157:H7. *(Outcome)* | *2011* | 1.19 cases/100,000 (New Baselines)* | December, 2012 |
| | *2010* | 1.0 cases/100,000 | December, 2011 |
| | *2009* | N/A | December, 2010 |
| | *2008* | N/A | 1.1 cases/100,000 (Historical Actual) |
| | *2007* | N/A | 1.2 cases/100,000 (Historical Actual) |
| | *2006* | N/A | 1.3 cases/100,000 (Historical Actual) |
| 212406: Reduce the incidence of infection with key foodborne pathogens: *Listeria monocytogenes*. *(Outcome)* | *2011* | .287 cases/100,000 (New Baselines)* | December, 2012 |
| | *2010* | .24 cases/100,000 | December, 2011 |
| | *2009* | N/A | December, 2010 |
| | *2008* | N/A | .29 cases/100,000 (Historical Actual) |
| | *2007* | N/A | .27 cases/100,000 (Historical Actual) |
| | *2006* | N/A | .31 cases/100,000 (Historical Actual) |
| 212407: Reduce the incidence of infection with key foodborne pathogens: *Salmonella* species. *(Outcome)* | *2011* | 15.1 cases/100,000 (New Baselines)* | December, 2012 |
| | *2010* | 6.8 cases/100,000 | December, 2011 |
| | *2009* | N/A | December, 2010 |
| | *2008* | N/A | 16.2 cases/100,000 (Historical Actual) |
| | *2007* | N/A | 14.9 cases/100,000 (Historical Actual) |
| | *2006* | N/A | 14.7 cases/100,000 (Historical Actual) |

* The FY 2011 targets are based on the FY 2006 – 2008 actual data, and start the next decade of targets as part of the Healthy People 2020 Initiative. The FY 2011 targets are therefore not comparable to the FY 2010 targets, which were set ten years ago for the Healthy People 2010 Initiative, based on FY 1997 actual data. Please see the performance paragraph in the goal by goal narrative below for further information.

| Measure | Data Source | Data Validation |
|---|---|---|
| 212404<br>212405<br>212406<br>212407 | FoodNet | The proactive use of food safety surveillance information and scientific data and tools to prevent illness and injury from foods is a significant focus of FDA. FDA collects data from the FoodNet Data Base to assess and communicate the specific risks associated with specific food products to American consumers and to industry on a routine basis as well as during foodborne illness outbreaks to reduce the incidence of infection with key foodborne pathogens. |

**Long Term Objective:** Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.

| Measure | FY | Target | Result |
|---|---|---|---|
| 212401: Increase by 40 percent the percentage of American consumers who correctly identify that trans fat increases the risk of heart disease. *(Outcome)* | *2007* | 45% | 61%<br>(Target Exceeded) |
| | *2005* | N/A | 32%<br>(Historical Baseline) |
| 212402: Increase by 10 percent the percentage of American consumers who correctly identify that saturated fat increases the risk of heart disease. *(Outcome)* | *2007* | 81% | 73%<br>(Target Not Met) |
| | *2005* | N/A | 74%<br>(Historical Baseline) |
| 212403: Improve by 10 percent the percentage of American consumers who correctly identify that omega-3 fat is a possible factor in reducing the risk of heart disease. *(Outcome)* | *2007* | 34% | 52%<br>(Target Exceeded) |
| | *2005* | N/A | 31%<br>(Historical Baseline) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 212401<br>212402<br>212403 | Health and Diet Survey | The Health and Diet Survey is a single-stage, random-digit-dialing telephone survey conducted by the U.S. Food and Drug Administration (FDA). It was administered in the fall of 2002 to a total of 2,743 non-institutionalized adult respondents in the 50 states and the District of Columbia. The purpose of the survey was to track and gather new information on consumer awareness, attitudes, and practices related to health and diet issues. In particular, the survey focused on foods and dietary supplements, two categories of the consumer products regulated by the FDA. On diet and health, the survey asked about (1) awareness of the relationship between diet and diseases (cancer, heart disease, high blood pressure), (2) knowledge of fats and cholesterol, (3) knowledge of dietary deficiencies, (4) dietary management practices, and (5) use and impact of food labels. On dietary supplements, the survey asked about (1) prevalence of use, (2) information sources and uses, (3) perceptions of dietary supplements and their labels, (4) substitution of dietary supplements for prescription or over-the-counter drugs, (5) adverse experiences with dietary supplements, and (6) children's and teenagers' use of diet. |

| Measure | FY | Target | Result |
|---|---|---|---|
| 212408: The number of American consumers who recognize dietary factors associated with chronic disease risk and steps they can take to reduce their risk. *(Outcome)* | *2011* | +10% | December, 2011 |
| | *2010* | Set Baseline | December, 2010 |
| | *2009* | N/A | N/A |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 212408 | NHANES | In FY 2010, FDA will use data from NHANES to obtain a baseline assessment of consumer awareness of dietary factors associated with disease risk and their knowledge of and ability to use the nutrition and ingredient information on the food label. FDA will increase consumer awareness through research-based, targeted education and outreach campaigns. FDA will use repeat survey/focus groups to determine increase in awareness and NHANES and USDA data to track changes in food intake patterns and biological responses. |

**1. Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt.** (213301)

**Context:** The likely number of submissions to the food and color additives premarket review program was uncertain for FY 2007 and FY 2008 because of statutory triggers in section 409(h) of the FD&C Act that might have dramatically increased the number of submissions to this program. The factors impacting the uncertainty in submission numbers have lessened and performance has stabilized. The FY 2011 target has been increased to 80%.

**Performance:** All petitions filed in FY 2008 have been completed as of the end of March 2009, exceeding the target for this measure by 40%. This program has consistently exceeded its performance goal each of the last four years. One reason goals have continued to be met is that the actual number of submissions has decreased over that period. An increase in the number or complexity of incoming submissions could reduce performance.

**2. Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft *Voluntary National Retail Food Regulatory Program Standards*.** (214101)

**Context:** Strong and effective regulatory programs at the state, local and tribal level are needed to prevent foodborne illness and reduce the occurrence of foodborne illness risk factors in retail and foodservice operations. The voluntary use of the Program Standards by a food inspection program reflects a commitment toward continuous improvement and the application of effective risk-based strategies for reducing foodborne illness. The success of the FDA National Retail Food Team in increasing enrollment and use of the Standards reflects continued recognition that the Standards help programs improve food safety in food service and retail food establishments. Effective use of the Standards is assured by having enrolled complete program self-assessments to identify program strengths and areas for improvement. The FY 2010 Targets shown in the table above are based on an expectation that additional local jurisdictions will enroll in FY 2010 and make progress toward meeting the Standards as the result, in part, of FY 2009 efforts by FDA to make funds available to jurisdictions who agree to provide FDA with written reports on their progress. With the additional funds that FDA made available to this program in FY 2009, FDA has increased the FY 2011 target to enrolling fifteen additional jurisdictions to the program. These targeted increases are more modest than previous year's enrollments in recognition that,

in addition to enrolling new jurisdictions, ORA personnel must devote time and resources to assisting the growing number of enrollees with Program Standards implementation.

**Performance:** FDA exceeded its FY 2009 target by increasing the number of states, local, and tribal retail food inspection programs enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards by 13 new jurisdictions. This raised the total number of enrolled jurisdictions to 333. FDA has consistently exceeded its targets for this measure for the past 3 years.

**3. The average number of days to subtype priority pathogens in food (Screening Only).** (214306)

**Context:** FDA Foods Program scientists are evaluating commercially available instrumentation that can be adapted to support the FDA regulatory mission. CFSAN has advanced two of these technology platforms to Field laboratories, the Bioplex and the ibis Biosensor systems. The instrumentation is laboratory-based and provides broad-range and strain-specific identification of infectious organisms for multiple applications (clinical and environmental). The application does not require any prior knowledge of the sample identity and can simultaneously identify and characterize bacterial, viral, fungal, and other infectious organisms. The technology is extremely high throughput and can analyze thousands of samples a week. CFSAN has a contract with the developer that has advanced to allow detection of multiple pathogens down to the species level (*Escherichia coli* O157:H7 may also be determined), CFSAN researchers have field-tested 400 tomato samples to determine the microbiome associated with this commodity. Further research will evaluate the ability to detect *Salmonella* genus and sero/subtyping specifics through the next year. This year, CFSAN will purchase at least two of the systems for placement in other laboratories. CFSAN researchers will then begin coordinated testing and refinement of the technology for FDA's needs. The FY 2011 for this goal is 5-8 working days.

**Performance:** The improvements in sample throughput, along with the high degree of specificity built into this technology, will dramatically improve our response and traceback capabilities. When fully deployed, this technology holds the promise of reducing the time to conduct these analyses from 5-10 days to 1-2 days.

**4. The number of completed administrative assessments of regulatory food safety systems in a mix of economically developed and developing countries to determine comparability of their food safety systems.** (214207)

**Context:** FDA allows food imports from almost any country and takes on the burden of ensuring the safety of imported foods as they arrive at U.S. ports of entry. Approximately 15-20% of all foods consumed in the U.S. originated from foreign sources: 80% of the seafood and 25-35% of the produce eaten by American consumers are imported. The FDA does not have the resources to inspect all products that reach U.S. border in any given year; however, it is the expectation of American consumers that these imported foods are as safe as foods produced domestically. In response to this concern, FDA will conduct administrative assessments of regulatory food safety systems in developed and developing countries to measure their performance against FDA program standards. These assessments will include reviews of inspections, investigations, sample collections and analyses, and enforcement, response, recovery, and outreach activities. The data generated by these assessments will be linked to FDA food safety monitoring activities, and the data will be recorded and analyzed so that the results can be used to enhance the safety of the U.S. food supply. In FY 2011, FDA will conduct five additional administrative assessments of foreign regulatory food safety systems.

**Performance:** Since this is a new goal, performance data for FY 2011 will not be available until December 2011.

**5. Number of consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. (**214208**)**

**Context:** There are an increasing number of produces marketed as cosmetics that contain drug or other "active" ingredients. These products are not well-characterized and may pose different and more significant safety issues than traditional cosmetic products. Internet sales are increasing, but the entire extent of this segment of the cosmetic market is not well characterized and problems in traceback to

remove unsafe products could be highly significant. Problems may not come immediately to FDA attention because of the significant under-reporting of adverse events associated with cosmetics. FDA feels that increasing consumer awareness of FDA's Adverse Event reporting System for cosmetics would be a major step in reducing this important public health risk.

**Performance:** Baseline data will be developed in FY 2010 thru focus group research. FDA will conduct research-based and targeted education and outreach campaigns followed by repeat survey/focus groups to determine increase in awareness of FDA's Adverse Event Reporting System for Cosmetics.

**6. Number of prior notice import security reviews.** (214201)

**Context:** FDA's Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. FDA will continue to focus much of its resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. consumer. All flagged entries (100%) are reviewed every year. FDA expects that as prior notice compliance activities increase and targeting for high risk products becomes more sophisticated, the total number of intensive prior notice security reviews conducted by the PNC may decrease in future years. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** During FY 2009, FDA received 9,546,831 prior notice submissions on which the PNC conducted 81,157 import security reviews (exceeding the performance target of 80,000 reviews) to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. A total of 798 shipments were refused for prior notice violations, which more than doubled the total number of refusals from the previous fiscal year. The PNC operations actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats. In addition, the PNC responded to more than 23,284 phone and e-mail inquiries, and conducted over 600 informed compliance calls to the import trade in order to facilitate better compliance with the submission of accurate, timely prior notice information.

**7. Number of import food field exams.** (214202)

**Context:** The volume of imported food shipments has been rising steadily in recent years and this trend is likely to continue. FDA reviewed approximately 9.8 million line entries of imported food out of an estimated 20.0 million lines of FDA regulated products in FY 2009. In FY 2010, FDA expects approximately 10.1 million line entries of imported food within a total of more than 23.2 million lines of FDA regulated entries. To manage this ever-increasing volume of imports, FDA uses risk management strategies to achieve the greatest food protection with available resources. While the percentage of imports physically examined may decline as imports continue their explosive growth, the exams that ORA conducts are more targeted and more effective than ever before. ORA continues to think that the best approach to improve the safety and security of food import lines is to devote resources to expand targeting and follow through on potentially high-risk import entries rather than simply increasing the percentage of food import lines given a field exam. In FY 2009, FDA used Food Protection Resources to increase the number of import food field exams by 20,000 exams which brought the FY 2009 Target to 120,000 exams over the FY 2008 accomplishments. In FY 2010, FDA will use the FY 2009 resources to increase the number of import food field exams by 20,000 exams which brings the FY 2010 Target to 140,000 exams. In FY 2011, the target is increased by 20,000 field exams for a new target of 160,000 exams.

**Performance:** In FY 2009, FDA exceeded the target of 120,000 by completing 138,916 field examinations of imported food lines. Explanation of why this goal was significantly exceeded: With the increase in funding, FDA was able to bring on a significant number of new investigators earlier than anticipated which enabled FDA to exceed this estimate. FDA will continue to adjust targets upward as our hiring continues.

**8. Number of Filer Evaluations of import filers.** (214203)

**Context:** The Food and Drug Administration (FDA) receives electronic import entry data for assessing the admissibility of regulated imported articles. The accuracy of these data directly relates to the level of confidence that American consumers can expect in the quality, safety and compliance of imported articles subject to FDA's jurisdiction. Entry data affects FDA's determination of the labeling, quality, safety, approval status, and efficacy of FDA-regulated import articles. FDA uses an electronic entry screening system, Operational and Administrative System for Import Support (OASIS), to screen import entry data transmitted by import filers. Filers who fail an evaluation must implement a Corrective Action Plan and pass a tightened evaluation. This protects public health by ensuring reporting compliance for imported articles that FDA regulates. FDA will continue to develop and apply methods to evaluate filer accuracy that are consistent with evolving security and import regulation practices. The FY 2010 and FY 2011 targets are being maintained at the FY 2009 level.

**Performance:** In FY 2009, FDA exceeded this goal of 1,000 by performing 1,208 filer evaluations. This goal is an agency-wide goal and performance data includes activities from all five program areas**;** however, the majority of the performance activities and resources are from the Foods program.

**9. Number of examinations of FDA refused entries.** (214204)

**Context:** FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics. This protection includes refusing entry of products into the U.S. when they are deemed violative and assuring these violative products are either destroyed or exported and do not enter into domestic commerce. Although primary responsibility for supervising destruction or exportation rests with the Bureau of Customs and Border Protection (CBP), FDA monitors the disposition of refused shipments and maintains an open file until the product is exported or destroyed. In cooperation with CBP, FDA will, at times, supervise destruction or examine products prior to export in order to assure that the refused product is actually exported. This performance goal only counts FDA supervised destruction or exportation of refused entries. In other cases FDA relies on notification from CBP that the refused products have been destroyed or exported. The FY 2009 target was increased to 5,000 examinations to better reflect the recent historical actuals for this goal. For FY 2010, the target is again being increased to 7,000 to better reflect recent actual accomplishments. The FY 2011 target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA exceeded this goal of 5,000 by performing 7,201 examinations of FDA refused entries as they were delivered for exportation to assure that the products refused by FDA were exported. This goal is an agency wide goal and performance data includes activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program. Explanation of why this goal was significantly exceeded: The increase in accomplishments compared to the performance target was due to the Agency's hiring initiative and resulting increase in personnel available to perform refusal follow-ups.

**10. Number of high risk food inspections.** (214205)

**Context:** High risk food establishments are those that produce, prepare, pack or hold foods that are at high potential risk of microbiological or chemical contamination due to the nature of the foods or the processes used to produce them. This category also includes foods produced for at risk populations such as infants. The Field intends to inspect such establishments annually, or more frequently for those who have a history of violations. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk food firms enter the market, or the definition of high risk evolves based on new information on food hazards. High-risk establishment inspection frequencies vary depending on the products produced and the nature of the establishment. Inspection priorities may be based on a firm's compliance history. The FY 2009 target was increased to 6,100 inspections of high-risk food establishments to better reflect the recent historical actuals for this goal. For FY 2010, the target has been increased to 6,750 to reflect the FY 2009 Appropriations. In FY 2011, the target is increased by 1,050 inspections for a new target of 7,800 inspections.

**Performance:** In FY 2009, FDA exceeded this goal of 6,100 by performing 6,182 inspections of high-risk domestic food establishments.

**11. Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange.** (214303)

**Context:** The electronic Laboratory Exchange Network (eLEXNET) is a seamless, integrated, secure network that allows multiple agencies (federal, State and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET enables health officials to assess risks, analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. As of the end of FY 2009, there are 224 total laboratories currently participating in eLEXNET overall. These labs include segments of a wide variety of food safety organizations on Federal, Military, State, and Local government levels. These labs also span the agricultural, environmental, public health, veterinary, and diagnostic disciplines as well. Of the 224 participating laboratories in all 50 states, 144 are actively entering or submitting data. There are 44 labs among them that are fully automated via Data Exchange and transfer their LIMS sample data on a regular, ongoing basis. The 100 other remaining laboratories enter data in eLEXNET through manual data entry. The overall goal of the FDA's eLEXNET program is to continue to integrate those labs participating in eLEXNET via Data Exchange and to identify new labs to expand our membership. Through continued expansion of our membership base and active data sources, the eLEXNET program will continue to serve as a key collaborative tool for food surveillance entities nationwide. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA met its performance goal by fully automating electronic data exchange between five new labs and FDA's eLEXNET (electronic Laboratory Exchange Network). This makes the total number of automated data exchange participant labs to 44. The automated data transfer does not require any human intervention and is completely maintenance free unless there is a change in the lab environment.

**12. Maintain accreditation for ORA labs.** (214206)

**Context:** FDA is a science-based agency that depends on its regulatory laboratories for timely, accurate, and defensible analytical results in meeting its consumer protection mandate. Our laboratories have enjoyed a long history of excellence in science upon which the agency has built its reputation as a leading regulatory authority in the world health community. Accreditation of laboratory quality management systems provides a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science. Such accreditations allow FDA to maintain its reputation as a source of scientifically sound information and guidance both domestically and in the international arena. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA met this laboratory accreditation goal. FDA maintained accreditation for 13 laboratories: Denver District Lab, Forensic Chemistry Center, Arkansas Regional Lab, Pacific Regional Lab Northwest, San Francisco District Lab, Winchester Engineering and Analytical Center, New York Regional Lab, Southeast Regional Lab, San Juan District Lab, Detroit District Lab, Pacific Regional Lab Southwest, and Kansas City District Lab. All ORA Field Laboratories are accredited to ISO 17025 by the American Association for Laboratory Accreditation. FCC is accredited by the ASCLD (American Society of Crime Laboratory Directors).

**13. Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week)** (214305)

**Context:** A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for the presence of contaminants. To address the need for this surge capacity, The Food Emergency Response Network (FERN), a joint effort between USDA/FSIS and HHS/FDA, was created. FERN is a nationwide laboratory network that integrates existing federal and State food testing laboratory resources capable of analyzing foods for agents of concern in order to prevent, prepare for, and respond to national

emergencies involving unsafe food products. Improvements in surge capacity will have public health value even in non-deliberate food contamination by assisting FDA in identifying and removing contaminated food products from the marketplace as soon as possible in order to protect the public health and mitigate disruption in the U.S. food supply chain. FDA awards FERN Cooperative Agreements for chemistry and radiological FERN labs to the States. After receiving the funding, State FERN laboratories can take up to one year to reach full capacity due to the need for training and testing to ensure confidence in the laboratory results. As a result, labs funded in one fiscal year will not show surge capacity until the following year. With FY 2008 Food Protection increases, ORA added three additional FERN chemical labs in FY 2008 which increased the surge capacity in FY 2009 to 1,650 chemical samples per week. With the FY 2009 Appropriation, ORA will add three additional FERN chemical labs in FY 2009 which will increase the surge capacity in FY 2010 to 2,100 chemical samples per week. FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA met this performance goal surge capacity target of 1,650 chem samples per week based on the awarding of cooperative agreements to 3 state chemistry labs in FY 2008 resulting in a surge capacity increase of 150 chem samples per lab (450 total) in FY 2009. FDA also maintained the surge capacity for 2,500 rad samples per week.

The FERN laboratories increasingly provide critical analytical surge capacity during food emergency events. An FDA assignment ("Surveillance, Inspection and Sample Collection and Analyses of Products Related to the Salmonella St. Paul Investigation" issued by ORA/CFSAN) directed samples to the FERN labs in the Salmonella outbreak in peppers, with 290 samples tested. FERN Chemistry laboratories participated in the #09-06 CFSAN Melamine Import Assignment (2008-2009), assisting FDA in the analysis of milk and protein samples, analyzing 340 samples. These FERN labs were a key factor in clearing an FDA sample backlog, which arose due to very high collection rates. FERN laboratories also participated in the FDA surveillance assignment for the political conventions. All of these efforts contribute to increasing FDA's capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of state, local, and tribal regulatory bodies.

**14. Reduce the incidence of infection with key foodborne pathogens.** (212404 – 212407)

**Context:** The Nation's challenges to food protection are increasing as consumers buy food from around the globe. FDA's Foods Program features a science and risk-based approach of prevention, intervention, and response to ensure the safety of domestic as well as imported foods. Federal, Tribal, and State partners use a combination of research, inspections, surveillance, regulation and guidance, standardization and education as strategies to improve food safety. The proactive use of food safety surveillance information and scientific data and tools to prevent illness and injury from foods is a significant focus of FDA. FDA collects data from the FoodNet Data Base to assess and communicate the specific risks associated with specific food products to American consumers and to industry on a routine basis as well as during foodborne illness outbreaks to reduce the incidence of infection with key foodborne pathogens. Foodborne illness surveillance information is also used to determine what additional food safety strategies are needed and to measure the effectiveness of interventions over time.

**Performance:** The FY 2010 targets for reducing the incidence of infection caused by *Campylobacter* species, *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* species were set in the year 2000 as part of the Healthy People 2010 Initiative. The targets for FY 2010 were all calculated as 50% reductions from 1997 baseline incidence levels for these foodborne pathogens. The targets for 2010 have not yet been achieved for any of the pathogens included in this objective (though *Campylobacter* species, *E. coli* O157:H7 and *Listeria monocytogenes* are very close, with 48%, 47% and 38% reductions, respectively, as of the 2008 data). Further investigation is needed to identify sources for emerging Salmonella serotypes, since that rate of infection has increased in the past decade. The FY 2011 targets start the next decade of targets as part of the Healthy People 2020 Initiative, and are therefore not comparable to the FY 2010 targets. In order to align the new targets for future reductions with more recent data, the baseline data for the FY 2011 targets is from FoodNet data collected from FY 2006 – FY 2008. Consequently, the FY 2011 targets show an increase over the Healthy People 2010 targets due to the new baseline. The Health and Human Services Office of Disease Prevention and Health Promotion

(ODPHP) has recently given guidance to the Healthy People work groups on target setting for Healthy People 2020, recommending improvement targets of 10% over the 10-year period.

**15. Increase consumer understanding of diet-disease relationships, and in particular, the relationships between dietary fats and the risk of coronary heart disease (CHD).** (212401, 212402, 212403)

**Context:** Coronary Heart Disease (CHD) is the leading cause of death among Americans, accounting for more than 1 in 5 deaths annually. CHD is also the leading cause of premature, permanent disability in the labor force. Dietary factors, especially consumption of some fats, play a significant role in CHD risk. One modifiable factor that is important for reducing mortality and morbidity associated with heart disease is consumer understanding of the consequences of dietary choices with respect to CHD. Increased understanding will strengthen motivation to adopt and maintain recommended healthy dietary behavior and to make informed dietary choices. The target is directly in line with several of the Department's priorities and strategic goals. First, improving the American diet through informed choice about fats that increase or reduce the risk of heart disease is one of several important steps toward reducing the enormous morbidity and mortality burden of CHD. This burden is borne disproportionately by minority populations, including African-Americans, Hispanics, and Native Americans. As the leading cause of death and a significant cause of illness and disability, CHD also imposes substantial costs on the U.S. health care system.

**Performance:** The FDA exceeded its goal to increase consumer understanding of the relationships between dietary fats and the risk of coronary heart disease for two out of three specified dietary fats. Baseline and target data for this goal are taken from the 2004 and 2008 Health and Diet Surveys (HDS). Results indicate that the proportion of consumers that understand that trans fat in the diet increases the risk of CHD increased from 32% in 2004 to 61% in 2008, or by 90%, which surpasses the FDA goal of 40%. The proportion that understands that omega-3 fatty acids reduce the risk of CHD increased from 31% to 52%, or by 67%, which also surpasses the goal of 10%. The proportion of consumers that understand that saturated fats increase the risk of CHD remained flat from 74% to 73%. The change, which is not statistically significant from 0%, falls short of FDA's goal of a 10% increase. Given the already high level of consumer understanding of saturated fats, perhaps public understanding of the saturated fat-CHD relationship has reached a plateau, or that the focus on trans fats over the last few years may have taken the place of what was otherwise ongoing communication about saturated fats. Regardless, on the whole, FDA has been successful at realizing a net increase in consumer understanding of the relationships between dietary fats and CHD.

**16. The number of American consumers who recognize dietary factors associated with chronic disease risk and steps they can take to reduce their risk.** (212408)

**Context:** One of the most important strategies in assuring that citizens lead long, healthy lives and minimize the likelihood of chronic disease is the use of science-based nutrition information to make wise choices about the foods they consume. The costs to inform, educate, and motivate consumers to these dietary choices are small compared to the costs to society of dealing with the chronic illnesses whose prevalence is based on a poor diet. The public health focus of this initiative is to expand and enhance food-labeling programs, education, outreach, and research to enable American consumers to make more informed and healthful food choices, maintain health, and reduce the risk of chronic diseases such as type 2 diabetes, cardiovascular disease, and obesity.

**Performance:** CFSAN will develop effective dietary guidance messages, education, and outreach programs. This will support efforts to increase consumer recognition of dietary factors that are associated with chronic disease risk and the steps they can take to reduce risk. CFSAN will report on the new FY 2010 target when the data becomes available in 2011.

# Human Drugs Performance Detail

**Long Term Objective:** Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

| Measure | FY | Target | Result |
|---|---|---|---|
| 223201: Percentage of Standard NDAs/BLAs within 10 months. *(Output)* | *2011* | 90% | Nov 30, 2012 |
| | *2010* | 90% | Nov 30, 2011 |
| | *2009* | 90% | Nov 30, 2010 |
| | *2008* | 90% | 84% (Target Not Met) |
| | *2007* | 90% | 88% (Target Not Met) |
| | *2006* | 90% | 95% (Target Exceeded) |
| 223202: Percentage of Priority NDAs/BLAs within 6 months. *(Output)* | *2011* | 90% | Nov 30, 2012 |
| | *2010* | 90% | Nov 30, 2011 |
| | *2009* | 90% | Nov 30, 2010 |
| | *2008* | 90% | 63% (Target Not Met) |
| | *2007* | 90% | 90% (Target Met) |
| | *2006* | 90% | 97% (Target Exceeded) |
| 223205: The total number of actions taken on abbreviated new drug applications in a fiscal year. *(Output)* | *2011* | 2000 | Nov 30, 2011 |
| | *2010* | 1900 | Nov 30, 2010 |
| | *2009* | 1900 | 2,006 (Target Exceeded) |
| | *2008* | 1780 | 1,934 (Target Exceeded) |
| | *2007* | N/A | 1,779 (Historical Actual) |
| | *2006* | N/A | 1,456 (Historical Actual) |
| 223207: Reduction in FDA approval time for the fastest 50 percent of standard New Molecular Entities/Biologics Licensing Applications approved for CDER and CBER, using the 3-year submission cohort for FY 2005-2007. *(Outcome)* | *2007* | 514 days | Nov 30, 2011 |
| | *2006* | N/A | Nov 30, 2010 |
| | *2005* | N/A | 639 days (Historical Actual) |

| Measure | *FY* | Target | Result |
|---|---|---|---|
| 223208: Reduction in FDA time to approval or tentative approval for the fastest 70 percent of original generic drug applications approved or tentatively approved of those submitted using the 3-year submission cohort for FY 2005-2007. *(Outcome)* | *2007* | 16.4 months | Nov 30, 2010 |
| | *2006* | N/A | 17.4 months (Historical Actual) |
| | *2005* | N/A | 17.8 months (Historical Actual) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 223201<br>223202<br>223101<br>223206<br>223208 | Review performance monitoring is being done in terms of cohorts, e.g., FY 2009 cohort includes applications received from October 1, 2008, through September 30, 2009. CDER uses the Document Archiving, Reporting, and Regulatory Tracking System (DARRTS). FDA has a quality control process in place to ensure the reliability of the performance data in DARRTS. The Pediatric Exclusivity Database tracks all data regarding pediatric exclusivity as mandated by FDAMA and reauthorized by BCPA. Specifically, this database tracks the number of WRs issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made. The Pediatric Page database captures all information regarding waivers, deferrals, and completed studies for applications that are subject to the Pediatric Research Equity Act. Published monographs that establish acceptable ingredients, doses, formulations, and consumer labeling for OTC drugs. | The Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) is CDER's enterprise-wide system for supporting premarket and postmarket regulatory activities. DARRTS is the core database upon which most mission-critical applications are dependent. The type of information tracked in DARRTS includes status, type of document, review assignments, status for all assigned reviewers, and other pertinent comments. CDER has in place a quality control process for ensuring the reliability of the performance data in DARRTS. Document room task leaders conduct one hundred percent daily quality control of all incoming data done by their IND and NDA technicians. Senior task leaders then conduct a random quality control check of the entered data in DARRTS. The task leader then validates that all data entered into DARRTS are correct and crosschecks the information with the original document. CDER uses the Pediatric Exclusivity database and the Pediatric Research Equity Act Tracking System (PREATS) to track information such as number of written requests issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made as well as information related to the PREA legislation. |

| Measure | Data Source | Data Validation |
|---|---|---|
| 223205<br>223207 | Review performance monitoring is being done in terms of cohorts, e.g., FY 2009 cohort includes applications received from October 1, 2008, through September 30, 2009. CDER uses the Document Archiving, Reporting, and Regulatory Tracking System (DARRTS). FDA has a quality control process in place to ensure the reliability of the performance data in DARRTS. The Pediatric Exclusivity Database tracks all data regarding pediatric exclusivity as mandated by FDAMA and reauthorized by BCPA. Specifically, this database tracks the number of WRs issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made. The Pediatric Page database captures all information regarding waivers, deferrals, and completed studies for applications that are subject to the Pediatric Research Equity Act. Published monographs that establish acceptable ingredients, doses, formulations, and consumer labeling for OTC drugs. | The Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) is CDER's enterprise-wide system for supporting premarket and postmarket regulatory activities. DARRTS is the core database upon which most mission-critical applications are dependent. The type of information tracked in DARRTS includes status, type of document, review assignments, status for all assigned reviewers, and other pertinent comments. CDER has in place a quality control process for ensuring the reliability of the performance data in DARRTS. Document room task leaders conduct one hundred percent daily quality control of all incoming data done by their IND and NDA technicians. Senior task leaders then conduct a random quality control check of the entered data in DARRTS. The task leader then validates that all data entered into DARRTS are correct and crosschecks the information with the original document. CDER uses the Pediatric Exclusivity database and the Pediatric Research Equity Act Tracking System (PREATS) to track information such as number of written requests issued and the number of products for which pediatric studies have been submitted and for which exclusivity determinations have been made as well as information related to the PREA legislation. |
| 223102 | FDA websites: CDER Drug and Biologic Approval Reports (http://www.fda.gov/cder/rdmt/default.htm); Guidance Documents (http://www.fda.gov/cder/guidance/index.htm); FDA Approves Treatment for Nerve-Poisoning Agents for Use by Trained Emergency Medical Services Personnel (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01473.html); FDA Approves First Generic Ciprofloxacin Injection, USP (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01438.html); Questions and Answers about Unapproved Drugs and FDA's Enforcement Action Against Carbinoxamine Products (http://www.fda.gov/cder/drug/unapproved_drugs/qa.pdf); Drugs Marketed in the United States That Do Not Have Required FDA Approval (http://www.fda.gov/cder/drug/unapproved_drugs/default.htm); Federal Register Notices; CDC/DHS Strategic National Stockpile (SNS) program. HHS website: HHS Awards BioShield Contract for Two Additional Medical Countermeasures for Radiological or Nuclear Incidents (http://www.hhs.gov/news/press/2006pres/20060213.html) | CDER has instituted multiple layers of verification and validation for ensuring the accuracy of performance information. CDER relies on data extracted from information systems to support demonstrating performance toward most performance goals and targets. CDER has developed manuals of policies and procedures (MaPPs) or other standard operating procedures for using or entering data into information systems. There are quality controls built in to the information systems – controls that help ensure the integrity and accuracy of the data entered. CDER has a number of analysts who have expertise in extracting information from these systems. Their knowledge and experience working with the data, and their familiarity and experience with the business of the Center provide another layer of validation. Further, the Center requires a multi-level clearance process for verifying and validating the accuracy of the information provided in the annual performance report. |

**Long Term Objective:** Improve information systems for problem detection and public communication about product safety.

| Measure | FY | Target | Result |
|---|---|---|---|
| 222303: Improve the safe use of drugs by patients and health care providers by reviewing safety labeling changes required under FDAAA within the timeframes established by FDAAA. *(Output)* | *2011* | 80% | Nov 30, 2011 |
| | *2010* | 80% | Nov 30, 2010 |
| | *2009* | N/A | 75% (Historical Actual) |
| 222201: The Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. *(Efficiency)* | *2011* | $12 per report | Nov 30, 2011 |
| | *2010* | $12 per report | Nov 30, 2010 |
| | *2009* | $12 per report | $10.79 per report (Target Exceeded) |
| | *2008* | $13 per report | $10.59 per report (Target Exceeded) |
| | *2007* | $15 per report | $13.64 per report (Target Exceeded) |
| | *2006* | N/A | $16.47 per report (Historical Actual) |
| 222202: The percent of manufacturer submitted expedited adverse event reports received electronically compared to all expedited adverse event reports received from industry. *(Outcome)* | *2011* | 85% | Nov 30, 2011 |
| | *2010* | 80% | Nov 30, 2010 |
| | *2009* | N/A | 83% (Historical Actual) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 222201<br>222202 | Drug Quality Reporting System (DQRS), Adverse Event Reporting System (AERS), OMB Form 300 on Drug Safety, UFMS cost data and published FDA CDER/CBER guidance for Industry, internet site http://www.fda.gov/cber/gdlns/barcode.htm. | AERS, UFMS, and OCIO quality control processes |

**Long Term Objective:** Detect safety problems earlier and better target interventions to prevent harm to consumers

| Measure | FY | Target | Result |
|---|---|---|---|
| 224201: Number of foreign and domestic high-risk human drug inspections. *(Output)* | *2011* | 750 | December, 2011 |
| | *2010* | 700 | December, 2010 |
| | *2009* | 600 | 687 (Target Exceeded) |
| | *2008* | 500 | 534 (Target Exceeded) |
| | *2007* | 500 | 583 (Target Exceeded) |
| | *2006* | 483 | 510 (Target Exceeded) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 224201 | Field Data Systems. | ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality. |

| Measure | FY | Target | Result |
|---|---|---|---|
| 222302: Percentage of television advertisements requiring submission reviewed within 45 days. *(Output)* | *2011* | 30% | Dec 31, 2011 |
| | *2010* | Issue guidance & establish baseline | Dec 31, 2010 |
| | *2009* | N/A | N/A |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

**1. Percentage of Standard NDAs/BLAs and Priority NDAs/BLAs within 10 months.** (223201 and 223202)

**Context:** This performance goal focuses primarily on improving the effectiveness and efficiency with which the FDA processes new drug and biologics licensing applications. Central to that focus is FDA's commitment to meeting PDUFA goals and requirements. The Food and Drug Administration Amendments Act of 2007 reauthorized collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. A key determinant in knowing if CDER is effective and efficient is to measure the time to "first action." The first action is the first regulatory action CDER takes (complete response, approvable, not approvable, or approval letter) at the end of the review of the original NDA/BLA submission (the first review cycle). The "first action time" refers to the time it takes to review and take an action on the original submission. This statistic is different from "total approval time" which is the time it takes from the original receipt of the application until it is approved, which may take more than one review cycle. "Total approval time" includes time spent reviewing an application in each of the review cycles plus the time taken by the sponsor to respond to the issues raised in the complete response or approvable/not approvable letter(s) and to re-submit the application for review. CDER's featured targets under this performance goal are to measure time to first action for "priority" submissions and "standard" submissions. Applications for drugs similar to those already marketed are designated standard, while priority applications represent drugs offering significant advances over existing treatments. In FY 2011, FDA continues to maintain the target set for this goal in the PDUFA legislation.

**Performance:** CDER tracks performance to these review goals by fiscal year cohorts. If an application is submitted in September of 2008, it will be tracked in the FY 2008 cohort even though much of the review work associated with the application, and the goal action date, may occur in the following fiscal year. As such, the most recent available performance information is for the FY 2008 cohort.

CDER did not meet the review performance goals for standard and priority reviews for the FY 2008 cohort. CDER reviewed 84% of standard NDAs/BLAs within 10 months and 63% of priority reviews within 6 months. Longer CDER review times for FY 2008 reflect the impact of several factors. The

FDA Amendments Act (FDAAA) of 2007 that reauthorized the Prescription Drug User Fee Act in FY 2008 also added a significant new authorities and requirements that have added or expanded tasks that must be performed within the process of human drug review. As CDER was undertaking an aggressive effort to hire new staff to handle the existing scope and level of review work, the Center has also been implementing new requirements to be addressed within the review process. This includes the increased use of advisory committees mandated under FDAAA—particularly for drugs receiving a priority review—coupled with a lengthier process to plan meetings using the more stringent advisory committee member screening process under FDAAA that allows significantly fewer waivers for conflicts of interest for otherwise qualified candidates. Similarly FDAAA Title IX risk management provisions add steps to the review to determine whether a Risk Evaluation and Mitigation Strategy (REMS) will be required at the time of new drug approval. These additional FDAAA-related processes have expanded the work required within review time goals that were established ten years earlier, under FDAMA. To ensure a rapid and compliant process CDER is continuing to review the expanded review process requirements, while training the significant number of newly-hired staff to enable them to achieve review expertise as rapidly as possible.

**2. The total number of actions taken on abbreviated new drug applications in a fiscal year.** (223205)

**Context:** Generics play an important and increasing role in providing safe, effective, and affordable drugs to the American public and thereby in controlling health care expenditures. The number of generic applications submitted to CDER's generic drug program has grown considerably over the past decade – nearly three-fold since 2001 – outpacing the growth in program personnel. In order to manage the increasing workload CDER has launched initiatives to streamline and modernize the generic review program. The growing capacity of the program is measured in total actions taken on generic drug applications. An action is defined as any approval, tentative approval, not approvable, and approvable decision taken on a generic drug application. The target for FY 2009 is 1,900 actions. In FY 2010 the target is 1,900 actions and in FY 2011 the target is 2,000 actions.

**Performance:** In FY 2009 CDER's generic program took 2,006 actions – exceeding the target measure by 106 actions

**3. Reduction in FDA approval time for the fastest 50 percent of standard New Molecular Entities/Biologics Licensing Applications approved for CDER and CBER, using the 3-year submission cohort for FY 2005-2007.** (223207)

**Context:** Reducing unnecessary delays in the approval time for safe and effective drugs that truly represent new therapies [i.e., new molecular entities (NMEs) and biologics] means earlier patient access for these medicines. Reducing unnecessary delays in drug approval also helps to both control the cost of new drug development, cited as a factor affecting the cost to consumers, and supports market competition among innovators. This is both good for the drug industry and good for consumers. New drug development presents uncertainties that increase the business risk and costs to the innovator. Higher costs can create barriers to competition both from new drugs with therapeutic value – but not blockbuster potential, and new innovators that don't have access to the capital available to more established pharmaceutical companies. Although some scientific and technical uncertainties are inherent and unavoidable in drug innovation, others can be reduced or eliminated, helping speed patient access to new drugs, and reducing the cost of drug development. FDA has begun major initiatives to reduce those sources of uncertainty. The targeted reductions in this FDA outcome goal represent approximately 10.5 percent reductions in total FDA review times for priority and standard NMEs and BLAs. Using Tufts estimates of potential cost reductions by phase of drug development, a 10 percent reduction in regulatory review time yields a 1.6 percent reduction in total capital costs, now estimated at $802 million, translating to a savings of $12.8 million per NME approved.

**Performance:** The FDA approval time for the fastest 50 percent of standard NME and biologics licensing applications (BLAs) approved in CDER and CBER for the FY 2003-2005 cohort is 639 days as compared to 575 days for the baseline FY 1999-2001 submission cohort. While this is an increase of 64 days over the baseline for the three-year cohort, the increase is largely driven by one of the fiscal year

reporting periods. The FY 2003 and FY 2004 figures are 575 and 581 respectively, on-track with the baseline period. The FY 2005 figure was 751 days and this drove the three-year cohort increase. The reporting methodology and the relatively small number of NMEs and BLAs receiving standard review priorities create susceptibilities to these types of spikes; it is anticipated that future performance will return to levels commensurate with the target performance.

**4. Reduction in FDA time to approval or tentative approval for the fastest 70 percent of original generic drug applications approved or tentatively approved of those submitted using the 3-year submission cohort for FY 2005-2007.** (223208)

**Context:** FDA achievement of this goal will create earlier access to lower cost drug alternatives for patients. The high cost of drugs limits patient access to treatment. The lower income and uninsured populations are particularly affected. Research has shown that 42 percent of the uninsured do not fill prescriptions because of financial reasons. The Center for Medicaid and Medicare Services has stated that the new Medicaid prescription drug coverage has come in under budget and points to the availability of more generic products as a factor in this outcome. Increasing the availability of generic drugs will make many important treatments more affordable to the poor and the elderly and significantly improve access to treatment. Optimal access and use of generic drugs will enable policy decision makers to contain costs in both the Medicare and Medicaid programs. This will only become more important as more of the top selling brand name drugs go off patent over the next few years.

**Performance:** The FDA approval time for the fastest 70 percent of original generic drug applications approved for the FY 2004-2006 cohort is 17.4 months as compared to 17.9 months for the baseline FY 1998-2000 submission cohort and 17.8 months from the FY 2003-2005 cohort. While this is an improvement of almost half a month over the previous reporting cohort, a reduction of one full month is required in the next reporting period to meet the target.

**5. Improve the safe use of drugs by patients and health care providers by reviewing safety labeling changes required under FDAAA within the timeframes established by FDAAA.** (222303)

**Context:** CDER is implementing a policy of more transparency in ensuring patients and physicians have the most up-to-date and complete information necessary to make treatment decisions. The FDA Amendments Act of 2007 (FDAAA) recognizes FDA's critical role in assuring the safe and appropriate use of drugs after they are marketed. FDAAA gives FDA substantial new resources for medical product safety, as well as a variety of regulatory tools and authorities to ensure the safe and appropriate use of drugs. Congress, along with the recommendations made over the past two years by the Institute of Medicine, the Government Accountability Office (GAO), and a multitude of others, directed FDA to shift its regulatory paradigm to recognize that ensuring that marketed products are used as safely and effectively as possible is equally as important as getting new safe and effective drugs to market quickly and efficiently. With increased focus and resources on post-marketing, CDER is establishing procedures and tools for tracking, managing, and monitoring safety issues in much the same way CDER tracks pre-market issues according to PDUFA requirements. Consequently, CDER has determined that the previous measure (identifying priority postmarketing safety reviews and acting upon those reviews within an established timeframe) does not reflect current risk management practices following implementation of new authorities regarding postmarket safety of drugs with the 2007 enactment of FDAAA, particularly new authorities related to safety labeling changes. CDER has determined a more meaningful measure is the number of safety labeling change supplements reviewed within the timeframes established by FDAAA. This measure draws a direct connection to the safe use of drugs by Safe Use patients and health care providers by ensuring that the most up-to-date safety information is available in a timely manner as specified in FDAAA.

**Performance:** In FY 2009, CDER reviewed 75% of safety labeling change supplements within the timeframe specified by FDAAA.

**6. The Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database.** (222201)

**Context:** The collection and analysis of data by FDA staff must occur throughout the entire life cycle of the product to identify unexpected safety risks associated with the use of a human drug that could not have been predicted by clinical trials and biostatistical analysis. Reports of these unexpected safety problems, called adverse events, are captured in the Adverse Event Reporting System (AERS), a critical component of FDA's post-marketing safety surveillance systems for all drug and therapeutic biologic products. Information captured in AERS allows FDA scientists and statisticians to search for patterns that may indicate an emerging safety hazard, which is the first step in analyzing the potential causes and formulating an effective risk management response. FDA is working to make AERS more efficient by improving the data entry work processes and reengineering the system to increase the percentage of electronic submissions, to reduce the amount of manual re-keying, along with other efficiencies. These system improvements will allow the FDA to reduce the average cost and time associated with turning a submitted Adverse Event Report into a verified record in the database. This improvement in efficiency will allow scientists and statisticians to access safety information sooner, and will free up resources that can be redirected to risk analysis activities that directly improve our ability to recognize and respond to drug safety problems. The FY 2011 target is being maintained at $12 per report.

**Performance:** The average cost associated with turning a submitted Adverse Event Report into a verified record in the database has been decreasing since FY 2003 due to FDA efforts to streamline its business processes and improve the information systems that are used to process records. In FY 2003, the cost per report was $21.91 per report. In FY 2008, the actual cost per report was $10.59 per report. In FY 2009 the cost per report rose slightly to $10.79 per report but was still below the target of $12 per report. The overall savings to FDA from electronic submission continues to increase due the increasing numbers of received reports. In the absence of electronic submissions, the program costs for manual data entry would be nearly double what they are today.

**7. The percent of manufacturer submitted expedited adverse event reports received electronically compared to all expedited adverse event reports received from industry.** (222202)

**Context:** Drug manufacturers are required to submit to FDA reports of adverse events they receive related to their products. These reports provide crucial information to help enable CDER to monitor the post-market safety of drug products in use. Currently, manufacturers may submit these reports to CDER by mail, fax, or electronically through CDER's MedWatch portal. As electronic reporting streamlines CDER processes, saves time and money, and ensures quicker reporting, CDER is committed to increasing the proportion of reports submitted electronically. FDA is currently developing an improved web-interface reporting system to be called MedWatch Plus. The MedWatch Plus portal will include a rational questionnaire which will help facilitate improved communication, ease of reporting, and enable more complete and higher quality reporting. This timelier and higher quality reporting will positively affect public heath by enabling improved scientific analysis of adverse event reporting and more timely and accurate detection of safety signals. CDER's target for FY 2010 is 80% of all manufacturing reports submitted electronically, increasing to 85% in FY 2011.

**Performance:** The percentage of all reports submitted electronically (not limited to industry reports) grew from 33% in FY 2006 to 83% in FY 2009.

**8. Number of foreign and domestic high-risk human drug inspections.** (224201)

**Context:** FDA is continuing to develop a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The Risk-Based Site Selection Model provides a risk score for each facility, which is a function of four component risk factors – Product, Process, Facility, and Knowledge. In the FY 2007 model, the Agency developed several enhancements and improvements and will continue to explore ways to enhance calculations of process risk and facility sub-scores in FY 2010. As enhancements are made to FDA's data collection efforts and to the Risk-Based Site Selection Model, FDA will improve its ability to focus inspections on the highest-risk public health concerns in a cost-effective way. For FY 2010, the target has been increased to 700 to reflect the FY 2009 Appropriations. In FY 2011, the target is increased by 50 inspections for a new target of 750 inspections.

**Performance:** FDA exceeded the FY 2009 goal of 600 by inspecting 687 high-risk foreign and domestic drug manufacturers.

**9. Percentage of television advertisements requiring submission reviewed within 45 days.** (222302)

**Context:** Under the Food and Drug Amendments Act of 2007 (FDAAA) FDA gained authority to require submission of television advertising for review 45 days before dissemination in order to protect the well-being of consumers and ensure advertising information remains consistent with prescribing information for the product under review. FDA is developing a risk-based set of standards to leverage limited resources in a manner that best protects the public health by assuring that TV ads accurately and effectively communicate key information about the product, including its major risks and its indications. These standards will focus reviews on products with particularly serious risks or at times when feedback on the risk and indication communication is critical, such as when a drug is first advertised on TV and after a drug has received significant safety labeling updates. In FY 2010, FDA will issue guidance to industry on the program and establish a baseline. In FY 2011 the target has been set at 30% of reviews of TV ads completed within 45 days for advertising identified as meeting the high-risk criteria.

**Performance:** As this is a new authority, prior performance data does not exist.

# Biologics Performance Detail

**Long Term Objective:** Increase the number of safe and effective new medical products available to patients

| Measure | FY | Target | Result |
|---|---|---|---|
| 233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. *(Output)* | *2011* | 90% | Nov 30, 2012 |
| | *2010* | 90% | Nov 30, 2011 |
| | *2009* | 90% | Nov 30, 2010 |
| | *2008* | 90% | 100% (Target Exceeded) |
| | *2007* | 90% | 100% (Target Exceeded) |
| | *2006* | 90% | 100% (Target Exceeded) |
| 233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. *(Output)* | *2011* | 90% | Apr 30, 2012 |
| | *2010* | 90% | Apr 30, 2011 |
| | *2009* | 90% | Apr 30, 2010 |
| | *2008* | 90% | 100% (Target Exceeded) |
| | *2007* | 90% | 100% (Target Exceeded) |
| | *2006* | 90% | 100% (Target Exceeded) |
| 233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. *(Output)* | *2011* | 90% | Nov 30, 2012 |
| | *2010* | 90% | Nov 30, 2011 |
| | *2009* | 90% | Nov 30, 2010 |
| | *2008* | 90% | 100% (Target Exceeded) |
| | *2007* | 90% | 100% (Target Exceeded) |
| | *2006* | 90% | 100% (Target Exceeded) |
| 233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. *(Output)* | *2011* | 90% | Nov 30, 2012 |
| | *2010* | 90% | Nov 30, 2011 |
| | *2009* | 90% | Nov 30, 2010 |
| | *2008* | 90% | 100% (Target Exceeded) |
| | *2007* | 90% | 100% (Target Exceeded) |
| | *2006* | 90% | 100% (Target Exceeded) |

| Measure | FY | Target | Result |
|---|---|---|---|
| 233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. *(Output)* | *2011* | 90% | Nov 30, 2012 |
| | *2010* | 90% | Nov 30, 2011 |
| | *2009* | 90% | Nov 30, 2010 |
| | *2008* | 90% | 100% (Target Exceeded) |
| | *2007* | 90% | 99% (Target Exceeded) |
| | *2006* | 90% | 100% (Target Exceeded) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 233201<br>233202<br>233203<br>233205<br>233206 | CBER's regulatory management systems | The Center for Biologics Evaluation and Research (CBER) uses various databases to manage its diverse programs and to assess performance. The principal CBER database is the Regulatory Management System-Biologics License Application (RMS-BLA). RMS-BLA is CBER's VAX-based, Oracle database used to track all biologics license applications and supplement submissions; provide information to facilitate the review process (product, application status, milestone tracking, facility, review committee, industry contacts and other information); and produce a wide variety of management reports. The Regulatory Information Management Staff (RIMS) monitors and is responsible for maintaining data quality and integrity in RMS-BLA. The Biologics Investigational New Drug Management System (BIMS) is CBER's VAX-based, Oracle database used to track all Investigational New Drug Applications (IND), Investigational Device Exemption (IDE) and Master Files (MF) submissions; provide product, application status, and other information to facilitate the review process; and produce a wide variety of management reports. There are numerous mechanisms established for quality control in the Document Control Center, the application review offices, RIMS, and several mechanisms are built into BIMS. The Blood Logging and Tracking System (BLT) records and tracks various applications reviewed by the Office of Blood Research and Review (OBRR). OBRR also has an NDA tracking system. Data retrieved from these systems are reviewed and validated by RIMS and the application review offices. If errors are detected, they are corrected. Federal regulations (21 CFR, Part 600.14 and 606.171) requires reporting of deviations in the manufacture of biological products that affect the safety, purity, or potency of the product. The Biological Product Deviation Report (BPDR) (previously called error and accident report) enables CBER to evaluate and monitor establishments, provide field staff and establishments with trend analyses of the reported deviations and unexpected events, and assist CBER in responding appropriately to reported biological product deviations. |

**Long Term Objective:** Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

| Measure | FY | Target | Result |
|---|---|---|---|
| 234101: Increase manufacturing diversity and capacity for pandemic influenza vaccine production. *(Output)* | *2011* | Apply novel technologies including mass spectrometry to quantify the absolute amount of hemagglutinin in the reference standards that are used to determine influenza vaccine potency. | Nov 30, 2011 |
| | *2010* | Complete and evaluate the pilot vaccine adverse-effects program and participate in at least one international workshop or conference. | Nov 30, 2010 |
| | *2009* | Started a pilot program to develop and evaluate new methods to detect possible adverse effects, both pre-specified and non-pre-specified, of newly licensed vaccines, including pandemic influenza vaccines, in large population databases. Participated in at least one international workshop or conference. | All targets met. |
| | *2008* | Facilitated development and evaluation of one new pandemic influenza vaccine and one new trivalent vaccine; demonstrated an improved method for evaluating the safety, potency or immunogenicity of influenza vaccines; and participated in one international workshop. | All targets met |
| | *2007* | Issued guidance on clinical data to support licensure of pandemic influenza vaccines; evaluated potency of five influenza vaccines; demonstrated methods for improved influenza manufacture. | All targets met |
| | *2006* | Developed clinical data concept paper and guidance documents; co-sponsored two workshops with WHO on pandemic vaccines. | All targets met |

| Measure | Data Source | Data Validation |
|---|---|---|
| 234101 | CBER's Office of Vaccines Research and Review; and CBER's Medical Director for Emerging and Pandemic Threat Preparedness | The data are validated by the appropriate CBER offices and officials. |

**Long Term Objective:** Detect safety problems earlier and better target interventions to prevent harm to consumers.

| Measure | FY | Target | Result |
|---|---|---|---|
| 234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)* | *2011* | 1,000 | December, 2011 |
| | *2010* | 1,000 | December, 2010 |
| | *2009* | 870 | 1,001 (Target Exceeded) |
| | *2008* | 870 | 1,014 (Target Exceeded) |
| 234203: Number of foreign and domestic human tissue establishment inspections. *(Output)* | *2011* | 533 | December, 2011 |
| | *2010* | 518 | December, 2010 |
| | *2009* | 380 | 434 (Target Exceeded) |
| | *2008* | 325 | 383 (Target Exceeded) |
| | *2007* | 325 | 427 (Target Exceeded) |
| | *2006* | N/A | 354 (Historical Actual) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 234202<br>234203 | Field Data Systems | ORA use the following two main information technology systems to track and verify field performance goal activities: Field Accomplishments and Compliance Tracking System (FACTS) and Operational and Administrative System Import Support (OASIS). FACTS include data on the number of inspections; field exams; sample collections; laboratory analyses; and the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported, as well as, where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality. |

**1. Complete review and action on standard original PDUFA NDA and BLA submissions within 10 months of receipt.** (233201)

**Context:** The Prescription Drug User Fee Act (PDUFA) authorizes the FDA to collect fees from the prescription drug and biologic drug industries to expedite the review of human drugs and biologics to shorten the time needed for these product to reach the market. Standard original BLAs are license applications for biological products, not intended as therapies for serious or life-threatening diseases. In FY 2011, FDA continues to maintain the target for this goal, which meets the performance commitments in the HHS Secretary's letter to Congressional leaders.

**Performance:** FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year, and complete performance data are not available until the prescribed review time, i.e., 10 months after receipt, is expired. In FY 2008, CBER exceeded its goal by completing review and action on 100 percent of 4 standard applications within 10 months of receipt, and has met or exceeded this performance goal since 1994. The FY 2009 performance data for this goal will not be available until November 2010.

**2. Complete review and act on priority original PDUFA NDA/BLA submissions within 6 months of receipt.** (233202)

**Context:** PDUFA authorizes the FDA to collect fees from the prescription drug and biologic drug industries to expedite the review of human drugs and biologics so they can reach the market more quickly. A BLA will receive priority review if the product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. In FY 2011, FDA continues to maintain the target for this goal, which meets the performance commitments in the HHS Secretary's letter to Congressional leaders.

**Performance:** FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year. Complete performance data are not available until the prescribed review time, i.e., 6 months after receipt, is expired. In FY 2008, CBER exceeded its goal by completing review and action on 100 percent of 4 priority applications within 6 months of receipt. CBER has met or exceeded this performance goal since 1994. The FY 2009 performance data for this goal will not be available until April 2010.

**3. Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt.** (233203)

**Context:** PDUFA authorizes the FDA to collect fees from the prescription drug and biologic industries to expedite the review of human drugs and biologics to shorten the time needed for these products to reach the market. An efficacy supplement is a change to an approved licensed product to modify the "approved effectiveness" of a product, such as, a new indication which normally requires clinical data. In FY 2011, FDA continues to maintain the target for this goal, which meets the performance commitments in the HHS Secretary's letter to Congressional leaders.

**Performance:** FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year. Complete performance data are not available until the prescribed review time, i.e., 10 months after receipt, is expired. In FY 2008, CBER exceeded its goal by completing review and action on 100 percent of 8 standard PDUFA efficacy supplements within 10 months of receipt. CBER has met or exceeded most of these performance goals since 1994. The FY 2009 performance data for this goal will not be available until November 2010.

**4. Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date.** (233205)

**Context:** For FY 2011, CBER maintained the goal of reviewing and acting upon complete blood bank and source plasma BLA submissions at 90% within 12 months after submission. Since CBER receives only a few complete blood bank and source plasma submissions, the actual performance may be significantly different than the target.

**Performance:** CBER tracks performance by year-of-receipt, which FDA calls the cohort year. Complete performance data are not available until the prescribed review time, i.e., 12 months after receipt, is expired. In FY 2008, CBER exceeded its goal by reviewing and acting on 100 percent of 5 submissions within 12 months of receipt. The FY 2009 performance data for this goal will not be available until November 2010.

**5. Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date.** (233206)

**Context:** In FY 2011, CBER maintained the goal of reviewing and acting upon complete blood bank and source plasma BLA supplement submissions within 12 months after submission.

**Performance:** CBER tracks performance by year-of-receipt, which FDA calls the cohort year. Complete performance data are not available until the prescribed review time, i.e., 12 months after receipt. In FY 2008, CBER exceeded its goal by reviewing and acting on 100 percent of 418 supplements within 12 months of receipt. The FY 2009 performance data for this goal will not be available until November 2010.

**6. Increase manufacturing diversity and capacity for pandemic influenza vaccine production.** (234101)

**Context:** During FY 2006, the Biologics Program received appropriated funding under P.L. 109-148 to establish the infrastructure and surge capability to react to a potential disease pandemic. Influenza pandemics are explosive global events in which most, if not all, persons worldwide are at risk for infection and illness. Pandemic influenza strains, such as avian or H1N1 influenza, can rapidly change. Vaccines will need to be produced for pandemic influenza strains on a short notice, and FDA needs to provide new and accelerated pathways to facilitate their rapid production and evaluation. This goal changes on a yearly basis to ensure continued progress in preparation for a pandemic outbreak. The FY 2011 pandemic preparedness target will be to apply novel technologies including mass spectrometry to quantify the absolute amount of hemagglutinin in the reference standards that are used to determine influenza vaccine potency.

**Performance:** In FY 2009, CBER accomplished its targets for this goal.

**7. Number of registered domestic blood bank and biologics manufacturing inspections.** (234202)

**Context:** FDA will enhance its risk-based compliance and enforcement activities by increasing inspections of registered manufacturers of biological products, which are essential for meeting national public health objectives. These products involve complex manufacturing processes and are in limited supply in some cases. Inspections for this performance goal are conducted to ensure compliance with current Good Manufacturing Practices (cGMPs) requirements and applicable standards, and to ensure the safety, purity and potency of biological products. The biologics inventory includes blood establishments, plasma derivative manufacturing establishments, and vaccine manufacturing establishments, especially seasonal and pandemic influenza vaccines. In FY 2010, the target has been increased to 1,000 inspections to reflect historical accomplishments. FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA exceeded this high risk inspection goal of 870 by inspecting 1,001 blood banks and biologics manufacturing establishments.

**8. Number of foreign and domestic human tissue establishment inspections.** (234203)

**Context:** Beginning in FY 2006 as a result of new regulations, the human tissue inspection goal was created. FDA's responsibility for enforcing the new regulations and the need to quickly assess compliance makes tissues one of the highest priorities. Two new rules took effect regarding human tissue: one requiring tissue facilities to register with FDA became effective January 2004; while the "Donor Eligibility Rule" became effective May 2005. The Field conducts tissue inspections to determine if human tissues for transplantation are in compliance with FDA tissue regulations and to assure consumer protection from unsuitable tissue products and disease transmission which may endanger public health. In FY 2009, FDA increased this goal by 55 additional tissue inspections, over the FY 2008 target, in order to cover more of the firms that registered as a result of the new regulations. In FY 2010, the target was increased by 138 inspections to reflect the FY 2009 Appropriations. In FY 2011, the target is increased by 15 inspections for a new target of 533 inspections.

**Performance:** In FY 2009, FDA exceeded the human tissue goal of 380 by conducting 434 inspections under new regulations.

# Animal Drugs and Feeds Performance Detail

**Long Term Objective:** Increase the number of safe and effective new medical products available to patients.

| Measure | FY | Target | Result |
|---|---|---|---|
| 242201: Review adverse experience reports to detect animal product hazards early. *(Output)* | *2011* | 56% | January 2012 |
| | *2010* | 50% | January 2011 |
| | *2009* | N/A | 34% (Historical Baseline) |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |
| 243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)* | *2011* | 90% w/in 180 days | January 2013 |
| | *2010* | 90% w/in 180 days | January 2012 |
| | *2009* | 90% w/in 180 days | January 2011 |
| | *2008* | 90% w/in 180 days | 100% of 4 w/in 180 days (Target Exceeded) |
| | *2007* | 90% w/in 200 days | 100% of 7 w/in 200 days (Target Exceeded) |
| | *2006* | 90% w/in 230 days | 100% of 7 w/in 230 days (Target Exceeded) |
| 243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. *(Output)* | *2011* | 90% w/in 500 days | January 2013 |
| | *2010* | 90% w/in 680 days | January 2012 |
| | *2009* | 90% w/in 700 days | January 2011 |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 242201 | Adverse Drug Experiences (ADE) database | CVM utilizes and maintains an Adverse Drug Experiences (ADE) database to provide an early warning or signaling system to the Center for adverse effects not detected during pre-market testing of FDA-approved animal drugs and for monitoring the performance of drugs not approved for use in animals. |
| 243201<br>243202 | Submission Tracking and Reporting System (STARS). | STARS tracks submissions, reflects the Center's target submission processing times and monitors submissions during the developmental or investigational stages and the resulting application for marketing of the product. |

**Long Term Objective:** Detect safety problems earlier and better target interventions to prevent harm to consumers.

| Measure | FY | Target | Result |
|---|---|---|---|
| 244202: Number of domestic and foreign high risk animal drug and feed inspections. *(Output)* | *2011* | 250 | December 2011 |
| | *2010* | 250 | December 2010 |
| | *2009* | 233 | 262 (Target Exceeded) |
| | *2008* | 233 | 244 (Target Exceeded) |
| 244203: Number of targeted prohibited material Bovine Spongiform Encephalopathy (BSE) inspections. *(Output)* | *2011* | 490 | December 2011 |
| | *2010* | 490 | December 2010 |
| | *2009* | 490 | 526 (Target Exceeded) |
| | *2008* | 490 | 555 (Target Exceeded) |
| | *2007* | 490 | 523 (Target Exceeded) |
| | *2006* | N/A | 516 (Historical Baseline) |
| 244204: Complete review and action on warning letters received within 15 days to better safeguard our food supply by ensuring that firms correct identified deviations and become compliant. *(Output)* | *2011* | 80% w/in 15 days | January 2012 |
| | *2010* | 80% w/in 15 days | January 2011 |
| | *2009* | N/A | 38% w/in 15 days (Historical Baseline) |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |
| 244301: The total number of state laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events. (Outcome) | *2011* | 3 | January 2012 |
| | *2010* | 2 | January 2011 |
| | *2009* | N/A | 0 (Historical Baseline) |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 244202<br>244203 | Field Data Systems | ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems, FACTS and OASIS, and will also include additional functionality. |
| 244204 | Compliance Management System (CMS) | An electronic case submission system used to process all violation letters. |
| 244301 | CVM | Data validated by the appropriate CVM program office |

**1. Review adverse experience reports to detect animal product hazards early.** (242201)

**Context:** Protecting the public health includes monitoring marketed animal drugs, food, food additives and veterinary devices to assure their safety and effectiveness. FDA relies on information from adverse event reporting to ensure the safety of animal drugs, feed, and devices. All information and insight learned from post approval experiences becomes information that proactively identifies and responds to hazards that threaten animal and public health, benefits the pre-approval process, industry, and the profession of veterinary medicine. Pet owners may be exposed to potent hormones, cancer drugs and other potentially toxic drugs. Inappropriate use of animal drugs in food producing species may also result in drug residues involving milk and meat.

**Performance:** FDA will increase the number of professional staff to review AERs and take corrective action prior to reaching a crisis state. FY 2009 baseline data reflects the Center for Veterinary Medicine (CVM) reviewed 34% of the AERs received. CVM expects to review 50% and 56% of the AERs received in FY 2010 and 2011, respectively.

**2. Complete review and action on original NADAs and reactivations of such applications received during the fiscal year.** (243201)

**Context:** The FY 2009, FY 2010 and FY 2011 goal and targets reflect the reauthorization of ADUFA and continued achievement of statutory review timeframe(s) over a five-year period (FY 2009-FY 2013). The goal and targets reflect one of the ADUFA user fee goals and CVM's ability to maintain FY 2008 review time frames for specified new animal drug application reviews.

**Performance:** Based on the final performance update for FY 2008, FDA exceeded all ADUFA performance goals. More information is forthcoming in the FY 2009 ADUFA Performance Report which is expected to be released in the 2nd quarter of FY 2010. FDA reviewed and acted on all four original NADAs and reactivations of such applications received during FY 2008 within 180 days. As of September 30, 2009, the preliminary performance assessment of FY 2009 data indicates FDA is exceeding the ADUFA goal(s). For FY 2010 and FY 2011, CVM plans to review and act on all original NADAs and reactivations of such applications received within 180 days.

**3. Complete review and action on Non-administrative original ANADAs and reactivations of such applications received during the fiscal year**. (243202)

**Context:** This new measure reflects the FY 2008 authorization of the new Animal Generic Drug User Fee Act (AGDUFA). The FY 2009, FY 2010 and FY 2011 goal and targets reflect one of the AGDUFA user fee goals to complete the review of 90% of specified abbreviated applications for the approval of

generic new animal drugs within incrementally decreasing time frames over a five-year period (FY 2009-FY 2013).

**Performance:** AGDUFA is a new performance goal and target as of FY 2009. More information is forthcoming in the FY 2009 AGDUFA Performance Report which is expected to be released in the 2nd quarter of FY 2010. As of September 30, 2009, the preliminary first year performance assessment of FY 2009 data indicates FDA is meeting the AGDUFA goal(s). For FY 2010 and FY 2011, CVM plans to review and act on all non-administrative original ANADAs and reactivations of such applications received within 680 days and 500 days, respectively.

**4. Number of domestic and foreign high risk animal drug and feed inspections.** (244202)

**Context:** Important features of the risk-based strategy for this revised goal are to reduce the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. In FY 2008, this revised goal focused on pre-market approval inspections and implementing risk-based current Good Manufacturing Practice (cGMP) inspection plans for animal drug and feed manufacturing facilities that utilized risk modeling to identify the highest risk firms to be inspected. The FY 2008 target was maintained in FY 2009 because this was a new, risk-based goal for which CVM had no historical experience and were unsure how the new site-selection methodology would evolve. In FY 2010, the target is being slightly increased as a result of the FY 2009 Appropriation while evaluation of the new methodology continues. For FY 2011, the target will remain at the FY 2010 level.

**Performance:** In FY 2009, FDA exceeded this inspection goal of 233 by inspecting 262 high risk animal drug and feed establishments.

**5. Number of targeted prohibited material BSE inspections** (244203)

**Context:** FDA developed a comprehensive public protection strategy of education, inspection and enforcement action to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) feed regulations. Using an inventory of all known renderers and feed mills processing products containing prohibited material, FDA will continue to conduct annual inspections to determine compliance with the BSE feed rule. Inventories of these firms may vary from year to year based on changes at the firm such as consolidations, business closures, relocations, etc. In FY 2011, FDA will continue to conduct inspections of 100% of the firms know to be processing with prohibited materials.

**Performance:** In FY 2009, FDA completed the inspection of all 526 firms known to be processing with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

**6. Complete review and action on warning letters received within 15 days to better safeguard our food supply by ensuring that firms correct identified deviations and become compliant.** (244204)

**Context:** Issuing warning letters is the agency's principal means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act (the Act) for violations of regulatory significance that may lead to enforcement action if not promptly and adequately corrected. FDA sends warning letters to individuals or firms, advising them of specific noted violations and requesting a written response as to the steps which will be taken to correct the violation.

**Performance:** As part of the FDA Enhanced Enforcement Strategy, FDA will: 1) streamline the warning letter process by only having the letter reviewed by the relevant offices; 2) prioritize follow-up on warning letters and other enforcement actions quickly to assess and follow-up on corrective action taken by industry after a warning letter is issued or a major product recall occurs; and 3) determine a firm has fully corrected violations raised in a warning letter, issue an official “close-out” notice and post this information on the FDA website, motivating manufacturers to take corrective actions promptly. CVM expects to complete review and action on 80% of the warning letters received within 15 days for both FY 2010 and 2011.

**7. The total number of state laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events.** (244301)

**Context:** The lack of coordination between federal and state veterinary diagnostic laboratories to respond to high priority chemical and microbial feed contamination events by examining animal tissues for infectious agents/toxins, puts animals at risk to both inadvertent and intentional introduction of contaminants. FDA will improve emergency response by developing a network of state and federal laboratories that integrate resources and expertise for timely and accurate reporting, identification, and analysis of animal feed contamination events through examination of animal tissues for infectious agents, toxins, and other causes of disease. The network will enhance the ability to conduct root cause analysis and develop the data, information, and protective measures needed to help prevent future outbreaks.

**Performance:** The network will coordinate the facilities, equipment and professional expertise of U.S. and federal veterinary diagnostic laboratories to provide the means for quick identification of reports of animal injury associated with animal feed contamination, and protocols for immediate diagnostic reporting to FDA. CVM expects to coordinate veterinary diagnostic response with two state laboratories for FY 2010 and three state laboratories for FY 2011.

# Medical Devices and Radiological Health Performance Detail

**Long Term Objective:** Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

| Measure | FY | Target | Result |
|---|---|---|---|
| 253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. *(Outcome)* | *2011* | 60% in 180 days and 90% in 295 days | Jan 31, 2013 |
| | *2010* | 60% in 180 days and 90% in 295 days | Jan 31, 2012 |
| | *2009* | 60% in 180 days and 90% in 295 days | Jan 31, 2011 |
| | *2008* | 60% in 180 days and 90% in 295 days | 80% of 20 in 180 days and 95% of 20 in 295 days (Target Exceeded) |
| | *2007* | 90% in 320 days | 96% of 33 (Target Exceeded) |
| | *2006* | 80% in 320 days | 81% of 40 (Target Exceeded) |
| 253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. *(Outcome)* | *2011* | 85% in 180 days and 95% in 210 days | Jan 31, 2013 |
| | *2010* | 85% in 180 days and 95% in 210 days | Jan 31, 2012 |
| | *2009* | 85% in 180 days and 95% in 210 days | Jan 31, 2011 |
| | *2008* | 85% in 180 days and 95% in 210 days | 91% of 157 in 180 days and 97% of 157 in 210 days (Target Exceeded) |
| | *2007* | 90% | 97% of 132 (Target Exceeded) |
| | *2006* | 80% | 95% of 136 (Target Exceeded) |
| 253205: Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. *(Outcome)* | *2011* | 90% in 90 days and 98% in 150 days | Jan 31, 2013 |
| | *2010* | 90% in 90 days and 98% in 150 days | Jan 31, 2012 |
| | *2009* | 90% in 90 days and 98% in 150 days | Jan 31, 2011 |
| | *2008* | 90% in 90 days and 98% in 150 days | 95% of 3,213 in 90 days and 99% of 3,213 in 150 days (Target Exceeded) |
| | *2007* | 80% in 90 days | 92% of 3,531 (Target Exceeded) |
| | *2006* | 75% in 90 days | 91% of 3,530 (Target Exceeded) |

| Measure | FY | Target | Result |
|---|---|---|---|
| 253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)* | *2011* | 300 | December, 2011 |
| | *2010* | 300 | December, 2010 |
| | *2009* | 300 | 305 (Target Exceeded) |
| | *2008* | 300 | 301 (Target Exceeded) |
| | *2007* | 295 | 323 (Target Exceeded) |
| | *2006* | 295 | 336 (Target Exceeded) |
| 253206: Reduction in FDA's total approval time for the fastest 50 percent of expedited PMAs approved, using the submission cohort for FYs 2005-2007. The baseline for this goal is the three year average of total FDA approval time for the fastest 50 percent approved for the applications filed during FYs 1999-2001. *(Outcome)* | *2007* | 330 days* | 318 (Target Exceeded) |
| | *2006* | NA | 357 (Historical Actual) |
| | *2005* | NA | 322 (Historical Actual) |

MDUFMA, and MDUFMA as amended review goals (Goals 253203, 253204, and 153205) are based on FDA review time only, and do not include time that elapses when the sponsor is responding to questions or issues raised by FDA. This means that FDA cannot determine exactly when all the applications in a review cohort will be completed. The actual results reported for this goal are as of the times noted, and as the final applications in the cohort are resolved, small changes to previously reported results may occur.

*The FY 2007 target of 330 days corrects a transcription error that was made when this goal was originally transferred to the current format in the FY 2007 Congressional Justification. In the FY 2007 through FY 2009 Congressional Justifications, the target was incorrectly stated as 290 days, which was the target for the Standard PMAs, not the Expedited PMAs. Please see the goal by goal narrative below for more information.

| Measure | Data Source | Data Validation |
|---|---|---|
| 253203<br>253204<br>253205<br>253201<br>253206 | CDRH Premarket Tracking System and Receipt Cohorts and Field Data Systems. | To help ensure Agency consistency in tracking and reporting Premarket activities, CDRH utilizes the Premarket Tracking System, which contains various types of data taken directly from the Premarket submissions. FDA employs certain conventions for monitoring and reporting performance; among these are groupings of Premarket submissions into decision and receipt cohorts. Decision cohorts are groupings of submissions upon which a decision was made within a specified time frame, while receipt cohorts are groupings of submissions that were received within a specified time frame. The Premarket performance goals are based on receipt cohorts. Final data for receipt cohorts are usually not available at the end of the submission year. Because the review of an application received on the last day of the submission year, e.g., a PMA with 180 day time frame, may not be completed for at least 6 months or longer, final data for the submission or goal year may not be available for up to a year or more after the end of the goal year. |

**Long Term Objective:** Improve information systems for problem detection and public communication about product safety.

| Measure | FY | Target | Result |
|---|---|---|---|
| 252201: The minimum number of reports per year that 80 percent of MedSun hospitals, enrolled for at least 11 months in the program will submit *(Outcome)* | *2011* | 7 | December 31, 2011 |
| | *2010* | 3 | December 31, 2010 |
| | *2009* | Ensure the active participation of 95% of MedSun facilities in FY 2009 (at least 1 report) | 98% (Target Exceeded) |
| | *2008* | Ensure the active participation of 95% of MedSun facilities in FY 2009 (at least 1 report) | 98% (Target Exceeded) |
| | *2007* | Ensure the active participation of 90% of MedSun facilities in FY 2009 (at least 1 report) | 90% (Target Met) |
| | *2006* | Ensure the active participation of 71% of MedSun facilities in FY 2009 (at least 1 report) | 86% (Target Exceeded) |
| 252202: By 2013, enroll 80% of the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. *(Outcome)* | *2011* | 75% | December, 2011 |
| | *2010* | 55% | December, 2010 |
| | *2009* | NA | 46% |
| | *2008* | NA | 13% |
| | *2007* | NA | NA |
| | *2006* | NA | NA |

| Measure | Data Source | Data Validation |
|---|---|---|
| 252201<br>252202 | CDRH Adverse Events Reports | FDA's adverse event reporting system's newest component is the Medical Device Surveillance Network (MedSun) program. MedSun is an initiative designed both to educate all health professionals about the critical importance of being aware of, monitoring for, and reporting adverse events, medical errors and other problems to FDA and/or the manufacturer, and to ensure that new safety information is rapidly communicated to the medical community thereby improving patient care. |

**Long Term Objective:** Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

| Measure | FY | Target | Result |
|---|---|---|---|
| 254202: Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters. *(Output)* | *2011* | 95% | December, 2011 |
| | *2010* | 90% | December, 2010 |
| | *2009* | NA | 68% (Historical Actual) |
| | *2008* | NA | 53% (Historical Actual) |
| | *2007* | NA | NA |
| | *2006* | NA | NA |
| 254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)* | *2011* | 1,445 | December, 2011 |
| | *2010* | 1,365 | December, 2010 |
| | *2009* | 1,340 | 1,471 (Target Exceeded) |
| | *2008* | 1,270 | 1,431 (Target Exceeded) |
| | *2007* | 1,195 | 1,468 (Target Exceeded) |
| | *2006* | 1,234 | 1,506 (Target Exceeded) |
| 254101: Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. *(Outcome)* | *2011* | 97% | December 31, 2011 |
| | *2010* | 97% | December 31, 2010 |
| | *2009* | 97% | 97% (Target Met) |
| | *2008* | 97% | 97% (Target Met) |
| | *2007* | 97% | 97% (Target Met) |
| | *2006* | 97% | 97% (Target Met) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 254202 | Center Tracking System and Mission Accomplishment and Regulatory Compliance Services (MARCS) system. | CDRH uses the Center Tracking System and the Mission Accomplishment and Regulatory Compliance Services (MARCS) system to track GMP Warning Letters and timeframes. |

| | | |
|---|---|---|
| 254201 | Field Data Systems. | ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality. |
| 254101 | Mammography Program Reporting and Information System (MPRIS) | The Mammography Program Reporting and Information System (MPRIS) is a set of applications used to support all aspects of the FDA implementation of the Mammography Quality Standards Act of 1992. This includes the collection, processing and maintenance of data on mammography facility accreditation and certification, FDA inspections and compliance actions. MPRIS is envisioned as a centralized repository of information that supports FDA's mission to improve the quality of mammography and improves the overall quality, reliability, integrity, and accessibility of facility certification, inspection, and compliance data by eliminating multiple versions of the data while expanding and automating data edits, validation, and security of a single integrated database. |

| Measure | FY | Target | Result |
|---|---|---|---|
| 252101: Number of technical analyses of postmarket device problems and performance. *(Output)* | *2011* | 140 | December 31, 2011 |
| | *2010* | 125 | December 31, 2010 |
| | *2009* | NA | 110 (Historical Actual) |
| | *2008* | NA | 70 (Historical Actual) |
| | *2007* | NA | NA |
| | *2006* | NA | NA |
| 253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. *(Output)* | *2011* | 1,200 | December 31, 2011 |
| | *2010* | 1,175 | December 31, 2010 |
| | *2009* | NA | 1,128 (Historical Actual) |
| | *2008* | NA | 956 (Historical Actual) |
| | *2007* | NA | NA |
| | *2006* | NA | NA |

| Measure | Data Source | Data Validation |
|---|---|---|
| 252101<br>253207 | CDRH E-Consults and Office of Science and Engineering Laboratories Productivity database. | Technical Analysis and Reviews are tracked and verified through the CDRH E-Consults and Office of Science and Engineering Laboratories databases. |

**1. Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days.** (253203)

**Context:** Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. PMAs involve potentially high-risk devices with the most chance of significantly improving the treatment of patients. The steps taken in MDUFMA, and MDUFMA as amended, that will reduce approval times for PMA applications are expected to reduce approval times for all filed applications, while recognizing that some applications may not ultimately meet FDA's standards for safety and effectiveness and that performance measures based on all applications will take more time to observe. Due to the renegotiation of MDUFMA, the Performance targets for Original PMA applications will be to arrive at a decision on 60% of Original PMA applications within 180 days and 90% within 295 days. This target will remain stable from FY 2008 through FY 2012.

**Performance:** CDRH exceeded the performance for the FY 2008 target by making decisions on 80% of 20 Original PMA applications in 180 days and 95% of 20 Original PMA applications in 295 days. The current baseline for FDA decision time for standard PMAs is 295 days. The cohort remains open. The FY 2009 performance data for this goal will not be available until January 2011.

**2. Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days.** (253204)

**Context:** Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. A decision will result in one of the following designations for each application: approval, approvable, approvable pending GMP inspection, not approvable, denial. PMAs involve potentially high-risk devices that have the highest likelihood of significantly improving the treatment of patients. Supplemental applications are generally submitted for changes in already approved products such as technology changes or the addition of a new indication. It is essential that FDA complete the review process for these products quickly and thoroughly. Due to the renegotiation of MDUFMA, the Performance targets for 180 day PMA Supplements will be to arrive at a decision on 85% of applications within 180 days and 95% within 210 days. This target will remain stable from FY 2008 through FY 2012.

**Performance:** CDRH exceeded performance for the FY 2008 target by making decisions on 91% of 157 PMA Supplements applications in 180 days and 97% of 157 PMA Supplements applications in 210 days . The cohort remains open. The FY 2009 performance data for this goal will not be available until January 2011.

**3. Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days.** (253205)

**Context:** Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. A decision will result in one of the following designations for each application: substantially equivalent or not substantially equivalent. This goal for review and decision on 510(k)s within 90 days addresses the statutory requirement to review a 510(k) within 90 days**.** Due to the renegotiation of MDUFMA, the Performance targets for 510(k)s will be to arrive at a decision on 90% of applications within 90 days and 98% within 150 days. This target will remain stable from FY 2008 through FY 2012.

**Performance:** CDRH exceeded performance for this FY 2008 target by making decisions on 95% of 3,213 510(k)s in 90 days and 99% of 3,213 510(k)s in 150 days. The cohort remains open. The FY 2009 performance data for this goal will not be available until January 2011.

**4. Number of Medical Device Bioresearch Monitoring (BIMO) inspections.** (253201)

**Context**: FDA's mission includes assuring the protection of human research subjects, the quality and integrity of research, and the advancement of new medical technologies. A FDA-regulated research community that consists of Clinical Investigators, Sponsors and Monitors, and Institutional Review Boards has a shared responsibility to oversee this research in a truthful and ethical manner. For FY 2010, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach. There are no projected changes to this goal in FY 2011. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA exceeded this goal of 300 by conducting 305 medical device related Bioresearch Monitoring inspections.

**5. Reduction in FDA's total approval time for the fastest 50 percent of expedited PMAs approved, using the submission cohort for FYs 2005-2007.** The baseline for this goal is the three year average of total FDA approval time for the fastest 50 percent approved for the applications filed during FYs 1999-2001. (253206)

**Context:** MDUFMA commits FDA to significant improvements in device review performance. This is important to the entire device industry, which is expanding in size and technical complexity. The industry is relying on FDA to take a leadership role in regulating a rapidly emerging frontier of medical device technology with timeliness, quality, scientific consistency, and international harmonization. Most of the device industry is small and rapidly changing. Many small and new start-up firms rely heavily on FDA for guidance and outreach, and the reviews from these firms take extra FDA time and energy. About 25 percent of PMAs are for breakthrough technologies; and over 25 percent of PMAs are from first-time submitters.

The area of expedited devices is particularly important because they are the most complex, raise new medical and scientific issues, and FDA often works with first time or small device sponsors. These devices are for uses that have not been approved yet, and could have great clinical impact.
This goal measures the approval time for the fastest 50% of the expedited PMAs that were submitted between FY 2005 and FY 2007.

Note: The FY 2007 target of 330 days in the table above corrects a transcription error that was made when this goal was originally transferred to the current format in the FY 2007 Congressional Justification. In the FY 2007 through FY 2009 Congressional Justifications, the target was incorrectly stated as 290 days, which was the target for the Standard PMAs, not the Expedited PMAs. The correct target for the Expedited PMAs is 330 days, as explained below.

The original proposed target for this Long Term Outcome Goal from the FY 2005 Congressional Justification called for a 30-day reduction in FDA's total approval time for the fastest 50 percent of both expedited and standard PMAs. As such, the targets were proposed as 330 days for expedited PMAs and 290 days for standard PMAs, a 30-day reduction from baselines of 360 days and 320 days, respectively. Due to a transcription error in converting the format of the original Long Term Outcome Goals to the GPRA goal format in the FY 2007 Congressional Justification submission, the standard PMA target of 290 days was incorrectly shown for the expedited PMA measure. In the FY 2011 Congressional Justification submission, the correct target of 330 days is specified for FDA total approval time of expedited PMAs.

**Performance:** The FDA approval time for the fastest 50 percent of Expedited PMAs approved for the FY 2005-2007 cohort is 318 days compared to the original 360 days for the baseline FY 1999-2001 submission cohort. FDA exceeded the FY 2007 target for expedited PMAs (330 days) by 12 days.

**6. The minimum number of reports per year that 80 percent of MedSun hospitals, enrolled for at least 11 months in the program will submit.** (252201)

**Context:** FDAMA gives FDA the mandate to replace universal user facility reporting with the Medical Product Surveillance Network (MedSun) that is composed of a network of user facilities that constitute a representative profile of user reports. MedSun is a critical component in increasing the percent of the population covered by active surveillance, which will allow for more rapid identification and analysis of adverse events.

**Performance:** In FY 2009, FDA expanded actively participating sites in MedSun Network to 98% and maintained a cohort of 350 facilities. To better understand whether participating sites are effectively submitting reports, FDA tailored the measure to track the minimum number of reports submitted by 80 percent of participating sites enrolled for 11 months in the program, for FY 2010 and 2011. In FY 2009, the minimum number of reports submitted for this population was one.

**7. By 2013, enroll 80% of the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program.** (252202)

**Context:** Improving electronic reporting of adverse events will help the FDA maintain its safety surveillance of FDA-regulated products. Information obtained from these reports may prompt a modification in use or design of the product, improves the safety profile of devices, and leads to increased patient safety. eMDR allows FDA to receive medical device adverse event reports electronically. eMDR will improve the agency's ability to detect important postmarket medical device issues and will reduce the reporting burden for both large and small volume medical device adverse event reporters.

**Performance:** In FY 2009, CDRH enrolled 46% of the top 15 MDR reporters into the eMDR program. CDRH is on track to meet the FY 2010 goal of enrolling at least 55% of the top 15 MDR reporters.

**8. Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters.** (254202)

**Context:** FDA's practice is to give industry an opportunity to take voluntary prompt action to correct violations. A Warning Letter is issued for violations of significant regulatory significance which may lead to enforcement actions if not promptly and adequately corrected. FDA inspectors issue Establishment Inspection Reports and other documents explaining the nature of observed violations. Timely Compliance Officer review is a key element in issuing Warning Letters in a timely manner.

**Performance:** In FY 2009, FDA was able to meet the 45 working day target for device warning letters 68% of the time. The target for FY 2010 is 90%.

**9. Number of domestic and foreign Class II and Class III device inspections.** (254201)

**Context:** The ultimate goal of preventing unsafe and ineffective devices from reaching the consumer will be advanced by detecting and intercepting unsafe and ineffective product at the manufacturing level. By utilizing risk-based inspection strategies and focusing on surveillance throughout a products life-cycle FDA will be better able to protect the public health by ensuring both the quality and effectiveness of medical devices available in the U.S. marketplace. For FY 2010, the target has been increased to 1,365 to reflect the FY 2009 Appropriations. In FY 2011, the target is increased by 80 inspections for a new target of 1,445 inspections.

**Performance:** FDA exceeded the FY 2009 medical device performance goal of 1,340 by inspecting 1,471 foreign and domestic high-risk Class II and Class III medical device manufacturers.

**10. Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems.** (254101)

**Context:** This goal will ensure that mammography facilities remain in compliance with established quality standards and improve the quality of mammography in the United States. Under the Mammography Quality Standards Act (MQSA), which was reauthorized in 2004, annual MQSA inspections are performed by trained inspectors with FDA, with State agencies under contract to FDA, and with States that are certifying agencies. State inspectors conduct approximately 90 percent of inspections. Inspectors perform science-based inspections to determine the radiation dose, to assess phantom image quality, and to empirically evaluate the quality of the facility's film processing. MQSA requires FDA to collect fees from facilities to cover the cost of their annual facility inspections. FDA also employs an extensive outreach program to inform mammography facilities and the public about MQSA requirements. These include: an Internet website, collaboration with NIH to provide a list of MQSA-certified facilities, and a toll-free facility hot line.

**Performance:** FDA met this goal in FY 2009 by ensuring that 97 percent of an estimated 8,800 mammography facilities met inspection standards with less than 3 percent level I (serious) problems. Inspection data continue to show facilities' compliance with the national standards for the quality of mammography images. Improving the quality of images should lead to more accurate interpretation by physicians and, therefore, to improved early detection of breast cancer. FDA works cooperatively with the States to achieve this goal.

**11. Number of technical analyses of postmarket device problems and performance.** (252101)

**Context:** Postmarket device problems and performance issues constitute one of the Center's primary public health priorities. Typically, the appearance of such problems begins with many ambiguities and gaps in understanding exactly what happened in the reported incident(s) and, more importantly, why. The Center's technical analysis of these problems illuminates each of these two questions, and points the way to an optimal science-based regulatory response involving the Center as a whole.

**Performance:** In FY 2009, CDRH completed 110 technical analyses of device problems. This baseline encompasses work by CDRH laboratory staff on Health Hazard Evaluations, PMI Action Teams, formal enforcement cases, Postmarket Surveillance Studies, development of inspectional guidances, field inspections, and regulatory sample analyses. The reports for which involve laboratory staff activities are typically selected because of the unusually difficult engineering questions that are posed. The technical analyses provided by CDRH's laboratory staff are used to assess the priority and hazards, determine the adequacy of proposed corrective actions, determine appropriate test methods, and develop case strategies for reported problems.

**12. Number of technical reviews of new applications and data supporting requests for premarket approvals.** (253207)

**Context:** The most challenging premarket device regulatory issues faced by CDRH typically involve (1) novel technologies in which the relevant technical questions are not obvious; (2) submissions in which there is a need for independent data to verify manufacturers' claims; or (3) new products for which there are no well validated test methods. Technical reviews by CDRH engineers and scientists bring specialized expertise to the process, frequently enabling the Center to address these challenges in a science-based decision process.

**Performance:** In FY 2009, CDRH completed 1,128 technical reviews of new applications. These reviews by CDRH's laboratory staff are associated with the submissions having the most novel, difficult, and complex engineering analyses and issues. For comparison, the total reviews by CDRH laboratory staff in FY 2009 corresponds to 13% of the total number of IDEs, 510(k)s, and PMA's received by CDRH in FY 2009. 356 of these reviews were associated with new PMA submissions or with pre-IDE interactions – typically associated with the most innovative new products.

# National Center for Toxicological Research Performance Detail

**Long Term Objective:** Provide consumers with clear and timely information to protect them from foodborne illness and promote better nutrition.

| Measure | FY | Target | Result |
|---|---|---|---|
| 262401: Develop biomarkers to assist in identifying the correlation between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health. *(Output)* | *2011* | Identify target genes that can predict potential for obesity and type 2 diabetes to provide individually tailored therapeutic treatment and dietary guidelines for use in improving health | December 2011 |
| | *2010* | Identify patterns in serum biomarkers to use in monitoring dietary intervention protocols to reduce obesity | December 2010 |
| | *2009* | N/A | Incorporated the linkage between physical responses to a healthier diet and genetic analyses via the Community Based Participatory Research (CBPR) project resulting in 93 blood samples and approximately 1.1 million genotypes (genetic makeup) identified for each participant (Historical Baseline) |
| | *2008* | N/A | Examined the effects of better nutrition on serum levels of certain vitamins and metabolites in children via the CBPR project. (Historical Baseline) |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 262401 | NCTR Project Management System; peer-review through FDA/NCTR Science Advisory Board (SAB) and the NTP Scientific Board of Counselors; presentations at national and international scientific meetings; use of the predictive and knowledge-based systems by the FDA reviewers and other government regulators; and manuscripts prepared for publication in peer-reviewed journals. | NCTR provides peer-reviewed research that supports FDA's regulatory function. To accomplish this mission, it is incumbent upon NCTR to solicit feedback from its stakeholders and partners, which include FDA product centers, other government agencies, industry, and academia. The NCTR SAB —composed of non-government scientists from industry, academia, and consumer organizations, and subject matter experts representing all of the FDA product centers—is guided by a charter that requires an intensive review of each of the Center's scientific programs at least once every five years to ensure high quality programs and overall applicability to FDA's regulatory needs. Scientific and monetary collaborations include Interagency Agreements with other government agencies, Cooperative Research and Development Agreements that facilitate technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the high quality of its research and the accuracy of data collected. Research protocols are often developed collaboratively by principal investigators and scientists at FDA product centers and are developed according to a standardized process outlined in the "NCTR Protocol Handbook." NCTR's Project Management System tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors experiments that fall within the GLP guidelines. NCTR's annual report of research accomplishments, goals, and publications is published and available on FDA.gov. Research findings are published in peer-reviewed journals and presented at national and international scientific conferences. |

**Long Term Objective:** Increase the number of safe and effective new medical products available to patients.

| Measure | FY | Target | Result |
|---|---|---|---|
| 263101: Use new omics technologies and pattern-recognition algorithms to analyze imaging data for early-stage disease diagnosis and to study how an FDA-regulated compound or product interacts with the human body. *(Output)* | *2011* | 1) Implement the Voluntary Exploratory Data Submission (VXDS) tool, called VISIONS (VXDS/IPRG Status and Information ON-line System) to accelerate the regulatory review process<br>2) Present preliminary data on markers that indicate nervous system damage from pediatric anesthetic use at national scientific meetings which may lead to improved guidelines | December 2011 |
| | *2010* | 1) Create a demonstrable tool to use in the drug-review process based upon the liver toxicity knowledge base<br>2) Develop translatable biomarkers for studying pediatric products (e.g. ketamine, methylphenidate, etc.) | December 2010 |
| | *2009* | Analyze imaging data by application of pattern-recognition algorithms to other tissues and diseases | 1) Novel methods reviewed to normalize the spectra generated from various MRI scanners, an approach that will translate across tissues (Target Met)<br>2) Pattern recognition algorithms were improved to interpret complex Magnetic Resonance Spectroscopy (MRS) scans to an accuracy rate of over 96% for nine types of tissues<br>(Target Met) |
| | *2008* | 1) Identify omics data in the review process<br>2) Determine limitations of the algorithms (e.g. staging disease) | 1) 7 VXDS submissions reviewed using omics tools (Target Met)<br>2) Algorithm developed to classify four disease categories<br>(Target Met) |
| | *2007* | 1) Test systems biology in drug review process to assess value in drug review and approval<br>2) Proof-of-principle that pattern recognition can supplement MRS brain scan interpretation | 1) Urinary biomarkers developed for kidney failure (Target Met)<br>2) Azidothymidine (AZT) effects on mitochondria identified (Target Met)<br>3) Prototype algorithm successfully developed from 30 MRS brain scans<br>(Target Met) |
| | *2006* | Present one finding utilizing novel technologies to assess changes in genes and pathology, and the relationship between chemical exposure, toxicity and disease. | Hepatotoxicity of type 2 diabetes drugs evaluated (Historical Baseline) |

| Measure | FY | Target | Result |
|---|---|---|---|
| 263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products. *(Output)* | *2011* | Deliver the alpha version of the FDA SNPTrack to support the FDA review of pharmacogenetics data and provide more personalized treatment options | December 2011 |
| | *2010* | Develop molecular signature and biomarker modules in ArrayTrack™ to support VXDS | December 2010 |
| | *2009* | Expand ArrayTrack™ to include two new libraries and classification methods for model building and predictions on clinical, nonclinical, and toxicological microarray data | ArrayTrack™ Version 3.5.0 developed (Target Met) |
| | *2008* | Create bioinformatics data package | SNPTrack Version 1 developed (Target Met) |
| | *2007* | Increase the utility of ArrayTrack™ and training for reviewers | 1) JMP® and ArrayTrack™ integration completed (Target Met) 2) Regulatory training on ArrayTrack™ offered to reviewers (Target Met) |
| | *2006* | Interpret DNA study using ArrayTrack™ | Microarray studies on nutritional supplements, comfrey, and aristolochic acid completed. (Target Met) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 263101<br>263102 | NCTR Project Management System; peer-review through FDA/NCTR SAB and the NTP Scientific Board of Counselors; presentations at national and international scientific meetings; use of the predictive and knowledge-based systems by the FDA reviewers and other government regulators; and manuscripts prepared for publication in peer-reviewed journals. | NCTR provides peer-reviewed research that supports FDA's regulatory function. To accomplish this mission, it is incumbent upon NCTR to solicit feedback from its stakeholders and partners, which include FDA product centers, other government agencies, industry, and academia. The NCTR SAB —composed of non-government scientists from industry, academia, and consumer organizations, and subject matter experts representing all of the FDA product centers—is guided by a charter that requires an intensive review of each of the Center's scientific programs at least once every five years to ensure high quality programs and overall applicability to FDA's regulatory needs. Scientific and monetary collaborations include Interagency Agreements with other government agencies, Cooperative Research and Development Agreements that facilitate technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the high quality of its research and the accuracy of data collected. Research protocols are often developed collaboratively by principal investigators and scientists at FDA product centers and are developed according to a standardized process outlined in the "NCTR Protocol Handbook." NCTR's Project Management System tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors experiments that fall within the GLP guidelines. NCTR's annual report of research accomplishments, goals, and publications is published and available on FDA.gov. Research findings are published in peer-reviewed journals and presented at national and international scientific conferences. |

**Long Term Objective:** Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

| Measure | FY | Target | Result |
|---|---|---|---|
| 263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. *(Output)* | *2011* | Validate FDA standard operating procedures (SOPs) for detection of nanoscale materials in FDA-regulated products in collaboration with ORA/Arkansas Regional Laboratory (ORA/ARL) | December 2011 |
| | *2010* | Establish and implement SOPs in research protocols for detection of nanoscale materials in FDA-regulated products in collaboration with ORA/ARL | December 2010 |
| | *2009* | Establish an operational joint NCTR/ORA Nanotechnology Core Facility to provide analytical support, materials characterizations, and electron microscopy support for nanomaterial studies | NCTR/ORA Nanotechnology Core Facility established and operational<br>(Target Met) |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 263201 | NCTR Project Management System; peer-review through FDA/NCTR SAB and the NTP Scientific Board of Counselors; presentations at national and international scientific meetings; use of the predictive and knowledge-based systems by the FDA reviewers and other government regulators; and manuscripts prepared for publication in peer-reviewed journals. | NCTR provides peer-reviewed research that supports FDA's regulatory function. To accomplish this mission, it is incumbent upon NCTR to solicit feedback from its stakeholders and partners, which include FDA product centers, other government agencies, industry, and academia. The NCTR SAB —composed of non-government scientists from industry, academia, and consumer organizations, and subject matter experts representing all of the FDA product centers—is guided by a charter that requires an intensive review of each of the Center's scientific programs at least once every five years to ensure high quality programs and overall applicability to FDA's regulatory needs. Scientific and monetary collaborations include Interagency Agreements with other government agencies, Cooperative Research and Development Agreements that facilitate technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the high quality of its research and the accuracy of data collected. Research protocols are often developed collaboratively by principal investigators and scientists at FDA product centers and are developed according to a standardized process outlined in the "NCTR Protocol Handbook." NCTR's Project Management System tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors experiments that fall within the GLP guidelines. NCTR's annual report of research accomplishments, goals, and publications is published and available on FDA.gov. Research findings are published in peer-reviewed journals and presented at national and international scientific conferences. |

**Long Term Objective:** Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

| Measure | FY | Target | Result |
|---|---|---|---|
| 264101: Develop risk assessment methods and build biological dose-response models in support of food protection. *(Output)* | *2011* | 1) Develop base guidelines to assess extent of kidney toxicity caused by the combination of melamine and cyanuric acid and ultimately improve diagnosis and treatment<br>2) Conduct a successful Food Emergency Response Network (FERN) Level 4 validation for RAPID-B *E. coli* O157 test method so it can be approved for use in regulatory reviews or food emergency situations<br>3) Develop and initiate approved protocols for RAPID-B tests for viruses and toxins to aid FDA in protecting public health from viruses and toxin contamination | December 2011 |
| | *2010* | 1) Rapidly detect toolkits for foodborne pathogens applicable to fresh produce; evaluate in field situations<br>2) Approved protocols developed and initiated for Bisphenol A (BPA), a component in baby bottles and formula containers | December 2010 |
| | *2009* | 1) Detect rapid pathogen<br>2) Identify antibiotic resistance markers | 1) RAPID-B detection of *E. coli* validated in nine food types (Target Met)<br>2) 775 antimicrobial resistance genes in *Salmonella* identified (Target Met) |
| | *2008* | Develop ricin screening assay | Cell-based assay and polymerase chain reaction (PCR)-based biochemical assay developed (Target Met) |
| | *2007* | Develop flow cytometry technology | 1) Test kits and methods developed for pathogens (Target Met)<br>2) Additional *Salmonella* biochip developed (Target Met) |
| | *2006* | Demonstrate one utility of an oligonucleotide-microarray method as an integrated strategy to respond to antibiotic resistant agents in foodborne pathogens and bioterror agents. | Method developed to screen 131 antibiotic resistance markers (Historical Baseline) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 264101 | NCTR Project Management System; peer-review through FDA/NCTR SAB and the NTP Scientific Board of Counselors; presentations at national and international scientific meetings; use of the predictive and knowledge-based systems by the FDA reviewers and other government regulators; and manuscripts prepared for publication in peer-reviewed journals. | NCTR provides peer-reviewed research that supports FDA's regulatory function. To accomplish this mission, it is incumbent upon NCTR to solicit feedback from its stakeholders and partners, which include FDA product centers, other government agencies, industry, and academia. The NCTR SAB —composed of non-government scientists from industry, academia, and consumer organizations, and subject matter experts representing all of the FDA product centers—is guided by a charter that requires an intensive review of each of the Center's scientific programs at least once every five years to ensure high quality programs and overall applicability to FDA's regulatory needs. Scientific and monetary collaborations include Interagency Agreements with other government agencies, Cooperative Research and Development Agreements that facilitate technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the high quality of its research and the accuracy of data collected. Research protocols are often developed collaboratively by principal investigators and scientists at FDA product centers and are developed according to a standardized process outlined in the "NCTR Protocol Handbook." NCTR's Project Management System tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors experiments that fall within the GLP guidelines. NCTR's annual report of research accomplishments, goals, and publications is published and available on FDA.gov. Research findings are published in peer-reviewed journals and presented at national and international scientific conferences. |

**Long Term Objective:** Detect safety problems earlier and better target interventions to prevent harm to consumers.

| Measure | FY | Target | Result |
|---|---|---|---|
| 264201: Develop standard biomarkers to establish risk measures for FDA-regulated products. (Output) | *2011* | N/A | N/A |
| | 2010 | 1) MicroArray Quality Control (MAQC)—develop draft guidelines for applying microarray standards<br>2) Identify gender-specific biomarkers that enable improved risk/benefit decisions for treatments | December 2010 |
| | 2009 | Evaluate biological effects of manganese nanoparticles | Research paper published showing manganese, copper, and silver nanoparticles altered 11 genes associated with neuro-degeneration<br>(Target Met) |
| | 2008 | Develop microarray data standards | 15 manuscripts on the MAQC-II results were submitted and 4 manuscripts were published<br>(Target Met) |
| | 2007 | Conduct research on carbon nanomaterials methods and ketamine | 1) Ketamine-induced neurotoxicity initiated in primate model<br>(Target Met)<br>2) Synthesis methods developed for nanotubes<br>(Target Met) |
| | 2006 | Present one finding utilizing neuropathology and behavioral risk evaluation in the prediction of human outcome to food-borne toxicants. | 1) Behavioral effects of acrylamide identified<br>(Historical Baseline)<br>2) Concurrent neuropathological analysis completed<br>(Historical Baseline) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 264201 | NCTR Project Management System; peer-review through FDA/NCTR SAB and the NTP Scientific Board of Counselors; presentations at national and international scientific meetings; use of the predictive and knowledge-based systems by the FDA reviewers and other government regulators; and manuscripts prepared for publication in peer-reviewed journals. | NCTR provides peer-reviewed research that supports FDA's regulatory function. To accomplish this mission, it is incumbent upon NCTR to solicit feedback from its stakeholders and partners, which include FDA product centers, other government agencies, industry, and academia. The NCTR SAB —composed of non-government scientists from industry, academia, and consumer organizations, and subject matter experts representing all of the FDA product centers—is guided by a charter that requires an intensive review of each of the Center's scientific programs at least once every five years to ensure high quality programs and overall applicability to FDA's regulatory needs. Scientific and monetary collaborations include Interagency Agreements with other government agencies, Cooperative Research and Development Agreements that facilitate technology transfer with industry, and informal agreements with academic institutions. NCTR also uses an in-house strategy to ensure the high quality of its research and the accuracy of data collected. Research protocols are often developed collaboratively by principal investigators and scientists at FDA product centers and are developed according to a standardized process outlined in the "NCTR Protocol Handbook." NCTR's Project Management System tracks all planned and actual expenditures on each research project. The Quality Assurance Staff monitors experiments that fall within the GLP guidelines. NCTR's annual report of research accomplishments, goals, and publications is published and available on FDA.gov. Research findings are published in peer-reviewed journals and presented at national and international scientific conferences. |

**1. Develop biomarkers to assist in identifying the correlation between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health.** (262401)

**Context:** NCTR's goal is to define the correlations between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health. This research will provide baseline data that supports the FDA goal of providing consumers clear and timely information to help promote personalized nutrition and health. Identifying biomarkers of health, susceptibility to chronic disease, and gene-micronutrient interactions is essential to gaining a more complete scientific understanding of health. NCTR is implementing a novel research program for personalized nutrition and health that relies on the "challenge homeostasis" concept for identifying markers of health and susceptibility. This approach implements a safe, but acute, challenge to the body's ability to regulate and maintain balance. NCTR will use its current omics capabilities, in conjunction with its expanded genomic analyses capabilities, to conduct this research. The intervention design proposed by NCTR establishes a model that may be used by the emerging International Micronutrient Genomics Project that will compare gene-micronutrient interactions across populations and cultures.

**Performance:** NCTR's Division of Personalized Nutrition and Medicine (DPNM) expanded its research into identifying correlations between an individual's nutrition, genetic profiles, and health. The Community Based Participatory Research (CBPR) project conducted in FY 2008 in the Lower Mississippi Delta examined the effects of better nutrition on serum levels of certain vitamins and metabolites in children. In FY 2009, a follow-on research approach using CBPR at a summer camp incorporated the linkage between physical responses to a healthier diet and genetic analyses. Research from the camp resulted in 93 blood samples and approximately 1.1 million genotypes (genetic makeup)

identified for each participant. Participants also wore devices which measured motion to determine calories expended. These datasets made it possible to analyze caloric intake and expenditures, and genetic makeup. The data generated can improve the basis of public health policies and provide information to those interested in developing improved access to food and healthcare. The FY 2010 goal is to begin to identify the patterns in serum biomarkers that can be used to define the correlations between an individual's diet and genetic profile to develop personalized dietary recommendations which may improve the health of individuals and communities. In FY 2011, NCTR plans to analyze the DNA sequence of 400 candidate genes from the CBPR participants to identify target genes that can predict potential for obesity and type 2 diabetes.

**2. Use new omics technologies and pattern-recognition algorithms to analyze imaging data for early-stage disease diagnosis and to study how an FDA-regulated compound or product interacts with the human body.** (263101)

**Context:** With the advent of new technologies such as toxicoinformatics, proteomics, metabolomics, and genomics, and the expanding capabilities of noninvasive imaging technologies, FDA has the necessary tools to detect disease at an earlier stage and to better understand how an FDA-regulated compound or product interacts with the human body. The accelerated rate at which technological advances are being made in the marketplace dictates that FDA accelerate its rate of innovation in the regulatory-research arena. Combining genomic knowledge with microPET imaging (Positron Emission Tomography imaging for small animals) is expected to facilitate the search for genetic predictors of drug response. Devices such as microPET that reveal clinical and pharmacogenomic information will serve to individualize medicine both for the diagnosis and treatment of disease, and allow for monitoring the efficacy of treatment regimens. The enormous amount of data generated by these technologies also requires the development of new tools to allow researchers and reviewers to use the data to evaluate potential risks related to use of an FDA-regulated compound or product.

**Performance:** In FY 2009, NCTR reviewed novel methods to normalize the spectra generated from various MRI scanners, an approach that will translate across tissues. In addition, pattern recognition algorithms to interpret complex Magnetic Resonance Spectroscopy (MRS) scans were improved to an accuracy rate of over 96% for nine types of tissues and are now capable of grading tumors. In FY 2010 NCTR has two goals in this area. The first goal, to develop translatable biomarkers for studying pediatric products, is especially critical as advances in pediatric and obstetric surgery have resulted in an increase in complexity, duration, and number of anesthetic procedures. To minimize risks to children resulting from the use of anesthesia, it is necessary to understand the effects of anesthetic drugs on the developing nervous system by determining the time-course of neuronal-cell death induced by ketamine administered repeatedly in living animals. NCTR will conduct studies using noninvasive microPET imaging to determine clinical relevance to the pediatric population. Secondly, in FY 2010, NCTR will create a demonstrable tool to use in the drug-review process based upon the liver toxicity knowledge base. Knowledge associated with liver toxicity is important to FDA in the drug review process, particularly given the fact that several FDA-approved drugs exhibited liver toxicity and have been removed from the market. As Americans routinely take combinations of prescription and over-the-counter drugs, herbal remedies, dietary supplements and alcohol, the adverse effect to the liver caused by drugs, and by the combination of drugs, is increasing dramatically. Development of a knowledge base for liver toxicity will be useful as a hypothesis-generating tool for designing liver toxicity-related experiments and as a reference tool in the FDA drug approval process. In FY 2011, NCTR will implement a VXDS data submission tool, called VISIONS that will accelerate the regulatory-review process. In addition, researchers will present preliminary data on markers that indicate nervous system damage from pediatric anesthetic use at national scientific meetings which may lead to improved product-use guidelines.

**3. Develop computer-based models and infrastructure to predict the health risk of biologically active products.** (263102)

**Context:** To effectively support large datasets generated using new technologies such as toxicoinformatics, proteomics, metabolomics, and genomics, NCTR scientists develop and enhance scientific analytical software in collaboration with colleagues from government, academia, and industry to advance the incorporation of this data analysis into the regulatory process. NCTR's key objective is to

develop computer-based models and infrastructure to predict the health risk of biologically active products. NCTR scientists invented ArrayTrack™, a software that allows for the management, analysis, and interpretation of vast amounts of omics data and is an important tool for the American public to benefit from the vast amount of bioinformatic data being generated from the new technologies. The expanded use of ArrayTrack™ and other bioinformatic tools allows FDA to support the rapid translation of scientific research into reliable and safer treatments and better risk evaluations by improving the analysis and management of available data**.**

**Performance:** ArrayTrack™ 3.5.0 was developed during FY 2009 and included several important enhancements. Two new libraries and classification methods were added for model building and predictions on clinical, nonclinical, and toxicological microarray data. In addition, the new version of ArrayTrack™ supports Protein and Metabolite Panels for data storage, analysis, and interpretation of proteomics and metabolomics. In FY 2010, new functions including the molecular signature and biomarker module will be developed in ArrayTrack™ to support VXDS. NCTR's goal in FY 2011 is to deliver the alpha version of the FDA SNPTrack to support the FDA review of pharmacogenetics data and provide more personalized treatment options.

**4. Develop science base for supporting FDA regulatory review of new and emerging technologies.** (263201)

**Context:** NCTR's goal to develop a science base to support the FDA regulatory review of new and emerging technologies by establishing a joint NCTR/ORA Nanotechnology Core Facility will strengthen the FDA's ability to prevent potential health-endangering products from entering the marketplace. It is anticipated that NCTR's nanotechnology research program will expand as the number of nanoscale products that the regulated community seeks to market increases. The FDA has already reviewed and approved some nanotechnology-based products, and expects a significant increase in the use of nanoscale materials in drugs, devices, biologics, cosmetics, and food. Improved understanding of nanomaterials, their transport, and their toxicity will provide a framework for regulatory guidelines for safe and effective use of nanomaterials in FDA-regulated foods, cosmetics, and medical products and provide early recognition of potential safety issues before they become adverse events in the patient population.

**Performance:** In FY 2009, NCTR established the NCTR/ORA Nanotechnology Core Facility to provide analytical support, materials characterizations, and electron microscopy support for a broad range of nanomaterial studies. NCTR is currently conducting studies to understand the toxicological and biological impact of animal exposure to nanomaterials. It is important for FDA to understand the toxicological consequences of the administration of nanoscale drugs, intentional exposure to nanoscale devices, and unintended exposure to nanoscale materials. Research plans in this area for FY 2010 include studies to quantify the migration of nanosilver from food-contact materials, and determine the conditions under which migration will occur. In FY 2010, the ORA/NCTR Nanotechnology Core Facility hopes to establish and implement SOPs in research protocols for detection of nanoscale materials in FDA-regulated products, and then to validate the SOPs at the agency-level in FY 2011.

**5. Develop risk assessment methods and build biological dose-response models in support of food protection.** (264101)

**Context:** To address research needs and build the FDA's capability to assess and reduce food-related health threats, NCTR researchers evaluate key regulatory issues of food safety, conduct multidisciplinary studies to develop risk-assessment methods, and develop biological dose-response models vital to food security. Identifying the prevalence of antibiotic-resistant genes and the genetic fingerprinting of these genes will help identify similar strains isolated from different samples. Another food-related health threat, especially for infants and children, is the presence of BPA, an endocrine disruptor that can mimic hormones and a compound used in a wide variety of household items including baby bottles, drinking bottles, and liners for canned food. NCTR will be initiating studies in collaboration with the National Institute of Environmental Health Sciences (NIEHS) National Toxicology Program to address the health concerns associated with exposures to low doses of BPA during critical periods of perinatal development. Effects reported include alterations in the central nervous system (CNS) anatomy, lesions in prostate and mammary glands, urinary tract abnormalities, and the early onset of puberty.

**Performance:** In FY 2009, NCTR developed risk assessment methods for detection of 775 antimicrobial resistance genes in *Salmonella*. Also, RAPID-B detection of *E.coli* was validated for nine food matrices including hamburger, spinach, jalapeno peppers, chocolate chip cookie dough, beef brisket, nut meat, hot dogs, bagged salad and salami. In FY 2010, NCTR will develop protocols and initiate studies on the toxicity of orally ingested BPA with the goal of identifying potential health risks, particularly for infants and children. NCTR will also work toward the development of rapid-detection toolkits for foodborne pathogens in FY 2010. The goal is for these toolkits to be applicable to fresh produce and also be usable in the field. These goals and the goal to identify antibiotic-resistant markers will allow the FDA to reduce the spread of foodborne outbreaks and enable the development of intervention strategies to reduce the frequency of multi-drug resistant pathogens in the U.S. food supply. NCTR has aggressive goals for FY 2011 in this area with plans to: 1) develop base guidelines to assess extent of kidney toxicity caused by the combination of melamine and cyanuric acid and ultimately improve diagnosis and treatment; 2) conduct a successful FERN Level 4 validation for the RAPID-B *E. coli* O157 test method so it can be approved for use in regulatory reviews or food emergency situations; and 3) develop and initiate protocols for RAPID-B tests for viruses and toxins to aid FDA in protecting public health from viruses and toxin contamination.

**6. Develop standard biomarkers to establish risk measures for FDA-regulated products.** (264201)

**Context:** NCTR's research to develop standard biomarkers to establish risk measures for FDA-regulated products prevent potential health-endangering products from remaining in and continuing to enter the marketplace. Although no future targets will be set for this performance measure beyond FY 2010, NCTR will continue to conduct this valuable research that results in an increased number of safe and effective medical products available to the public. However, the performance targets in this area of research will be addressed under Measures 262401, 263101, and 263102 for FY 2011 and beyond. The Measure 264201 is being retired. It was written in very general terms to address biomarker research at NCTR. Over time, this measure has been superseded by the three measures mentioned above which are written in more specific terms but will encompass the research NCTR would have previously submitted under Measure 264201.

**Performance:** In FY 2009, NCTR scientists published a research paper entitled "Expression changes of dopaminergic system related genes in Pc-12 induced by manganese, silver, or copper." The results indicated that manganese, copper, and silver nanoparticles altered 11 genes associated with neuro-degeneration. NCTR will continue the important work of exploring the toxicological effects of nanoparticles. In FY 2010, the participants of the MAQC project, under the leadership of NCTR, will develop draft guidelines for applying microarray standards that will provide the research and regulatory communities with a foundation to confidently use microarrays in clinical practice and regulatory decision-making. The goal of this project is to ensure that accurate and reliable predictions can be made based on an individual's microarray profile and that companies will bring more effective diagnostic tools to market. Further, in FY 2010, NCTR will identify gender-specific biomarkers that will enable improved risk/benefit decisions for treatments. It is expected to substantially reduce error rates when compared to using standard biomarkers which apply to both sexes.

# Office of Regulatory Affairs Performance Detail

**Long Term Objective:** Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

| Measure | FY | Target | Result |
|---|---|---|---|
| 253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)* | *2011* | 300 | December, 2011 |
| | *2010* | 300 | December, 2010 |
| | *2009* | 300 | 305 (Target Exceeded) |
| | *2008* | 300 | 301 (Target Exceeded) |
| | *2007* | 295 | 323 (Target Exceeded) |
| | *2006* | 295 | 336 (Target Exceeded) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 253201 | CDRH Premarket Tracking System and Receipt Cohorts and Field Data Systems. | To help ensure Agency consistency in tracking and reporting Premarket activities, CDRH utilizes the Premarket Tracking System, which contains various types of data taken directly from the Premarket submissions. FDA employs certain conventions for monitoring and reporting performance; among these are groupings of Premarket submissions into decision and receipt cohorts. Decision cohorts are groupings of submissions upon which a decision was made within a specified time frame, while receipt cohorts are groupings of submissions that were received within a specified time frame. The Premarket performance goals are based on receipt cohorts. Final data for receipt cohorts are usually not available at the end of the submission year. Because the review of an application received on the last day of the submission year, e.g., a PMA with 180 day time frame, may not be completed for at least 6 months or longer, final data for the submission or goal year may not be available for up to a year or more after the end of the goal year. |

**Long Term Objective:** Detect safety problems earlier and better target interventions to prevent harm to consumers.

| Measure | FY | Target | Result |
|---|---|---|---|
| 214201: Number of prior notice import security reviews. *(Output)* | *2011* | 80,000 | December, 2011 |
| | *2010* | 80,000 | December, 2010 |
| | *2009* | 80,000 | 81,157 (Target Exceeded) |
| | *2008* | 80,000 | 80,543 (Target Exceeded) |
| | *2007* | 60,000 | 84,088 (Target Exceeded) |
| | *2006* | 45,000 | 89,034 (Target Exceeded) |
| 214202: Number of import food field exams. *(Output)* | *2011* | 160,000 | December, 2011 |
| | *2010* | 140,000 | December, 2010 |
| | *2009* | 120,000 | 138,916 (Target Exceeded) |
| | *2008* | 85,000 | 100,718 (Target Exceeded) |
| | *2007* | 71,000 | 94,743 (Target Exceeded) |
| | *2006* | 73,376 | 94,545 (Target Exceeded) |
| 214203: Number of Filer Evaluations. *(Output)* | *2011* | 1,000 | December, 2011 |
| | *2010* | 1,000 | December, 2010 |
| | *2009* | 1,000 | 1,208 (Target Exceeded) |
| | *2008* | 1,000 | 1,356 (Target Exceeded) |
| | *2007* | 1,000 | 1,355 (Target Exceeded) |
| | *2006* | 1,000 | 1,441 (Target Exceeded) |
| 214204: Number of examinations of FDA refused entries. *(Output)* | *2011* | 7,000 | December, 2011 |
| | *2010* | 7,000 | December, 2010 |
| | *2009* | 5,000 | 7,201 (Target Exceeded) |
| | *2008* | 4,000 | 5,926 (Target Exceeded) |
| | *2007* | 3,000 | 5,510 (Target Exceeded) |
| | *2006* | 3,000 | 5,846 (Target Exceeded) |

| Measure | FY | Target | Result |
|---|---|---|---|
| 214205: Number of high risk food inspections. *(Output)* | *2011* | 7,800 | December, 2011 |
| | *2010* | 6,750 | December, 2010 |
| | *2009* | 6,100 | 6,182 (Target Exceeded) |
| | *2008* | 5,700 | 6,230 (Target Exceeded) |
| | *2007* | 5,625 | 6,421 (Target Exceeded) |
| | *2006* | 5,963 | 6,795 (Target Exceeded) |
| 214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. *(Outcome)* | *2011* | 5 data exchange additions/conversions | December, 2011 |
| | *2010* | 5 data exchange additions/conversions | December, 2010 |
| | *2009* | 5 data exchange additions/conversions | 5 data entry labs (Target Met) |
| | *2008* | 5 data entry labs | 11 data entry labs (Target Exceeded) |
| 224201: Number of foreign and domestic high-risk human drug inspections. *(Output)* | *2011* | 750 | December, 2011 |
| | *2010* | 700 | December, 2010 |
| | *2009* | 600 | 687 (Target Exceeded) |
| | *2008* | 500 | 534 (Target Exceeded) |
| | *2007* | 500 | 583 (Target Exceeded) |
| | *2006* | 483 | 510 (Target Exceeded) |
| 234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)* | *2011* | 1,000 | December, 2011 |
| | *2010* | 1,000 | December, 2010 |
| | *2009* | 870 | 1,001 (Target Exceeded) |
| | *2008* | 870 | 1,014 (Target Exceeded) |
| 234203: Number of human tissue establishment inspections. *(Output)* | *2011* | 533 | December, 2011 |
| | *2010* | 518 | December, 2010 |
| | *2009* | 380 | 434 (Target Exceeded) |
| | *2008* | 325 | 383 (Target Exceeded) |
| | *2007* | 325 | 427 (Target Exceeded) |
| | *2006* | 250 | 354 (Target Exceeded) |

| Measure | FY | Target | Result |
|---|---|---|---|
| 244202: Number of domestic and foreign high risk animal drug and feed inspections. *(Output)* | *2011* | 250 | December, 2011 |
| | *2010* | 250 | December, 2010 |
| | *2009* | 233 | 262 (Target Exceeded) |
| | *2008* | 233 | 244 (Target Exceeded) |
| 244203: Number of targeted prohibited material BSE inspections. *(Output)* | *2011* | 490 | December, 2011 |
| | *2010* | 490 | December, 2010 |
| | *2009* | 490 | 526 (Target Exceeded) |
| | *2008* | 490 | 555 (Target Exceeded) |
| | *2007* | 490 | 523 (Target Exceeded) |
| | *2006* | 516 | 516 (Target Met) |
| 254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)* | *2011* | 1,445 | December, 2011 |
| | *2010* | 1,365 | December, 2010 |
| | *2009* | 1,340 | 1,471 (Target Exceeded) |
| | *2008* | 1,270 | 1,431 (Target Exceeded) |
| | *2007* | 1,195 | 1,468 (Target Exceeded) |
| | *2006* | 1,234 | 1,506 (Target Exceeded) |
| 214206: Maintain accreditation for ORA labs. *(Outcome)* | *2011* | 13 labs | December, 2011 |
| | *2010* | 13 labs | December, 2010 |
| | *2009* | 13 labs | 13 labs (Target Met) |
| | *2008* | 13 labs | 13 labs (Target Met) |
| | *2007* | 13 labs | 13 labs (Target Met) |
| | *2006* | 13 labs | 13 labs (Target Met) |
| 214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)* | *2011* | 2,500 rad & 2,100 chem | December, 2011 |
| | *2010* | 2,500 rad & 2,100 chem | December, 2010 |
| | *2009* | 2,500 rad & 1,650 chem | 2,500 rad & 1,650 chem (Target Met) |
| | *2008* | 2,500 rad & 1,200 chem | 2,500 rad & 1,200 chem (Target Met) |
| | *2007* | 1,000 rad & 1,200 chem | 1,000 rad & 1,200 chem (Target Met) |
| | *2006* | 1,200 chem | 1,200 chem (Target Met) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 214201<br>214202<br>214203<br>214204<br>214205<br>214303<br>224201<br>234202<br>234202<br>244202<br>244203<br>254201<br>214206<br>214305 | Field Data Systems. | ORA uses two main information technology systems to track and verify field performance goal activities: the Field Accomplishments and Compliance Tracking System (FACTS) and the Operational and Administrative System Import Support (OASIS). FACTS includes data on the number of inspections; field exams; sample collections; laboratory analyses; and, the time spent on each. OASIS, which is coordinated with U.S. Customs and Border Protection, provides data on what FDA regulated products are being imported as well as where they are arriving. It also provides information on compliance actions related to imports. FDA is currently developing the Mission Accomplishment and Regulatory Compliance Services (MARCS) system. MARCS will incorporate the capabilities of these two field legacy systems and include additional functionality. |

**1. Number of Medical Device Bioresearch Monitoring (BIMO) inspections.** (253201)

**Context**: FDA's mission includes assuring the protection of human research subjects, the quality and integrity of research, and the advancement of new medical technologies. A FDA-regulated research community that consists of Clinical Investigators, Sponsors and Monitors, and Institutional Review Boards has a shared responsibility to oversee this research in a truthful and ethical manner. For FY 2010, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach. There are no projected changes to this goal in FY 2011. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA exceeded this goal of 300 by conducting 305 medical device related Bioresearch Monitoring inspections.

**2. Number of prior notice import security reviews.** (214201)

**Context:** FDA's Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. FDA will continue to focus much of its resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. consumer. All flagged entries (100%) are reviewed every year. FDA expects that as prior notice compliance activities increase and targeting for high risk products becomes more sophisticated, the total number of intensive prior notice security reviews conducted by the PNC may decrease in future years. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** During FY 2009, FDA received 9,546,831 prior notice submissions on which the PNC conducted 81,157 import security reviews (exceeding the performance target of 80,000 reviews) to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. A total of 798 shipments were refused for prior notice violations, which more than doubled the total number of refusals from the previous fiscal year. The PNC operations actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats. In addition, the PNC responded to more than 23,284 phone and e-mail inquiries, and conducted over 600 informed compliance calls to the import trade in order to facilitate better compliance with the submission of accurate, timely prior notice information.

**3. Number of import food field exams on products with suspect histories.** (214202)

**Context:** The volume of imported food shipments has been rising steadily in recent years and this trend is likely to continue. FDA reviewed approximately 9.8 million line entries of imported food out of an estimated 20.0 million lines of FDA regulated products in FY 2009. In FY 2010, FDA expects

approximately 10.1 million line entries of imported food within a total of more than 23.2 million lines of FDA regulated entries. To manage this ever-increasing volume of imports, FDA uses risk management strategies to achieve the greatest food protection with available resources. While the percentage of imports physically examined may decline as imports continue their explosive growth, the exams that ORA conducts are more targeted and more effective than ever before. ORA continues to think that the best approach to improve the safety and security of food import lines is to devote resources to expand targeting and follow through on potentially high-risk import entries rather than simply increasing the percentage of food import lines given a field exam. In FY 2009, FDA used Food Protection Resources to increase the number of import food field exams by 20,000 exams which brought the FY 2009 Target to 120,000 exams over the FY 2008 accomplishments. In FY 2010, FDA will use the FY 2009 resources to increase the number of import food field exams by 20,000 exams which brings the FY 2010 Target to 140,000 exams. In FY 2011, the target is increased by 20,000 field exams for a new target of 160,000 exams.

**Performance:** In FY 2009, FDA exceeded the target of 120,000 by completing 138,916 field examinations of imported food lines. Explanation of why this goal was significantly exceeded: With the increase in funding, FDA was able to bring on a significant number of new investigators earlier than anticipated which enabled FDA to exceed this estimate. FDA will continue to adjust targets upward as our hiring continues.

**4. Number of Filer Evaluations of import filers.** (214203)

**Context:** The Food and Drug Administration (FDA) receives electronic import entry data for assessing the admissibility of regulated imported articles. The accuracy of these data directly relates to the level of confidence that American consumers can expect in the quality, safety and compliance of imported articles subject to FDA's jurisdiction. Entry data affects FDA's determination of the labeling, quality, safety, approval status, and efficacy of FDA-regulated import articles. FDA uses an electronic entry screening system, Operational and Administrative System for Import Support (OASIS), to screen import entry data transmitted by import filers. Filers who fail an evaluation must implement a Corrective Action Plan and pass a tightened evaluation. This protects public health by ensuring reporting compliance for imported articles that FDA regulates. FDA will continue to develop and apply methods to evaluate filer accuracy that are consistent with evolving security and import regulation practices. The FY 2010 and FY 2011 targets are being maintained at the FY 2009 level.

**Performance:** In FY 2009, FDA exceeded this goal of 1,000 by performing 1,208 filer evaluations. This goal is an agency-wide goal and performance data includes activities from all five program areas**;** however, the majority of the performance activities and resources are from the Foods program.

**5. Number of examinations of FDA refused entries.** (214204)

**Context:** FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics. This protection includes refusing entry of products into the U.S. when they are deemed violative and assuring these violative products are either destroyed or exported and do not enter into domestic commerce. Although primary responsibility for supervising destruction or exportation rests with the Bureau of Customs and Border Protection (CBP), FDA monitors the disposition of refused shipments and maintains an open file until the product is exported or destroyed. In cooperation with CBP, FDA will, at times, supervise destruction or examine products prior to export in order to assure that the refused product is actually exported. This performance goal only counts FDA supervised destruction or exportation of refused entries. In other cases FDA relies on notification from CBP that the refused products have been destroyed or exported. The FY 2009 target was increased to 5,000 examinations to better reflect the recent historical actuals for this goal. For FY 2010, the target is again being increased to 7,000 to better reflect recent actual accomplishments. The FY 2011 target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA exceeded this goal of 5,000 by performing 7,201 examinations of FDA refused entries as they were delivered for exportation to assure that the products refused by FDA were exported. This goal is an agency wide goal and performance data includes activities from all five

program areas; however, the majority of the performance activities and resources are from the Foods program. Explanation of why this goal was significantly exceeded: The increase in accomplishments compared to the performance target was due to the Agency's hiring initiative and resulting increase in personnel available to perform refusal follow-ups.

**6. Number of high risk food inspections.** (214205)

**Context:** High risk food establishments are those that produce, prepare, pack or hold foods that are at high potential risk of microbiological or chemical contamination due to the nature of the foods or the processes used to produce them. This category also includes foods produced for at risk populations such as infants. The Field intends to inspect such establishments annually, or more frequently for those who have a history of violations. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk food firms enter the market, or the definition of high risk evolves based on new information on food hazards. High-risk establishment inspection frequencies vary depending on the products produced and the nature of the establishment. Inspection priorities may be based on a firm's compliance history. The FY 2009 target was increased to 6,100 inspections of high-risk food establishments to better reflect the recent historical actuals for this goal. For FY 2010, the target has been increased to 6,750 to reflect the FY 2009 Appropriations. In FY 2011, the target is increased by 1,050 inspections for a new target of 7,800 inspections.

**Performance:** In FY 2009, FDA exceeded this goal of 6,100 by performing 6,182 inspections of high-risk domestic food establishments.

**7. Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange.** (214303)

**Context:** The electronic Laboratory Exchange Network (eLEXNET) is a seamless, integrated, secure network that allows multiple agencies (federal, State and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET enables health officials to assess risks, analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. As of the end of FY 2009, there are 224 total laboratories currently participating in eLEXNET overall. These labs include segments of a wide variety of food safety organizations on Federal, Military, State, and Local government levels. These labs also span the agricultural, environmental, public health, veterinary, and diagnostic disciplines as well. Of the 224 participating laboratories in all 50 states, 144 are actively entering or submitting data. There are 44 labs among them that are fully automated via Data Exchange and transfer their LIMS sample data on a regular, ongoing basis. The 100 other remaining laboratories enter data in eLEXNET through manual data entry. The overall goal of the FDA's eLEXNET program is to continue to integrate those labs participating in eLEXNET via Data Exchange and to identify new labs to expand our membership. Through continued expansion of our membership base and active data sources, the eLEXNET program will continue to serve as a key collaborative tool for food surveillance entities nationwide. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA met its performance goal by fully automating electronic data exchange between five new labs and FDA's eLEXNET (electronic Laboratory Exchange Network). This makes the total number of automated data exchange participant labs to 44. The automated data transfer does not require any human intervention and is completely maintenance free unless there is a change in the lab environment.

**8. Number of foreign and domestic high-risk human drug inspections.** (224201)

**Context:** FDA is continuing to develop a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The Risk-Based Site Selection Model provides a risk score for each facility, which is a function of four component risk factors – Product, Process, Facility, and Knowledge. In the FY 2007 model, the Agency developed several enhancements and improvements and will continue to explore ways to enhance calculations of process risk and facility sub-scores in FY 2010. As enhancements are made to FDA's data collection efforts and

to the Risk-Based Site Selection Model, FDA will improve its ability to focus inspections on the highest-risk public health concerns in a cost-effective way. For FY 2010, the target has been increased to 700 to reflect the FY 2009 Appropriations. In FY 2011, the target is increased by 50 inspections for a new target of 750 inspections.

**Performance:** FDA exceeded the FY 2009 goal of 600 by inspecting 687 high-risk foreign and domestic drug manufacturers.

**9. Number of registered domestic blood bank and biologics manufacturing inspections.** (234202)

**Context:** FDA will enhance its risk-based compliance and enforcement activities by increasing inspections of registered manufacturers of biological products, which are essential for meeting national public health objectives. These products involve complex manufacturing processes and are in limited supply in some cases. Inspections for this performance goal are conducted to ensure compliance with current Good Manufacturing Practices (cGMPs) requirements and applicable standards, and to ensure the safety, purity and potency of biological products. The biologics inventory includes blood establishments, plasma derivative manufacturing establishments, and vaccine manufacturing establishments, especially seasonal and pandemic influenza vaccines. In FY 2010, the target has been increased to 1,000 inspections to reflect historical accomplishments. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA exceeded this high risk inspection goal of 870 by inspecting 1,001 blood banks and biologics manufacturing establishments.

**10. Number of foreign and domestic human tissue establishment inspections.** (234203)

**Context:** Beginning in FY 2006 as a result of new regulations, the human tissue inspection goal was created. FDA's responsibility for enforcing the new regulations and the need to quickly assess compliance makes tissues one of the highest priorities. Two new rules took effect regarding human tissue: one requiring tissue facilities to register with FDA became effective January 2004; while the "Donor Eligibility Rule" became effective May 2005. The Field conducts tissue inspections to determine if human tissues for transplantation are in compliance with FDA tissue regulations and to assure consumer protection from unsuitable tissue products and disease transmission which may endanger public health. In FY 2009, FDA increased this goal by 55 additional tissue inspections, over the FY 2008 target, in order to cover more of the firms that registered as a result of the new regulations. In FY 2010, the target was increased by 138 inspections to reflect the FY 2009 Appropriations. In FY 2011, the target is increased by 15 inspections for a new target of 533 inspections.

**Performance:** In FY 2009, FDA exceeded the human tissue goal of 380 by conducting 434 inspections under new regulations.

**11. Number of domestic and foreign high risk animal drug and feed inspections.** (244202)

**Context:** Important features of the risk-based strategy for this revised goal are to reduce the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. In FY 2008, this revised goal focused on pre-market approval inspections and implementing risk-based current Good Manufacturing Practices (cGMP) inspection plans for animal drug and feed manufacturing facilities that utilized risk modeling to identify the highest risk firms to be inspected. The FY 2008 target was maintained in FY 2009 because this was a new, risk-based goal for which FDA had no historical experience, and were unsure how the new site-selection methodology would evolve. In FY 2010, the target is being slightly increased as a result of the FY 2009 Appropriation while evaluation of the new methodology continues. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA exceeded this inspection goal of 233 by inspecting 262 high risk animal drug and feed establishments.

**12. Number of targeted prohibited material BSE inspections** (244203)

**Context:** FDA developed a comprehensive public protection strategy of education, inspection and enforcement action to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) feed regulations. Using an inventory of all known renderers and feed mills processing products containing prohibited material, FDA will continue to conduct annual inspections to determine compliance with the BSE feed rule. Inventories of these firms may vary from year to year based on changes at the firm such as consolidations, business closures, relocations, etc. In FY 2011, FDA will continue to conduct inspections of 100% of the firms known to be processing with prohibited materials.

**Performance:** In FY 2009, FDA completed the inspection of all 526 firms known to be processing with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

**13. Number of domestic and foreign Class II and Class III device inspections.** (254201)

**Context:** The ultimate goal of preventing unsafe and ineffective devices from reaching the consumer will be advanced by detecting and intercepting unsafe and ineffective product at the manufacturing level. By utilizing risk-based inspection strategies and focusing on surveillance throughout a products life-cycle FDA will be better able to protect the public health by ensuring both the quality and effectiveness of medical devices available in the U.S. marketplace. For FY 2010, the target has been increased to 1,365 to reflect the FY 2009 Appropriations. In FY 2011, the target is increased by 80 inspections for a new target of 1,445 inspections.

**Performance:** FDA exceeded the FY 2009 medical device performance goal of 1,340 by inspecting 1,471 foreign and domestic high-risk Class II and Class III medical device manufacturers.

**14. Establish and maintain accreditation for ORA labs.** (214206)

**Context:** FDA is a science-based agency that depends on its regulatory laboratories for timely, accurate, and defensible analytical results in meeting its consumer protection mandate. Our laboratories have enjoyed a long history of excellence in science upon which the agency has built its reputation as a leading regulatory authority in the world health community. Accreditation of laboratory quality management systems provides a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science. Such accreditations allow FDA to maintain its reputation as a source of scientifically sound information and guidance both domestically and in the international arena. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA met this laboratory accreditation goal. FDA maintained accreditation for 13 laboratories: Denver District Lab, Forensic Chemistry Center, Arkansas Regional Lab, Pacific Regional Lab Northwest, San Francisco District Lab, Winchester Engineering and Analytical Center, New York Regional Lab, Southeast Regional Lab, San Juan District Lab, Detroit District Lab, Pacific Regional Lab Southwest, and Kansas City District Lab. All ORA Field Laboratories are accredited to ISO 17025 by the American Association for Laboratory Accreditation. FCC is accredited by the ASCLD (American Society of Crime Laboratory Directors).

**15. Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week)** (214305)

**Context:** A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for the presence of contaminants. To address the need for this surge capacity, The Food Emergency Response Network (FERN), a joint effort between USDA/FSIS and HHS/FDA, was created. FERN is a nationwide laboratory network that integrates existing federal and State food testing laboratory resources capable of analyzing foods for agents of concern in order to prevent, prepare for, and respond to national emergencies involving unsafe food products. Improvements in surge capacity will have public health value even in non-deliberate food contamination by assisting FDA in identifying and removing contaminated food products from the marketplace as soon as possible in order to protect the public health

and mitigate disruption in the U.S. food supply chain. FDA awards FERN Cooperative Agreements for chemistry and radiological FERN labs to the States. After receiving the funding, State FERN laboratories can take up to one year to reach full capacity due to the need for training and testing to ensure confidence in the laboratory results. As a result, labs funded in one fiscal year will not show surge capacity until the following year. With FY 2008 Food Protection increases, ORA added three additional FERN chemical labs in FY 2008 which increased the surge capacity in FY 2009 to 1,650 chemical samples per week. With the FY 2009 Appropriation, ORA will add three additional FERN chemical labs in FY 2009 which will increase the surge capacity in FY 2010 to 2,100 chemical samples per week. In FY 2011, the target is maintained at the FY 2010 level.

**Performance:** In FY 2009, FDA met this performance goal surge capacity target of 1,650 chem samples per week based on the awarding of cooperative agreements to 3 state chemistry labs in FY 2008 resulting in a surge capacity increase of 150 chem samples per lab (450 total) in FY 2009. FDA also maintained the surge capacity for 2,500 rad samples per week.

The FERN laboratories increasingly provide critical analytical surge capacity during food emergency events. An FDA assignment ("Surveillance, Inspection and Sample Collection and Analyses of Products Related to the Salmonella St. Paul Investigation" issued by ORA/CFSAN) directed samples to the FERN labs in the Salmonella outbreak in peppers, with 290 samples tested. FERN Chemistry laboratories participated in the #09-06 CFSAN Melamine Import Assignment (2008-2009), assisting FDA in the analysis of milk and protein samples, analyzing 340 samples. These FERN labs were a key factor in clearing an FDA sample backlog, which arose due to very high collection rates. FERN laboratories also participated in the FDA surveillance assignment for the political conventions. All of these efforts contribute to increasing FDA’s capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of state, local, and tribal regulatory bodies.

# Tobacco Performance Appendix Detail

**Long Term Objective:** Protecting the Public Health from the Harmful Effects of Tobacco Use

| Measure | FY | Target | Result |
|---|---|---|---|
| 280001: Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. *(Output)* | *2011* | Select initial set of data and calculate baseline for long term assessment of public health impact of tobacco regulation and associated FDA programs | January 2012 |
| | *2010* | Identify population-based data available to begin assessing impact of tobacco control regulations, their impact on youth and adult access to and use of tobacco products | January 2011 |
| | *2009* | NA | NA |
| | *2008* | NA | NA |
| | *2007* | NA | NA |
| | *2006* | NA | NA |

| Measure | Data Source | Data Validation |
|---|---|---|
| 280001 | CTP's Office of Science | The data will be validated by the appropriate CTP offices and officials. |

**Long Term Objective:** Tobacco Product Scientific Standard Setting and Tobacco Product Review

| Measure | FY | Target | Result |
|---|---|---|---|
| 280002: Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. *(Output)* | *2011* | Select initial set of harmful ingredients and establish adequate testing methods | January 2012 |
| | *2010* | Identify potential set of harmful ingredients; establish criteria for evaluating testing methods | January 2011 |
| | *2009* | NA | NA |
| | *2008* | NA | NA |
| | *2007* | NA | NA |
| | *2006* | NA | NA |

| Measure | Data Source | Data Validation |
|---|---|---|
| 280002 | CTP's Office of Science | The data are validated by the appropriate CTP offices and officials. |

**Long Term Objective:** Compliance and Regulatory Activities

| Measure | FY | Target | Result |
|---|---|---|---|
| 280003: Increase compliance with tobacco product regulation by increasing the percentage of States and Territories with which FDA has developed a contract program to support the enforcement and public health goals of the 1996 rule to assure that retailers refuse sales of cigarettes and smokeless tobacco products to adolescents under the age of 18. *(Outcome)* | *2011* | 75% | January 2012 |
| | *2010* | 25% | January 2011 |
| | *2009* | NA | Baseline: 0% |
| | *2008* | NA | NA |
| | *2007* | NA | NA |
| | *2006* | NA | NA |

| Measure | Data Source | Data Validation |
|---|---|---|
| 280003 | CTP's Office of Regulations and Compliance | The data are validated by the appropriate CTP offices and officials. |

**Long Term Objective:** Tobacco Product Public Education and External Communications

| Measure | FY | Target | Result |
|---|---|---|---|
| 280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. *(Output)* | *2011* | Implement and refine education program directed to retailers and the general public, especially youth. | January 2012 |
| | *2010* | Develop education program directed to retailers and the general public, especially youth. | January 2011 |
| | *2009* | NA | NA |
| | *2008* | NA | NA |
| | *2007* | NA | NA |
| | *2006* | NA | NA |

| Measure | Data Source | Data Validation |
|---|---|---|
| 280004 | CTP's Office of Public Education and External Relations | The data are validated by the appropriate CTP offices and officials. |

**1. Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. (**280001**)**

**Context**: A major goal of the tobacco program will be implementing policies to protect the public health by reducing morbidity and mortality related to the use of tobacco products. FDA needs to conduct research and evaluation studies to better understand how marketing and advertising of tobacco products influences use of tobacco products by various sectors of the public; to evaluate the early impact of the tobacco regulations issued in 2009 and 2010; and to develop baseline measures to better assess the impact of later provisions in the statute. This may include research on the behavioral effects of industry marketing methods, the impact of governmental and other tobacco-use risk educational programs, and the

impact of minors' access to tobacco products, tobacco marketing restrictions, and smokeless warning labels. These studies may be funded through contracts, grants, interagency agreements, or contracts, grants, or cooperative agreements with other entities such as universities or private foundations.

**Performance:** This is a new performance goal; data will be available in FY 2012.

2. **Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. (**280002**)**

**Context**: FDA is authorized to conduct research in support of its regulation of tobacco products. This effort is supported by one of the requirements of the Tobacco Control Act, which beginning in FY 2010, requires regulated industry to submit information to FDA on all ingredients used in cigarettes and some other tobacco products. In order to begin the ongoing review of the population health effects of those ingredients and their impact on tobacco usage, FDA will need a substantial capacity to conduct laboratory research. In addition scientific information developed by FDA will be applied in developing ongoing controls for marketed products, such as Good Manufacturing Practices and inspection and testing procedures, and Tobacco Product Standards. FDA will also need scientific capacity to provide support for the future processes of reviewing applications for new tobacco products and products claimed to reduce the risks of tobacco use. While FDA may be able to provide some laboratory and research capability within the agency at the National Center for Toxicological Research and at some field laboratories (ORA), it is expected that a much larger capacity will be needed. Other public health agencies such as CDC and NIH clearly have the expertise and potential laboratory capacity to conduct research in many areas related to tobacco, and FDA is considering the possibility of utilizing the expertise of these Federal agencies as well as other expert scientific resources. FDA will implement research efforts using a potential combination of contracts, cooperative agreements, and inter-agency agreements, all funded from tobacco program funds. This work will inform future substantial equivalent tobacco product review activities, among other requirements of the Tobacco Control Act.

**Performance:** This is a new performance goal; data will be available in FY 2012.

3. **Increase compliance with tobacco product regulation by increasing the percentage of States and Territories with which FDA has developed a contract program to support the enforcement and public health goals of the 1996 rule to assure that retailers refuse sales of cigarettes and smokeless tobacco products to adolescents under the age of 18.** (280003)

**Context:** The Tobacco Control Act requires FDA to reissue a rule by March 2010 that incorporates specific portions of the 1996 rules on tobacco aimed at limiting access by youths under age 18 to purchase tobacco products, and also limiting marketing practices and advertising aimed at youths. This rule will take effect in June 2010. A key element in deterring youth access to tobacco, as it was under the 1996 rule, will be contracts with the States and Territories to conduct compliance checks to assure that retailers refuse sales of tobacco to adolescents under the age of 18. There are civil money penalties for illegally selling cigarettes or smokeless tobacco to minors. Ultimately, by reducing the sale, access, and allure of tobacco products to minors, this rule and its enforcement, as well as education and other efforts, will constitute a critical component of FDA's contributions to the overall HHS goals of reducing disease and deaths caused by tobacco products.

**Performance:** This is a new performance goal; data will be available in FY 2012.

4. **Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. (**280004**)**

**Context:** FDA's new authority to regulate tobacco products brings new transparency for the public about the ingredients, constituents, manufacturing and research processes for tobacco products, as well as about the risks associated with tobacco use. These new FDA authorities also mean new compliance requirements for those involved with the manufacture, distribution, marketing and sales of tobacco products. FDA's new Center of Tobacco Products (CTP) will develop a comprehensive educational

program that will help improve understanding and awareness among the industry, importers, retailers, health professionals, tobacco control groups, and the general public about the new regulations that FDA is implementing (and for the regulated industry, information on how to comply with these new requirements). FDA also plans to develop a broad program of tobacco control and prevention education and communications programs designed to reach the public with specific attention paid to as many racial, ethnic, cultural, and social elements of the population as possible. One of the primary ways to reduce the risks associated with tobacco use among youth is to increase educational efforts regarding the hazards of tobacco use, and specifically, to convey new information about tobacco product constituents, resulting from the information submitted to FDA by the industry and from the results of FDA's research activities. In FY 2011, FDA will continue its Stakeholder Discussion Series that began in FY 2010 to fully explore ideas and options for overarching principles for the implementation of the Tobacco Control Act and the establishment of more effective communications mechanisms between and among FDA and various stakeholder groups.

**Performance:** This is a new performance goal; data will be available in FY 2012.

# Headquarters and Office of the Commissioner Performance Detail

**Program:** Office of the Commissioner/ Office of International Programs
**Long Term Objective:** Enhance partnerships and communications.

| Measure | FY | Target | Result |
|---|---|---|---|
| 291301: The number of FDA foreign posts to increase collaboration with foreign counterparts. *(Outcome)* | *2011* | 17 | October 1, 2011 |
| | *2010* | 15 | October 1, 2010 |
| | *2009* | N/A | 12 foreign posts (Historical Actual) |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |
| 291302: The number of agencies who participate in the Regulators Forum of the International Conference on Harmonization. *(Outcome)* | *2011* | 14 | October 1, 2011 |
| | *2010* | 12 | October 1, 2010 |
| | *2009* | N/A | 10 (Historical Actual) |
| | *2008* | N/A | 6 (Historical Actual) |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 291301 | Internal Tracking, "Foreign Offices Approval Status" chart, which tracks the progress of steps involved in the approval process. | Foreign posts are considered established upon approval of the National Security Decision Directive (NSDD) 38. |
| 291302 | Regulatory Forums are invitation only events. An internal tracking system is used to record and monitor a list of invitees. | The meeting host records the names of attendees and reports this information as a part of the summary meeting report. |

**Program:** Office of the Commissioner/ Office of the Chief Scientist
**Long Term Objective:** Strengthen the scientific foundation of FDA's regulatory mission

| Measure | FY | Target | Result |
|---|---|---|---|
| 291101: Percentage of Fellows retained at FDA after completing the Fellowship program. *(Outcome)* | *2011* | Set target based on data from pilot evaluation | October 1, 2011 |
| | *2010* | Develop pilot evaluation of program | October 1, 2010 |
| | *2009* | N/A | N/A |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 291101 | FDA will develop an Internal Tracking System to track number of offers made to Fellows and number of Fellows that are hired. | FDA will utilize existing HR systems to validate the number of actual hires. |

**Program:** Office of the Commissioner/ Office of Critical Path Programs
**Long Term Objective:** Improve information systems for problem detection and public communication about product safety

| Measure | FY | Target | Result |
|---|---|---|---|
| 292202: Number of people for which FDA is able to evaluate product safety through miniature Sentinel*pilots. *(Outcome)* | *2011* | 70 million | October 1, 2011 |
| | *2010* | 55 million | October 1, 2010 |
| | *2009* | N/A | 35 million |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |
| 292203: Number of safety analyses that are conducted using Medicare and Medicaid SafeRx* project. *(Output)* | *2011* | 13 | October 1, 2011 |
| | *2010* | 10 | October 1, 2010 |
| | *2009* | N/A | 7 |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 292202 | Automated Healthcare databases from Federal Partners' Collaboration (i.e., CMS, DoD, VA)<br><br>Mini-Sentinel Pilot contractor (i.e., Harvard Pilgrim Health Care) automated Healthcare data from private sources (non-government) | Data validation is based on a review of the access to both publicly and privately available automated healthcare data. Participating Federal Partners will verify patient population numbers that are accessible for evaluation of safety signals. Harvard Pilgrim Health Care will verify patient population numbers accessible for evaluation of safety signals, to include all distributed partners within the contract. |
| 292203 | FDA Principal Lead for FDA-CMS Interagency Agreement to analyze safety signals from automated healthcare databases | Data validation is based on a review of the past period's activities and verification by the CMS Contracting Officer's Technical Representative (COTR) that verifies workload on ongoing basis to monitor funding provided by FDA to CMS for this collaborative safety project. FDA provides guidance on which safety signals to investigate and collaboratively reviews the data. |

**Program:** Office of the Commissioner/ Office of Orphan Product Development
**Long Term Objective:** Increase the number of safe and effective new medical products available to patients

| Measure | FY | Target | Result |
|---|---|---|---|
| 293201: The total number of decisions on applications for promising orphan drug and humanitarian use device designations. *(Output)* | *2011* | 312 | October 1, 2011 |
| | *2010* | 290 | October 1, 2010 |
| | *2009* | N/A | 269 (Historical Actual) |
| | *2008* | N/A | 205 (Historical Actual) |
| | *2007* | N/A | 201 (Historical Actual) |
| | *2006* | N/A | 195 (Historical Actual) |
| 293202: The number of medical devices facilitated in development by the new Pediatric Device Consortia Grant Program. *(Output)* | *2011* | 1 | October 1, 2011 |
| | *2010* | 1 | October 1, 2010 |
| | *2009* | N/A | N/A |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 293201 | The data will be pulled from the OPD data base, which is updated daily. | Every decision has a written and signed document that is scanned into the data base; the original is filed and can be retrieved by hand. |
| 293202 | Each pediatric device consortia grantee submits a quarterly report that provides a description of the medical devices they are facilitating in development. | The OPD grant officers will monitor the grants and follow-up with the grantees to validate the information provided in the quarterly reports. |

**Program:** Office of the Commissioner/ Office of Pediatric Therapeutics
**Long Term Objective:** Enhance partnerships and communications.

| Measure | FY | Target | Result |
|---|---|---|---|
| 293203: Number of pediatric scientific and ethical issues identified through collaboration with the 27 European Union countries coordinated with the EMEA. *(Output)* | *2011* | 10 | October 1, 2011 |
| | *2010* | 10 | October 1, 2010 |
| | *2009* | N/A | 10 (Historical Actual) |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 293203 | Nvivo 8 Software, which is maintained by OPT, is used to track the monthly exchange of pediatric information between FDA and the European Medicine Agency (EMA). The information tracked includes the number of Pediatric Investigational Plans (PIPs) received from EMA, the number of PIPs for which OPT provided information to EMA and the number of PIPs and general topics discussed. Since Nvivo is text-based software, it also captures and stores FDA's and EMA's background information for each product discussed at the monthly exchanges. This background information is obtained from various FDA databases, such as DARRTS, and from EMA's Summary Reports. Following each monthly exchange, notes are written to capture the scientific and ethical issues discussed. | Quality control of the Nvivo 8 Software is performed, which includes identification of duplicate reports, to assure reliability of the data. |

**Long Term Objective:** Provide patients and consumers with better access to clear and timely risk-benefit information for medical products

| Measure | *FY* | Target | Result |
|---|---|---|---|
| 293204: Number of new medical products studied in children, labeling changes and safety reviews completed. *(Output)* | *2011* | 30 | October 1, 2011 |
| | *2010* | 25 | October 1, 2010 |
| | *2009* | *N/A* | 21 (Historical actual) |
| | *2008* | *N/A* | 12 (Historical Actual) |
| | *2007* | *N/A* | 12 (Historical Actual) |
| | *2006* | *N/A* | 13 (Historical Actual) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 293204 | Drug and Biologic Product labeling that relate to pediatrics are posted on the FDA OPT website http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/UCM163159.pdf<br><br>Listing of products with safety reporting to the Pediatric Advisory Committee (PAC) meetings is also updated on the OPT link http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm123229.htm | All FDA drug and biologic products that receive new Pediatric Labeling changes are tracked and listed by the date of labeling change.<br><br>The list of labeling dates is reviewed by OPT personnel on a regular basis, 1-2 times a month, to track and determine the dates for mandated safety reviews to the PAC to occur within 2 years from date of labeling change.<br><br>Full listing of products with safety reporting to the PAC are updated after each PAC on the website with links to the meetings and background materials. |

**Program:** Office of the Commissioner/ Office of Combination Products
**Long Term Objective:** Improve the medical product review process to increase the predictability and transparency of decisions using the best available science

| Measure | FY | Target | Result |
|---|---|---|---|
| 293205: Percentage of requests for Designations processed within the 60 day statutory requirement. *(Output)* | *2011* | 95% | October 1, 2011 |
| | *2010* | 95% | October 1, 2010 |
| | *2009* | *N/A* | 100% (Historical Actual) |
| | *2008* | *N/A* | 100% (Historical Actual) |
| | *2007* | *N/A* | 100% (Historical Actual) |
| | *2006* | *N/A* | 100% (Historical Actual) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 293205 | OCP's internal tracking database | For every RFD submitted to OCP, the tracking database records the receipt date, the RFD filing and the date that the final decision is issued. Based on these dates, the tracking database calculates the number of days that OCP spent processing the RFD. The dates generated are compared against the 60 day statutory requirement of issuing a decision after filing. OCP's established administrative processes and procedures for RFDs ensure quality of the data. First, quality of the data is maintained through the issuance of dated letters to the submitter. When an RFD is filed, a letter is sent to the submitter informing them of the filing date. When a final decision is made, a designation letter is also sent to the submitter informing them of the final Agency's determination. As such, if there is any discrepancy on these dates, the submitter will contact OCP and inform us of the potential error. Second, OCP manually checks, upon filing, the dates generated by the tracking database to ensure that the dates have been calculated correctly. If appropriate, the office will take the necessary steps to correct any error to make sure that the information contained in the database is accurate. |

**Program:** Office of the Commissioner/ Office of Special Health Issues
**Long Term Objective:** Provide patients and consumers with better access to clear and timely risk-benefit information for medical products

| Measure | FY | Target | Result |
|---|---|---|---|
| 292301: The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. *(Output)* | *2011* | 3 | October 1, 2011 |
| | *2010* | 2 | October 1, 2010 |
| | *2009* | N/A | 1 (Historical Actual) |
| | *2008* | N/A | N/A |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 292301 | Office of Special Health Issues Strategic Planning Assessments | The number of new multi-faceted educational programs are measured through the OSHI annual strategic planning efforts, where completed and ongoing projects are reviewed and the upcoming year's projects are prioritized. OSHI determines if the multi-faceted educational programs are carried out by using a monthly internal staff survey to capture the separate components of the programs (i.e. webinars, CME programs, journal articles, etc.). This information is summarized and assessed on a quarterly basis as part of the FDA-TRACK program. Both the primary data source (OSHI strategic planning assessments), and the secondary data source (FDA-TRACK monthly surveys), are compared to validate the data. |

**Program:** Office of the Commissioner/ Office of Women's Health
**Long Term Objective:** Enhance partnerships and communications.

| Measure | FY | Target | Result |
|---|---|---|---|
| 294201: Number of site visits of Office of Women's Health-funded investigators (multiple year recipients) conducting laboratory-based research. *(Output)* | *2011* | 7 | October 1, 2011 |
| | *2010* | 5 | October 1, 2010 |
| | *2009* | N/A | 4 (Historical Actual) |
| | *2008* | N/A | 4 (Historical Actual) |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |
| 291303: The number of collaborations and partnerships to maximize Outreach activities. *(Output)* | *2011* | 350 | October 1, 2011 |
| | *2010* | 300 | October 1, 2010 |
| | *2009* | N/A | 250 (Historical Actual) |
| | *2008* | N/A | 250 (Historical Actual) |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 294201 | Office of Women's Health Internal ACCESS data base | Data is validated for these performance goals through the Unified Financial Management System (UFMS) and Gov Trip |
| 291303 | Office of Women's Health internal ACCESS data base | Data is validated from several sources for these performance goals including the Federal Procurement Data System (FPDS), the Unified Financial Management System (UFMS) |

**Program:** Office of the Commissioner/ Office of Financial Management
**Long Term Objective:** Strengthen FDA's base of operations

| Measure | FY | Target | Result |
|---|---|---|---|
| 291402: FDA's implementation of HHS's Unified Financial Management System (UFMS). *(Efficiency)* | *2011* | Expand FDA's reporting capabilities; define the TO-BE UFMS processes and a comprehensive training program. | September 2011 |
| | *2010* | Continue OBI dev., UFMS 2010 initiatives (To be defined), improve AS-IS UFMS processes to gain transparency, agility and efficiency and in the process address deficiencies in the areas of SOD violations and other control deficiencies. | September 2010 |
| | *2009* | Begin migration to version 11-5-10 of ORACLE Federal Financials | UFMS was successfully upgraded to 11.5.10 for all OPDIVS. |
| | *2008* | Stabilize UFMS environment Explore/ analyze effects of moving to a later version of ORACLE Federal Financials | All HHS OPDIVS are now in UFMS production. Stabilization for IHS is underway (Target Met) |
| | *2007* | Finalize decision on an activity-based costing application and make it operational for its user fee programs | Finalized the decision on an activity-based costing application and made it operational for its user fee programs. (Target Met) |
| | *2006* | Pilot activity-based costing application for PDUFA FDA's legacy core financial system decommissioned | Goal accomplished through various activities discussed under Performance text (Target Met) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 291402 | FDA Office of Management & Systems, 2001 FAIR Act Inventory. The agency will rely on the data from the Federal Procurement Data System (FPDS). The sources encompassed in the General Ledger & Federal Administrator, the Purchasing & Accounts Payable; and the Accounts Receivable. These sources are being prepared to transition to the Financial Business solutions systems. | FDA will ensure consistency in the tracking and reporting of the administrative management performance goals. In addition, FDA is taking steps to routinely monitor this data and take appropriate actions as needed. Data is from a variety of sources for these performance goals including the Annual Chief Financial Officer's Report, Civilian and Commission Corps personnel databases, monthly and annual full-time equivalent (FTE) reports and data-runs, the FDA FAIR Act Inventory and the FY 2001 FDA Workforce Restructuring Plan, monthly statements from bank card companies and the FDA Small Purchase System. |

**Program:** Office of the Commissioner/ Office of Management
**Long Term Objective:** Strengthen FDA's base of operations

| Measure | FY | Target | Result |
|---|---|---|---|
| 291403: Number of Business Process Improvement Projects supported through start of Implementation. *(Output)* | *2011* | 17 | October 1, 2011 |
| | *2010* | 15 | October 1, 2010 |
| | *2009* | N/A | 13 (Historical Baseline) |
| | *2008* | N/A | 10 (Historical Baseline) |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 291403 | FDA will rely on data obtained, analyzed and maintained through contract services. | FDA will ensure consistency in the tracking and reporting of business process improvement performance goals. Upon award of contract, Contractor will assist FDA in monitoring and meeting performance goals. Data will be gathered through a variety of sources which may include agency databases, reports, interviews and surveys. |

**Program:** Office of the Commissioner/ Office of Information Management
**Long Term Objective:** Strengthen FDA's base of operations

| Measure | FY | Target | Result |
|---|---|---|---|
| 291404: Percentage of servers that are high efficiency energy star compliant. *(Output)* | *2011* | 95% | October 1, 2011 |
| | *2010* | 50% | October 1, 2010 |
| | *2009* | N/A | 25% (Historical Actual) |
| | *2008* | N/A | 5% (Historical Actual) |
| | *2007* | N/A | 0% (Historical Actual) |
| | *2006* | N/A | 0% (Historical Actual) |
| 291405: Percentage of application availability during non-scheduled, emergency outages. *(Output)* | *2011* | 99.9% | October 1, 2011 |
| | *2010* | 98% | October 1, 2010 |
| | *2009* | N/A | 95% (Historical Actual) |
| | *2008* | N/A | 95% (Historical Actual) |
| | *2007* | N/A | N/A |
| | *2006* | N/A | N/A |

| Measure | Data Source | Data Validation |
|---|---|---|
| 291404 | The FDA will use power consumption levels prior to and after migration to the new servers in addition to number of physical vs. virtual servers. | Due to the lack of power sub-metering in the agency's current primary Parklawn facility (decommissioning in the summer of FY2010), the agency will calculate current power consumption based on "faceplate" figures. Reduction in power will be validated with sub-metered power figures at the new facilities. Further validation will be provided via pre- and post-migration physical and virtual server count comparisons. Equipment purchased or leased under current contracts must be Energy Star compliant where applicable. For CJ 2011, 95% of new |
| 291405 | Server utilization reports from automated data center server monitoring provide statistics regarding the availability of the servers that provide access to applications. | This is validated via outage reports provided by FDA users. |

**Program:** Office of the Commissioner/ Office of Crisis Management
**Long Term Objective:** Improve information systems for problem detection and public communication about product safety.

| Measure | FY | Target | Result |
|---|---|---|---|
| 292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)* | *2011* | Enhance FDA's Consumer Complaint Reporting System to provide a more efficient means of reviewing and processing reports involving FDA regulated products; expand the geospatial capabilities of EON IMS to increase usage during incident response and recovery by 25%. | September 2011 |
| | *2010* | Pilot EON IMS data sharing with Federal and State counterparts. Enhance surveillance and detection capabilities within the Office of Emergency Operations. Revise and exercise FDA's Emergency Operations Plan and provide training on the plan and annexes. Coordinate participation in inter-agency work-groups, and implement an Agency-wide National Incident Management System (NIMS) plan | September 2010 |
| | *2009* | Continued enhancement of EON IMS and GIS capabilities. Coordinate FDA's participation in exercises and interagency work-groups, update remaining emergency response plans, and develop an Agency-wide National Incident Management System (NIMS) implementation plan. | EON IMS Version 3.3.4 implemented Aug 09. Includes a web-based portal for regulated industry; state and local health officials to submit reports of potentially harmful food as required by the Food & Drug Administration Amendment Act of 2007 (FDAAA). OCM updated the FDA Emergency Response Plan, 3 incident-specific emergency response plans and created a draft FDA NIMS Implementation Plan and agency Incident Command System (ICS) structure. (Target Met) |

| Measure | FY | Target | Result |
|---|---|---|---|
| 292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)* | *2008* | Continued enhancement of EON IMS increased knowledge mgmt and GIS capabilities. Test FDA emergency response plan for pandemic flu and coordinate FDA's participation in other exercises and workgroup. | EON IMS Version 3.3 implemented Aug 08. Includes significant enhancements to further its knowledge mgmt and GIS capabilities. FDA-wide Incident Command System (ICS) training conducted for Head-quarters and field offices. Finalized Pandemic Influenza Emergency Response Plan and began planning an FDA Pandemic Influenza Exercise for Oct 2008. (Target Met) |
| | *2007* | Continue Enhancement EON IMS Coordinate FDA's participation in exercises, including TOPOFF 4 Develop an FDA emergency response plan for pandemic influenza | EON IMS version 3.2.1 implemented December 2007 and used in the preparation and response to natural disasters and crises and emergencies. FDA emergency response plan for pandemic influenza developed Sept 2007. (Target Met) |
| | *2006* | Enhance functionality and continue deployment of the EON IMS through out the Agency (HQ, Centers, Field offices) | EON IMS Version 2.4 August 06. deployed to OCM/ OEO located in FDA field offices and used to prep and respond to emergencies (Target Met) |

| Measure | Data Source | Data Validation |
|---|---|---|
| 292201 | Office of Crisis Management Emergency Operations Network Incident Management System (EON IMS) and Field Data Systems | Data validation is based on a review of the past period's activities and the Emergency Operations Network Incident Management System plan and schedule. The percentage increase over FY2010 baseline will be based on the number of maps created for use during incident response and recovery. Improved accuracy and completeness of complaint data entered into FACTS for OCM/OEO review and processing. |

**1. The number of FDA foreign posts to increase collaboration with foreign counterparts.** (291301)

**Context:** The foreign posts will allow FDA to work more closely with its foreign counterparts to help ensure the safety and quality of FDA-regulated products. The activities of these offices include, gathering information on product manufacturing and transport, leveraging scientific and inspectional resources, working with third parties to assist in ensuring compliance, and providing technical assistance to increase the capacity of selected counterpart agencies.

**Performance:** In FY 2009, we established 12 FDA overseas posts and staffed 9 of those posts in China (Beijing, Shanghai, and Guangzhou), India (New Delhi and Mumbai), Europe (Brussels and London), and Latin America (San Jose and Santiago). In FY 2010, we plan to staff the 3 posts established but not staffed in FY2009 in Parma, Mexico City and Amman, and establish 3 additional overseas posts. In FY 2011, we plan to staff the 3 posts established but not staffed in FY2010, and establish 2 additional

overseas posts. Establishing the 2 additional overseas posts in FY2011 is dependent upon receiving the additional user fee funding as requested.

**2. The number of agencies who participate in the Regulators Forum of the International Conference on Harmonization.** (291302)

**Context:** FDA will work to increase the participation of counterpart agencies in the ICH Regulators Forum, which should hasten the implementation of the ICH-adopted harmonized guidelines for the regulation of drugs and biologics. These activities will increase consumer protection by improving the safety and quality of FDA-regulated products produced in other areas of the world. In FY 2010 we plan to work to have 2 additional agencies present per meeting, for a total of 12 agencies present at these meetings. In FY 2011, we plan to add an additional 2 additional agencies present per meeting, for a total of 14 agencies.

**Performance:** In FY 2009 there were 4 additional agencies (outside the routine ICH partners from Europe, the US, Japan, Canada, Switzerland, and WHO) present at these meetings.

**3. Percentage of Fellows retained at FDA after completing the Fellowship program.** (291101)

**Context:** The Commissioner's Fellowship Program was initiated in the fall of 2008 and is a two-year program designed to train a cadre of highly accomplished scientists in FDA regulatory science across devices, drugs, biologics, foods, and cosmetics. The Commissioner's Fellowship Program brings highly motivated and promising individuals to FDA where they will contribute to and learn regulatory science and policy, enriching both their careers and FDA's capacity. The Fellows will be outstanding candidates recruited from academia, industry, and other governmental agencies. They will learn about FDA's core mission, review processes, policies, and scientific and public health challenges, be supported in their professional development, and engage with a senior mentor in specific high priority projects directly related to FDA's public health mission. In a successful program, many Fellows will remain at FDA after completing their program; others will carry an understanding of FDA with them in their future careers. In FY 2012, a target for the percentage of Fellows retained will be established based on a planned evaluation program that will be developed and executed in FY 2011.

**Performance:** The Fellowship Program is new; 50 fellows started the 2 year Program in the fall of 2008, and 50 more will begin in fall of 2009. In FY 2010, we will undertake a pilot evaluation of the Program to determine quality of the Program, and the quality of the candidates and Fellows. (This evaluation will be a pilot, because there will only be one cohort of Fellows to review at that point, so there will be little data on the percentage hired and how they are performing as permanent employees. We will also need to pilot the evaluation instrument.). A full formal evaluation will be performed in 2011 and regularly thereafter. As part of this evaluation, we will determine appropriate hiring targets for the Program, and include these as the targets for 2012 and later years.

**4. Number of people for which FDA is able to evaluate product safety through multiple miniature Sentinel pilots.** (292202)

**Context:** The goal of the ***Sentinel Initiative*** is to create a national, integrated, electronic system (the Sentinel System) for monitoring medical product safety. FDAAA sets a goal of access to 25 million people by July 2010 and 100 million by July 2012 to monitor product safety. The System, which will be developed and implemented in stages, will ultimately enable FDA to leverage the capabilities of multiple, large databases (e.g., electronic health record systems, medical claims databases) to augment the Agency's existing safety monitoring capability. As currently envisioned, Sentinel will facilitate targeted queries, within the bounds of established privacy and security safeguards, across large remote data systems and be scalable to enable small or large queries using broad or narrowly focused data. Sentinel, ultimately, will expand and strengthen FDA's ability to monitor the performance of a product throughout its entire life cycle and facilitate data mining and other research-related activities. Consistent, dedicated funding will be required; estimates are approximately $30M per year.

**Performance:** A miniature sentinel using private-sector data is expected to be up and running in early FY 2010, with the ability to query safety data in accordance with strict privacy and security safeguards on as many as possibly 60 million people. With the addition of a collaborative project with Federal partners, expectations are to be able to almost double current access by late FY 2011.

**5. Number of safety analyses that are conducted using Medicare and Medicaid data through the SafeRx Project.** (292203)

**Context:** Several projects are under way using Medicare and Medicaid data that are testing the ability to analyze safety on FDA-regulated products. The SafeRx project is using Medicare and Medicaid data to perform in-depth safety analyses. Analyses involve many types of active surveillance and epidemiology methodologies, which may last many months. Each analysis enables experts to test and evaluate tools necessary to perform almost real-time surveillance and also more thorough epidemiology studies.

**Performance:** Performance of safety analyses is expected to expand from 7 in 2009 to 10 in 2010 to 13 in 2011.

**6. The total number of decisions on applications for promising orphan drug and humanitarian use device designations.** (293201)

**Context:** FDA has a public health mission, as mandated by the Orphan Drug Act of 1983, and the Safe Medical Devices Act of 1990, to provide incentives for the development of promising new drugs and medical devices, respectively, for people with rare diseases and conditions, which is estimated to be more than 25 million people in the United States. The measure is an indication of the amount of progress by drug and medical device sponsors in getting an eventual market approval for these promising orphan products. OOPD does a significant amount of outreach to increase awareness of the statutory incentives and grants programs, and assists sponsors in moving promising products towards market approvals. The OOPD has a grant programs to promote clinical research studies for promising orphan products (drugs, biologics, medical devices, and medical foods) and another grant program to promote the development of pediatric medical devices.

**Performance:** In FY 2008, OPD made an estimated 192 decisions on orphan drug designation applications and 13 decisions on humanitarian device designation applications. In FY 2009, through August 20, 2009, OPD has made an estimated 222 decisions on orphan drug designation applications and 23 decisions on humanitarian device designation applications. In FY 2010, OPD expects to achieve the FY 2009 totals, and increase this amount by 10 percent in FY 2011.

**7. The number of medical devices facilitated in development by the new Pediatric Device Consortia Grant Program**

**Context:** The goal of the statutory Pediatric Device Consortia Grant Program is to promote pediatric device development, which as lagged far behind the development of device technology for adults. The Pediatric Device Consortia grants facilitate the development of needed medical devices for children. According to statute, the consortia will facilitate the development, production, and distribution of medical devices for children by: (1) Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers; (2) Mentoring and managing pediatric device projects through the development process, from concept formation, to prototype development, to clinical development, to marketing; (3) Connecting innovators and physicians to existing Federal and non-Federal resources for funding of device development; (4) Assessing the scientific and technical merit of proposed pediatric device projects; and (5) Providing assistance as needed on business development, personnel training, prototype development, post-market and other activities.

**Performance:** This is a new performance metric for a newly established program so there are no previous results to report. We anticipate that we will facilitate the development of 1 new pediatric device in FY 2010 and in FY 2011.

**8. Number of pediatric scientific and ethical issues identified through collaboration with the 27 European countries coordinated with the EMEA.** (293203)

**Context:** The goal of our international collaborations is to prevent children from becoming a global commodity by conducting trials of the highest ethical and scientific rigor and decreasing their risk. This involves intense coordination of hundreds of protocols being submitted to the various agencies for identification of potential problems/issues. At present, OPT coordinates at least monthly teleconference exchanges between FDA (CDER and CBER) and the European Medicines Agency (EMEA). Issues identified at each of these monthly teleconferences pertain to safety, clinical trial design, endpoints or ethics. These issues are ones that require additional collaboration. An example of an issue pertains to heart safety concerns with a product (Aplidin), which is under investigation to treat a specific cancer in children (neuroblastoma). OPT identified this issue and invited all involved parties to a discussion of this issue, which resulted in additional safety monitoring by EMEA. In the future, we hope to expand the number of countries and collaborations to include Japan, Canada and PAHO.

**Performance:** The exchange of scientific information between FDA and the European Medicines Agency began in September 2007 and by July 2009, information has been exchanged for over 400 products. Of these, 168 products have been discussed at monthly teleconferences. Ten scientific/ethical issues requiring further discussion or oversight were identified in FY 2008 and in FY 2009. We project identification of 10 additional issues in FY 2010 and 10 in FY 2011.

**9. Number of new medical products studied in children, labeling and safety reviews completed.** (293204)

**Context:** The Office of Pediatric Therapeutics has been statutorily charged by Congress to report to the Pediatric Advisory Committee (PAC) all adverse events for products studied under the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). Originally, the mandate applied to drugs granted pediatric exclusivity under the Best Pharmaceuticals for Children Act (BPCA). FDAAA 2007 expanded the mandate to include drugs receiving a pediatric labeling change under BPCA, as well as drugs and biologicals under the Pediatric Research Equity Act (PREA) and pediatric devices that receive a Humanitarian Device Exemption (HDE). As a result, OPT has assumed greater responsibility and workload for safety reviews and public reporting and vetting of adverse events. In addition, OPT works with all involved FDA and external constituents to facilitate and enhance pediatric studies in order to obtain additional labeling information on efficacy, safety and dosing for children. Furthermore, OPT tracks and publicly posts the updated safety information for product labeling as well as the PAC recommendations and actions taken. An example of an important pediatric drug safety review that led to new labeling was that for ADHD products, Concerta and Adderall XR, where additional safety information to include psychiatric adverse events was added to labeling. In FY 2010, the target is 25, and in FY 2011, the target is 30 new medical products studied in children.

**Performance:** The number of new medical products studied in children, labeling changes and safety reviews completed under the Congressionally mandated pediatric legislation, BPCA and PREA, are: FY 2006: 12; FY 2007: 17; FY 2008: 17; FY 2009: 21.

**10. Percentage of requests for Designations processed within the 60 day statutory requirement.** (293205)

**Context:** By statute, OCP determines the classification and assignment of a drug, device, biological product and combination product. Under 21 CFR Part 3, an RFD (request for designation) is the regulatory vehicle used for that purpose. As technology advances, sometimes product classification and assignment is unclear. A company submits an RFD requesting a formal determination from OCP. The RFD determination made by OCP is a legally binding action that also identifies such things as the key governing regulations, the center/OCP contacts for next steps. In so doing, this should assist developers by decreasing uncertainty and allowing the firm to move directly to their next development steps. The FY 2010 and 2011 targets are set at 95% processed within the 60 days requirement.

**Performance:** In FY 2008, 39 total combination and non-combination product assignments were issued by OCP, all within the 60-day time frame (100%). Over half (22 of 39) of product assignment requests were determined to be combination products. Of the 22 combination product assignments issued, 19 combination products were determined to be drug-device combinations, 2 were device-biologic combinations, and 1 was a drug-biologic combination. The remaining (17 of 39) product assignment requests were determined to be non-combination product assignments. Of the 17 non-combination product assignments issued, 8 were determined to be drugs, 3 were devices, and 6 were biologics/tissues.

In FY 2009, a total of 30 requests for designation were active. Of these, 16 were not eligible for determination, i.e., 9 were withdrawn by the sponsor prior to issuance of an FDA decision and 7 were pending but not overdue at the end of FY 2009. Of the remaining 14 requests that were eligible for determination, 14 (100%) were processed within the 60-day statutory requirement. Over half (9 of 14) of product assignment requests were determined to be combination products. Of the 9 combination product assignments issued, 6 combination products were assigned to CDER, 2 were assigned to CDRH, and 1 was assigned to CBER. The remaining (5 of 14) product designation requests were determined to be non-combination products. Of the 5 non-combination product designations issued, 3 were determined to be drugs, and 2 were devices. The OCP annual report to Congress on these results will be issued in FY2010.

**11. The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues.** (292301)

**Context:** Multi-faceted educational programs for patient advocates and health professionals are important ways for these groups to understand FDA's role and decision-making process on issues that are critical to them. Meetings and workshops allow FDA and participants to engage actively in dialogue, ask questions, and provide feedback on important aspects that might be unknown to each side. Web-based webinars, accredited continuing education modules, and written journal or newsletter articles allow patients and health professionals to more deeply explore and understand the far-reaching impact of the issues with which FDA grapples to protect the public health.

**Performance:** In FY 2009 FDA developed one educational program on opioid REMS which consisted of an educational workshop; a webinar; four educational meetings with patient advocates and health professionals; and an article published in a health professional newsletter. For FY 2010, OSHI plans to develop two multi-faceted educational programs on topics such as expanded access and issues related to medical product safety (e.g., pharmacy curriculum on the science of safety, REMS, safe use of glucose meters). In FY 2011, OSHI will develop one additional educational program on significant public health issues yet to be determined. At the conclusion of FY 2011, OSHI plans to have a total of 3 multi-faceted educational programs.

**12. Number of site visits of Office of Women's Health-funded investigators (multiple year recipients) conducting laboratory-based research.** (294201)

**Context:** Site visits are an integral part of the FDA OWH Research & Development Program. They ensure that the research that investigators have proposed is being conducted as originally planned and to the highest scientific and ethical standards and that the funds received in this competitive scientific awards program are being appropriately used towards the intended scientific goal and that appropriate spending plans are in place.

**Performance:** In FY 2009, OWH made 4 site visits to facilities conducting OWH-funded laboratory-based research. In 2010, OWH anticipates increasing the number of site visits to 5 depending on the funding of lab based studies that are submitted and approved for funding. OWH further anticipates increasing the site visits from the projected total of 5 site visits in 2010 to 7 total site visits in 2011.

**13. The number of collaborations and partnerships to maximize Outreach activities.** (291303)

**Context:** Partnerships & collaborations are an integral part of the FDA OWH Outreach Program. OWH creates easy to read, concise, and credible consumer health materials about FDA regulated products such as medications, LASIK surgery, HPV vaccine, and mammography, among others. These materials are

focus group tested, available in English and Spanish, and readily available for download from the FDA website. Through a variety of partnerships and collaborations, the penetration of the OWH publications in the community is expanded. These partnerships will help maximize the offices' collaboration efforts and educational program outcomes by reaching new audiences through these new partnerships through linking directly to the FDA OWH website and drive traffic from their websites to FDA OWH for consumer health information. Giving women health information empowers them to have discussions with their medical practitioner and enables them to make wise decisions for themselves and their families.

**Performance:** OWH developed 250 partnerships during Fiscal Years 2006 and 2007 maintaining these partnerships through 2008. OWH anticipates increasing its existing partnerships from 250 as identified in 2009 to 300 partnerships in 2010. OWH further anticipates increasing its partnerships in 2011 by an additional 50 reaching a total of 350 established partnerships by the end of 2011.

**14. FDA's implementation of HHS's Unified Financial Management System (UFMS).** (291402)

**Context:** The Department announced in FY 2001 that it intended to establish a unified financial management system to replace its operating division's individual financial management systems. The goal of the UFMS project is to reduce costs, mitigate security risks, and provide timely and accurate information across DHHS. FDA, CDC, NIH, and the Program Support Center (which covers the remaining components other than CMS and its contractors) began the design of the UFMS. Although this goal had originally been dropped after FDA had implemented UFMS, FDA has continued to be involved in the implementation of the UFMS system across the Department. A new FY 2008 target has been added based on FDA's efforts to stabilize the UFMS environment now that all OPDIVS have gone live, and to explore/analyze the effects of moving to a later version of ORACLE Federal Financials, bringing DHHS one step closer to FMFIA compliance. In FY 2009 the Department will migrate to Oracle Federal Financials version 11-5-10 and also implement iProcurement and PRISM as the global solutions for requisitioning and acquisitions.

**Performance:** UFMS has been fully implemented in FDA. Because UFMS is an integrated system and all OPDIVs must share it, FDA remains involved and participates in all future phased implementations of other OPDIVs in the Department. As such, in FY 2006, we participated in the Program Support Center's phased implementation of UFMS and did so again in FY 2007 for Indian Health Services (which went live on October 1, 2007). In FY 2008, FDA is stabilizing the UFMS environment and exploring/analyzing the effects of moving to a later version of ORACLE Federal Financials. . In FY 2009, FDA Upgraded to UFMS Release 4.1 (Oracle 11.5.10.2) and completed several O&M 2009 initiatives successfully including, AFPS Interface Enhancements, Grants Management, FDA Go Live with PMIS Interface, PO Mass Cancellation, Audit Portal Migration, Cash Management, Smart Pay II, User Provisioning Automation V 1.5 and Supplier Management Automation. In 2009 UFMS also had 3 Point Releases that it used to deploy some of these initiatives and other enhancements and brake fixes. Also several Oracle Security and Performance Patches were and continue to be deployed to make UFMS compliant with Federal and business standards. Plans for FY 2010 include continue OBI development work with a planned Beta deployment in 2010, complete deployment of the Supplier Management Automation Program and other UFMS 2010 initiatives (Performance Assessment and Business Availability, OCI Tactical and Strategic Enhancements, Improve CAN Realignment and Improve Year End CAN Management), continue documentation and improvements of the e2e AS-IS UFMS processes to gain transparency, agility and efficiency and in the process address deficiencies in the areas of SOD violations and other control deficiencies.

**15. Number of Business Process Improvement Projects supported through Implementation.** (291403)

**Context:** OM coordinates with the FDA Centers and Offices to drive performance improvement using formal Business Process Improvement techniques focusing on achieving better results; efficient use of resources and enabling better management. OM has been instrumental in improving FDA business processes and is responsible for analyzing various agency processes and facilitating the implementation of agency approved recommendations for process improvements.

Examples of efforts underway include:

- Improvement of the cross-center Drug Inspectorate process by augmenting the current 11 Level Three drug inspectors with an additional 56 in 2010 and another 63 in 2011 to better enhance the FDA's mission of promoting and protecting public health.
- Improvement of CBER's Managed Review Process by improving review team tools and addressing database issues affecting data capture to enhance the quality and efficiency/effectiveness of submission reviews.
- Improvement of ORA's High Throughput Labs process by boosting performance of the network based around the sample flow and assignment to labs, analyst productivity, performance metrics, case reporting and data management.

**Performance:** To date, a total of 18 core operational processes have been studied. Of the 18, thirteen process improvement projects are in various stages of implementation. Ten began implementation in FY 2008 and three began implementation in FY 2009. Three projects reached completion. In FY 2010 we plan to support through the start of implementation two of the operational processes studied and in FY 2011 we will support another two of the operational processes through the start of implementation.

**16. Percentage of servers that are high efficiency energy star compliant.** (291404)

**Context:** FDA's server environment is outdated. FDA will replace current outdated data center servers with high efficiency energy star compliant servers for applications supporting the regulatory mission of the FDA. This will enable the FDA the agility to collect, store, analyze large volumes of regulatory, scientific, and risk based information from multiple internal and external sources promoting pro-active decisions and timely responses to issues impacting the Public Health.

**Performance**: The FDA began purchasing high efficiency energy star compliant servers in 2008 and replaced approximately 5% of the server environment by the end of FY2008 with the high efficiency energy star compliant servers. By the end of FY 2009, 25% of the server environment was replaced with high efficiency energy star compliant servers. By the end of FY 2010, 50% of the server environment will be high efficiency energy star compliant servers and by the end of FY 2011, 95% of the environment will be high efficiency energy star compliant servers.

**17. Percentage of application availability during non-scheduled, emergency outages.** (291405)

**Context:** OIM must ensure that critical systems (i.e., Prior Notice, drug registry, etc.) are available 24x7 in order to carry out the mission of the FDA; reducing the risk of adulterated, misbranded or unapproved food and medical products entering commerce.

**Performance:** The FDA currently provides 95% availability to customers to utilize mission critical applications. This percentage is based on non-scheduled emergency outages. By the end of FY 2010, FDA is targeting 98% availability to customers to utilize mission critical applications and by the end of FY 2011, FDA is targeting 99.9% availability to customers to utilize mission critical applications.

**18. Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products.** (292201)

**Context:** FDA's Office of Crisis Management (OCM), which includes the Office of Emergency Operations and Office of Security Operations, is charged with meeting the DHHS goal to improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with the requirements of the National Response Plan, National Incident Management System and several Homeland Security Presidential Directives (HSPD), including HSPD-5, "Management of Domestic Incidents," HSPD-8, "National Preparedness," and HSPD-9, "Defense of United States Agriculture and Food." In FY 2009, FDA will continue to enhance the Emergency Operations Network Incident Management System (EON IMS) and Geographic Information System (GIS) capabilities and continue to coordinate FDA's participation in exercises and work-groups, including National Level Exercises (NLEs).

**Performance:** In FY 2009, designed, developed and implemented production system version 3.3.4 of the Emergency Operations Network Incident Management System (EON IMS) to establish a web-based portal for regulated industry; state and local health officials to submit reports of potentially harmful food as required by the Food & Drug Administration Amendment Act of 2007 (FDAAA). The FDA Office of Crisis Management/Office of Emergency Operations uses the EON IMS to assist in the coordination and strategic management of FDA's response to numerous incidents regarding FDA regulated commodities, including outbreaks, natural disasters, and actual or potential product defects that pose a risk to human or animal health; e.g.; melamine contaminated pet food, peanut butter contaminated with salmonella, and botulism in chili sauce. OCM used the mapping capabilities of EON IMS to generate geo-coded maps to support preparedness efforts for the 2009 hurricane season, response activities related to outbreaks involving salmonella in imported produce, flooding in the mid-west, and wildfires and earthquakes in California. EON IMS has also been used to support preparedness exercises that have included international, federal, state and local partners. OCM updated the FDA Emergency Response Plan, 3 incident-specific emergency response plans and develop an agency-wide National Incident Management System (NIMS) implementation plan in FY 2009.

OCM will enhance FDA's Incident Command System (ICS) structure and its ability to respond to food-related events in FY 2010 by improving response capabilities by incorporating subject matter expertise into strategic planning and day to day operations; improve Agency preparedness by conducting exercises to assess response capabilities to foodborne illness/outbreaks; and further integrate emergency policy and planning into Agency emergency operations.

OCM will enhance FDA's Consumer Complaint Reporting System in FY 2011 to provide a more efficient means of reviewing and processing reports involving FDA regulated products. In addition OCM will expand the geospatial capabilities of EON IMS to increase usage during incident response and recovery.

# FDA Linkages to HHS Strategic Plan

The table below shows the alignment of FDA's strategic goals with HHS Strategic Plan goals.

| HHS Strategic Goals | **FDA Goal 1:** Strengthen FDA for today and tomorrow. | **FDA Goal 2:** Improve patient & consumer safety. | **FDA Goal 3:** Increase access to new medical and food products. | **FDA Goal 4:** Improve quality and safety of manufactured products and the supply chain. |
|---|---|---|---|---|
| **1 Health Care** Improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care. | | | | |
| 1.1 Broaden health insurance and long-term care coverage. | | | | |
| 1.2 Increase health care service availability and accessibility. | | | X | |
| 1.3 Improve health care quality, safety and cost/value. | | X | X | X |
| 1.4 Recruit, develop, and retain a competent health care workforce. | X | | | |
| **2 Public Health Promotion and Protection, Disease Prevention, and Emergency Preparedness** Prevent and control disease, injury, illness and disability across the lifespan, and protect the public from infectious, occupational, environmental and terrorist threats. | | | | |
| 2.1 Prevent the spread of infectious diseases. | | X | X | X |
| 2.2 Protect the public against injuries and environmental threats. | | X | | |
| 2.3 Promote and encourage preventive health care, including mental health, lifelong healthy behaviors and recovery. | | X | | X |
| 2.4 Prepare for and respond to natural and man-made disasters. | | X | X | X |
| **3 Human Services** Promote the economic and social well-being of individuals, families, and communities. | | | | |
| 3.1 Promote the economic independence and social well-being of individuals and families across the lifespan. | | | | |
| 3.2 Protect the safety and foster the well being of children and youth. | | | | |
| 3.3 Encourage the development of strong, healthier and supportive communities. | | | | |
| 3.4 Address the needs, strengths and abilities of vulnerable populations. | | | | |
| **4 Scientific Research and Development** Advance scientific and biomedical research and development related to health and human services. | | | | |
| 4.1 Strengthen the pool of qualified health and behavioral science researchers. | X | | | |
| 4.2 Increase basic scientific knowledge to improve human health and human development. | X | X | X | X |
| 4.3 Conduct and oversee applied research to improve health and well-being. | X | X | X | X |
| 4.4 Communicate and transfer research results into clinical, public health and human service practice. | X | X | | |

# Strategic Alignment of Program Activities and Annual Performance Goals with FDA's Strategic Goals and Objectives

FDA strives to maintain alignment of its major program activities and associated annual performance goals with FDA's strategic goals and objectives. This appendix demonstrates this alignment in the following two tables. The first table shows the framework of FDA's Strategic Action Plan, and lists the reference number for each strategic goal and objective. The second table uses the reference numbers to align each Center's or Office's Subprogram areas (which define the major program activities) and associated annual performance goals with a strategic objective.

**FDA's Strategic Goal Framework**

| Strategic Goal and Objective Reference Number | Strategic Goals and Long-Term Objective Statements |
|---|---|
| **1.0** | **Strengthen FDA for Today and Tomorrow** |
| 1.1 | Strengthen the scientific foundation of FDA's regulatory mission |
| 1.2 | Cultivate a culture that promotes transparency, effective teamwork, and mutual respect, and ensures integrity and accountability in regulatory decision making |
| 1.3 | Enhance partnerships and communications |
| 1.4 | Strengthen FDA's base of operations |
| **2.0** | **Improve Patient and Consumer Safety** |
| 2.1 | Strengthen the science that supports product safety |
| 2.2 | Improve information systems for problem detection and public communication about product safety |
| 2.3 | Provide patients and consumers with better access to clear and timely risk-benefit information for medical products |
| 2.4 | Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition |
| **3.0** | **Increase Access to New Medical and Food Products** |
| 3.1 | Increase the number of safe and effective new medical products available to patients |
| 3.2 | Improve the medical product review process to increase the predictability and transparency of decisions using the best available science |
| 3.3 | Increase access to safe and nutritious new food products |
| **4.0** | **Improve the Quality and Safety of Manufactured Products and the Supply Chain** |
| 4.1 | Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution |
| 4.2 | Detect safety problems earlier and better target interventions to prevent harm to consumers |
| 4.3 | Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication |

## Alignment of FDA Program Activities and Performance Measures to Strategic Objectives

Center for Food Safety and Applied Nutrition (Foods and Cosmetics)

| Sub-Program | FDA's Related Strategic Objective | Performance Measure Reference Number | Performance Measure |
|---|---|---|---|
| Prioritizing Prevention | 3.3 | 213301 | Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt |
| | 4.1 | 214101 | Number of state, local and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. |
| | 4.2 | 214303 | Convert data from the new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange |
| | | 212404 | Reduce the incidence of infection with key foodborne pathogens: *Campylobacter* species |
| | | 212405 | Reduce the incidence of infection with key foodborne pathogens: *Escherichia coli* O157:H7. |
| | | 212406 | Reduce the incidence of infection with key foodborne pathogens: *Listeria monocytogenes*. |
| | | 212407 | Reduce the incidence of infection with key foodborne pathogens: *Salmonella* species. |
| Strengthening Surveillance and Enforcement: Strengthening Surveillance | 4.2 | 214306 | The average number of days to subtype priority pathogens in food (Screening Only). |
| | | 214207 | The number of completed administrative assessments of regulatory food safety systems in a mix of economically developed and developing countries to determine comparability of their food safety systems. |
| | | 214201 | Number of prior notice import security reviews. |
| | | 214202 | Number of import food field exams. |
| | | 214203 | Number of Filer Evaluations. |
| | | 214204 | Number of examinations of FDA refused entries. |
| | | 214206 | Maintain accreditation for ORA labs. |
| Strengthening Surveillance and Enforcement: Strengthening Enforcement | 4.2 | 214205 | Number of high risk food inspections |
| Improve Response and Recovery | 4.2 | 214305 | Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). |
| Nutrition and Labeling Strategies for Better Health | 2.4 | 214208 | The number of American consumers who recognize dietary factors associated with chronic disease risk and steps they can take to reduce their risk. |
| Reinventing Cosmetics Safety | 4.2 | 214208 | Number of consumers who are aware of FDA’s Adverse Event Reporting System for Cosmetics. |

## Alignment of FDA Program Activities and Performance Measures to Strategic Objectives

Center for Drug Evaluation and Research (Human Drugs)

| Sub-Program | FDA's Related Strategic Objective | Performance Measure Reference Number | Performance Measure |
|---|---|---|---|
| New Drug Review | 3.2 | 223201 | Percentage of Standard NDA/BLAs within 10 months |
| | | 223202 | Percentage of Priority NDA/BLAs within 6 months |
| Generic Drug Review | 3.2 | 223205 | The total number of actions taken on abbreviated new drug applications in a fiscal year |
| Drug Quality | 4.2 | 224201 | Number of foreign and domestic high-risk human drug inspections |
| Post Market Safety Oversight | 2.2 | 222303 | Improve the safe use of drugs by patients and health care providers by reviewing safety labeling changes required under FDAAA within the timeframes established by FDAAA. |
| | | 222202 | The percent of manufacturer submitted expedited adverse event reports received electronically compared to all expedited adverse event reports received from industry |
| | | 222201 | The Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. |
| Oversight of Drug Promotion | 4.2 | 222302 | Percentage of television advertisements requiring submission reviewed within 45 days |

## Alignment of FDA Program Activities and Performance Measures to Strategic Objectives

Center for Biologics Evaluation and Research

| Sub-Program | FDA's Related Strategic Objective | Performance Measure Reference Number | Performance Measure |
|---|---|---|---|
| Cell, Tissues and Gene Therapy Pre-Market Review and Post-Market Safety | 3.1 | 233201 | Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt |
| | | 233202 | Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt |
| | | 233203 | Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt |
| | 4.2 | 234203 | Number of human foreign and domestic tissue establishment inspections |
| Vaccine Pre-Market Review and Post-Market Safety | 3.1 | 233201 | Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt |
| | | 233202 | Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt |
| | | 233203 | Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt |
| | 4.1 | 234101 | Increase manufacturing diversity and capacity for pandemic influenza vaccine production |
| Blood and Blood Products Pre-Market Review and Post-Market Safety | 3.1 | 233205 | Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date |
| | | 233206 | Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date |
| | 4.2 | 234202 | Number of registered domestic blood bank and biologics manufacturing inspections |

## Alignment of FDA Program Activities and Performance Measures to Strategic Objectives

Center for Veterinary Medicine

| Sub-Program | FDA's Related Strategic Objective | Performance Measure Reference Number | Performance Measure |
|---|---|---|---|
| Prioritizing Prevention | 3.1 | 243201 | Complete review and action on original NADAs & reactivations of such applications received during the fiscal year. |
| | | 243202 | Complete review and action on Non-administrative original ANADAs & reactivations of such applications received during the fiscal year. |
| Strengthening Surveillance and Enforcement: Strengthening Surveillance | 3.1 | 242201 | Review adverse experience reports to detect animal product hazards early |
| Strengthening Surveillance and Enforcement: Strengthening Enforcement | 4.2 | 244202 | Number of domestic and foreign high risk animal drug and feed inspections. |
| | | 244203 | Number of targeted prohibited material Bovine Spongiform Encephalopathy (BSE) inspections. |
| | | 244204 | Complete review and action on warning letters received within 15 days to better safeguard our food supply by ensuring that firms correct identified deviations and become compliant. |
| Improve Response and Recovery | 4.2 | 244301 | The total number of state laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events. |
| Animal Drug Review | 3.1 | 243201 | Complete review and action on original NADAs & reactivations of such applications received during the fiscal year. |
| | | 243202 | Complete review and action on Non-administrative original ANADAs & reactivations of such applications received during the fiscal year. |
| Postmarket Safety and Compliance (Medical) | 3.1 | 242201 | Review adverse experience reports to detect animal product hazards early |

## Alignment of FDA Program Activities and Performance Measures to Strategic Objectives

Center for Devices and Radiological Health

| Sub-Program | FDA's Related Strategic Objective | Performance Measure Reference Number | Performance Measure |
|---|---|---|---|
| Premarket Review | 3.2 | 253203 | Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. |
| | | 253204 | Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. |
| | | 253205 | Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. |
| | | 253201 | Number of Medical Device Bioresearch Monitoring (BIMO) inspections |
| Postmarket Safety | 2.2 | 252201 | The minimum number of reports per year that 80 percent of MedSun hospitals, enrolled for at least 11 months in the program will submit |
| | | 252202 | By 2013, enroll 80% of the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. |
| Compliance and Enforcement | 4.1 | 254202 | Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters |
| | | 254201 | Number of domestic and foreign Class II and Class III device inspections. |
| Science | 4.1 | 252101 | Number of technical analyses of postmarket device problems and performance. |
| | | 253207 | Number of technical reviews of new applications and data supporting requests for premarket approvals. |
| Mammography Quality Standards Act (MQSA) | 4.1 | 254101 | Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. |

**Alignment of FDA Program Activities and Performance Measures to Strategic Objectives**

Office of Regulatory Affairs (Field Operations for all programs)

| Sub-Program | FDA's Related Strategic Objective | Performance Measure Reference Number | Performance Measure |
|---|---|---|---|
| Focus on Prevention | 4.2 | 214303 | Convert data from the new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange |
| Strengthen Surveillance and Risk Analysis | 4.2 | 214201 | Number of prior notice import security reviews. |
| | | 214202 | Number of import food field exams. |
| | | 214203 | Number of Filer Evaluations. |
| | | 214204 | Number of examinations of FDA refused entries. |
| | | 214206 | Maintain accreditation for ORA labs. |
| Expand Risk-Based Inspection and Enforcement | 4.2 | 214205 | Number of high risk food inspections |
| | | 244202 | Number of domestic and foreign high risk animal drug and feed inspections. |
| | | 244203 | Number of targeted prohibited material Bovine Spongiform Encephalopathy (BSE) inspections. |
| Rapidly Respond to Outbreaks and Facility Recovery | 4.2 | 214305 | Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). |
| Provide Field Support to the Human Drugs Program | 4.2 | 224201 | Number of foreign and domestic high-risk human drug inspections |
| Provide Field Support to the Biologics Program | 4.2 | 234202 | Number of registered domestic blood bank and biologics manufacturing inspections |
| | | 234203 | Number of human foreign and domestic tissue establishment inspections |
| Provide Field Support to the Animal Drugs Program | 4.2 | 244202 | Number of domestic and foreign high risk animal drug and feed inspections. |
| Provide Field Support to the Devices Program | 3.2 | 253201 | Number of Medical Device Bioresearch Monitoring (BIMO) inspections |
| | 4.2 | 254201 | Number of domestic and foreign Class II and Class III device inspections. |

## Alignment of FDA Program Activities and Performance Measures to Strategic Objectives

National Center for Toxicological Research

| Sub-Program | FDA's Related Strategic Objective | Performance Measure Reference Number | Performance Measure |
|---|---|---|---|
| Personalized Nutrition and Medicine | 2.4 | 262401 | Develop biomarkers to assist in identifying the correlation between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health |
| Strengthen Surveillance and Risk Analysis | 4.1 | 264101 | Develop risk assessment methods and build biological dose-response models in support of food protection |
| Enhancing Medical Product Safety | 3.1 | 263101 | Use new omics technologies and pattern-recognition algorithms to analyze imaging data for early-stage disease diagnosis and to study how an FDA-regulated compound or product interacts with the human body. |
| | | 263102 | Develop computer-based models and infrastructure to predict the health risk of biologically active products. |
| | 3.2 | 263201 | Develop science base for supporting FDA regulatory review of new and emerging technologies. |
| | 4.2 | 264201 | Develop standard biomarkers to establish risk measures for FDA-regulated products. |

## Alignment of FDA Program Activities and Performance Measures to Strategic Objectives

Center for Tobacco Products*

* FDA's authority to regulate tobacco products was granted recently, and is not directly reflected in FDA's 2007 Strategic Action Plan

| Sub-Program | FDA's Related Strategic Objective | Performance Measure Reference Number | Performance Measure |
|---|---|---|---|
| Protecting the Public Health from the Harmful Effects of Tobacco Use | 2.0 | 280001 | Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. |
| Tobacco Product Scientific Standard Setting and Tobacco Product Review | 1.1 | 280002 | Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. |
| Compliance and Regulatory Activities | 4.3 | 280003 | Increase compliance with tobacco product regulation by increasing the percentage of States and Territories with which FDA has developed a contract program to support the enforcement and public health goals of the 1996 rule to assure that retailers refuse sales of cigarettes and smokeless tobacco products to adolescents under the age of 18. |
| Tobacco Product Public Education and External Communications | 2.0 | 280004 | Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. |

**Alignment of FDA Program Activities and Performance Measures to Strategic Objectives**

Office of the Commissioner

(Head-quarters and cross-cutting programs)

| Sub-Program | FDA's Related Strategic Objective | Performance Measure Reference Number | Performance Measure |
|---|---|---|---|
| Office of International Programs | 1.3 | 291301 | The number of FDA foreign posts to increase collaboration with foreign counterparts. |
| | | 291302 | The number of agencies who participate in the Regulators Forum of the International Conference on Harmonization. |
| Office of Ithe Chief Scientist | 1.1 | 291101 | Percentage of Fellows retained at FDA after completing the Fellowship program. |
| Office of Critical Path Programs | 2.2 | 292202 | Number of people for which FDA is able to evaluate product safety through miniature Sentinel*pilots. |
| | | 292203 | Number of safety analyses that are conducted using Medicare and Medicaid SafeRx* project. |
| Office of Orphan Product Development | 3.1 | 293201 | The total number of decisions on applications for promising orphan drug and humanitarian use device designations. |
| | | 293202 | The number of medical devices facilitated in development by the new Pediatric Device Consortia Grant Program |
| Office of Pediatric Therapeutics | 1.3 | 293203 | Number of pediatric scientific and ethical issues identified through collaboration with the 27 European Union countries coordinated with the EMEA. |
| | 2.3 | 293204 | Number of new medical products studied in children, labeling changes and safety reviews completed. |
| Office of Combination Products | 3.2 | 293205 | Percentage of requests for Designations processed within the 60 day statutory requirement. |
| Office of Special Health Issues | 2.3 | 292301 | The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. |
| Office of Women's Health | 1.3 | 294201 | Number of site visits of Office of Women's Health-funded investigators (multiple year recipients) conducting laboratory-based research. |
| | | 291303 | The number of collaborations and partnerships to maximize Outreach activities. |
| Office of Financial Operations | 1.4 | 291402 | FDA's implementation of HHS's Unified Financial Management System (UFMS). . |
| Office of Management | 1.4 | 291403 | Number of Business Process Improvement Projects supported through start of Implementation. |
| Office of Information Management | 1.4 | 291404 | Percentage of servers that are high efficiency energy star compliant. |
| | | 291405 | Percentage of application availability during non-scheduled, emergency outages. |
| Office of Crisis Management | 2.2 | 292201 | Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. |

# Summary of Full Cost

*(Budgetary Resources in Millions)*

| HHS Strategic Goals and Objectives | OPDIV | | |
|---|---|---|---|
| **Fiscal Year** | **FY 2009** | **FY 2010** | **FY 2011** |
| **1: Health Care** Improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care. | | | |
| **1.1** Broaden health insurance and long-term care coverage. | | | |
| **1.2** Increase health care service availability and accessibility. | **$423** | **$448** | **$483** |
| 213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. | 21 | 22 | 23 |
| 233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. | 62 | 65 | 71 |
| 233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. | 40 | 43 | 47 |
| 233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. | 93 | 99 | 108 |
| 233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. | 22 | 23 | 26 |
| 233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. | 21 | 22 | 25 |
| 253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. | 42 | 44 | 47 |
| 253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. | 19 | 20 | 21 |
| 253205: Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. | 104 | 110 | 115 |
| **1.3** Improve health care quality, safety and cost/value. | **$1,074** | **$1,179** | **$1,321** |
| 223201: Percentage of Standard NDAs/BLAs within 10 months. | 384 | 441 | 491 |
| 223202: Percentage of Priority NDAs/BLAs within 6 months. | 79 | 74 | 82 |
| 223205: The total number of actions taken on abbreviated new drug applications in a fiscal year. | 100 | 115 | 145 |
| 222201: The Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. | 11 | 10 | 10 |
| 222302: Percentage of television advertisements requiring submission reviewed within 45 days. | 24 | 25 | 26 |
| 224201: Number of foreign and domestic high-risk human drug inspections. | 169 | 180 | 200 |
| 234202: Number of registered domestic blood bank and biologics manufacturing inspections. | 29 | 28 | 29 |
| 234203: Number of foreign and domestic human tissue establishment inspections. | 11 | 16 | 17 |
| 243201: Complete review and action on original NADAs & reactivations of such applications received during the fiscal year. | 55 | 59 | 67 |
| 243202: Complete review and action on Non-administrative original ANADAs and reactivations of such applications received during the fiscal year. | 7 | 11 | 11 |
| 244202: Number of domestic and foreign high risk animal drug and feed inspections. | 27 | 35 | 45 |
| 244203: Number of targeted prohibited material BSE inspections. | 43 | 41 | 43 |

| | | | |
|---|---|---|---|
| 254101: Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. | 27 | 32 | 33 |
| 254202: Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters. | 30 | 32 | 35 |
| 253207: Technical reviews of new applications and data supporting requests for premarket approvals. | 20 | 21 | 21 |
| 254201: Number of domestic and foreign Class II and Class III device inspections. | 57 | 59 | 66 |
| **1.4** Recruit, develop, and retain a competent health care workforce. | | | |
| **2: Public Health Promotion and Protection, Disease Prevention, and Emergency Preparedness** Prevent and control disease, injury, illness and disability across the lifespan, and protect the public from infectious, occupational, environmental and terrorist threats | | | |
| **2.1** Prevent the spread of infectious diseases. | **$420** | **$446** | **$581** |
| 214306: The average number of days to subtype priority pathogens in food (Screening Only). | 26 | 27 | 46 |
| 214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. | 15 | 19 | 28 |
| 214207: The number of completed administrative assessments of regulatory food safety systems in a mix of economically developed and developing countries to determine comparability of their food safety systems. | 22 | 23 | 37 |
| 212404: Reduce the incidence of infection with key foodborne pathogens: Campylobacter species. | 44 | 44 | 63 |
| 212405: Reduce the incidence of infection with key foodborne pathogens: Escherichia coli O157:H7. | 44 | 44 | 63 |
| 212406: Reduce the incidence of infection with key foodborne pathogens: Listeria monocytogenes. | 44 | 44 | 63 |
| 212407: Reduce the incidence of infection with key foodborne pathogens: Salmonella species. | 44 | 44 | 63 |
| 214201: Number of prior notice import security reviews. | 9 | 9 | 9 |
| 214202: Number of import food field exams. | 102 | 115 | 132 |
| 214203: Number of Filer Evaluations. | 32 | 37 | 39 |
| 234101: Increase manufacturing diversity and capacity for pandemic influenza vaccine production. | 37 | 37 | 38 |
| **2.2** Protect the public against injuries and environmental threats. | **$565** | **$660** | **$833** |
| 214208: Consumer awareness of FDA's Adverse Event Reporting System for Cosmetics. | 6 | 10 | 9 |
| 214204: Number of examinations of FDA refused entries. | 32 | 37 | 39 |
| 214205: Number of high risk food inspections. | 237 | 276 | 383 |
| 214206: Maintain accreditation for ORA labs. | 184 | 224 | 277 |
| 222202: The percent of manufacturer submitted expedited adverse event reports received electronically compared to all expedited adverse event reports received from industry. | 11 | 10 | 10 |
| 242201: Review adverse event reports to detect animal product hazards early. | 3 | 3 | 3 |
| 244204: Complete review and action on warning Letters received within Agency timeframes to better safeguard our food supply by ensuring firms correct identified deviations to come into compliance. | 7 | 10 | 10 |

| | | | |
|---|---|---|---|
| 252201: The minimum number of reports per year that 80 percent of MedSun hospitals, enrolled for at least 11 months in the program will submit. | 25 | 27 | 29 |
| 252202: By 2013, enroll 80% of the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. | 38 | 41 | 44 |
| 252101: Technical analyses of postmarket device problems and performance. | 23 | 24 | 28 |
| **2.3** Promote and encourage preventive health care, including mental health, lifelong healthy behaviors and recovery. | **$28** | **$241** | **$447** |
| 212408: The number of American consumers who recognize dietary factors associated with chronic disease risk and steps they can take to reduce their risk. | 23 | 24 | 26 |
| 280001: Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. | 5 | 38 | 82 |
| 280002: Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. | 0 | 64 | 146 |
| 280003: Increase compliance with tobacco product regulation by increasing the percentage of States and Territories with which FDA has developed a contract program to support the enforcement and public health goals of the 1996 rule to assure that retailers refuse sales of cigarettes and smokeless tobacco products to adolescents under the age of 18. | 0 | 69 | 96 |
| 280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. | 0 | 45 | 97 |
| **2.4** Prepare for and respond to natural and man-made disasters. | **$29** | **$23** | **$29** |
| 214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). | 26 | 18 | 20 |
| 244301: The number of state laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events. | 2 | 5 | 9 |
| **3: Human Services** Promote the economic and social well-being of individuals, families and communities. | | | |
| **3.1** Promote the economic independence and social well-being of individuals and families across the lifespan. | | | |
| **3.2** Protect the safety and foster the well being of children and youth. | | | |
| **3.3** Encourage the development of strong, healthy and supportive communities. | | | |
| **3.4** Address the needs, strengths and abilities of vulnerable populations. | | | |
| **Strategic Goal 4: Scientific Research and Development** Advance scientific and biomedical research and development related to health and human services. | | | |
| **4.1** Strengthen the pool of qualified health and behavioral science researchers. | | | |
| **4.2** Increase basic scientific knowledge to improve human health and human development. | **$51** | **$51** | **$60** |
| 262401: Develop biomarkers to assist in identifying the correlation between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health. | 0 | 0 | 26 |
| 263101: Use new omics technologies and pattern-recognition algorithms to analyze imaging data for early-stage disease diagnosis and to study how an FDA-regulated compound or product interacts with the human body. | 33 | 32 | 10 |

| | | | |
|---|---|---|---|
| 263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. | 6 | 6 | 7 |
| 264101: Develop risk assessment methods and build biological dose-response models in support of food protection. | 12 | 14 | 16 |
| **4.3** Conduct and oversee applied research to improve health and well-being. | **$25** | **$30** | **$26** |
| 253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. | 17 | 18 | 19 |
| 263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products. | 9 | 12 | 7 |
| **4.4** Communicate and transfer research results into clinical, public health and human service practice. | **$136** | **$151** | **$191** |
| 222303: Improve the safe use of drugs by patients and health care providers by reviewing safety labeling changes required under FDAAA within the timeframes established by FDAAA. | 136 | 151 | 191 |
| **Total** | **$2,751** | **$3,230** | **$3,971** |

# Summary of Findings and Recommendations for FDA Evaluations

1. Final Report on the Postmarketing Requirement/Postmarketing Commitment Backlog Review

**Purpose** Section 921 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) added a requirement for FDA to review the entire Backlog of postmarketing study commitments (PMCs) and postmarketing requirements (PMRs) on an annual basis to determine which commitments should be revised or released. The objectives of this review were to: propose recommendations for FDA re-evaluation or closure of PMRs and PMCs, identify PMRs and PMCs that need study/trial completion dates, and analyze commitments that are recommended for closure/re-evaluation to determine why the studies/trials may be no longer necessary or feasible.

**Findings** On the date FDAAA was enacted, 63 percent of Backlog PMRs/PMCs were categorized as pending, 15 percent ongoing, 14 percent submitted, and 7 percent delayed.

After reviewing and updating the PMR/PMC status, the largest segment of Backlog PMRs/PMCs are accurately categorized as submitted (36 percent), followed by delayed (15 percent), ongoing (14 percent), and pending (14 percent).

Previously it appeared that most studies/trials had not yet been initiated, leading to public criticism of both FDA and the pharmaceutical and biotech industry for not conducting their studies/trials. However, the updated status data show that most PMRs/PMCs have been initiated and more than half of them were either submitted, fulfilled, or released.

**Recommendations**

- Standardize sponsor annual status report submissions and streamline FDA annual status report reviews by creating an interactive form that requires sponsors to enter all necessary data. Accurately process fulfill and release letters, creating multiple letters if necessary, to ensure that the status is updated when a PMR/PMC is closed.

- Write PMRs/PMCs to meet specific objectives rather than specific protocols or studies, so that if the original study/trial proves infeasible, there is still flexibility to fulfill the commitment with another study/trial. FDA should notify sponsors with a standard template response that they may not provide feedback for a protocol submission so sponsors may initiate their studies/trials and not fall off schedule while awaiting protocol feedback that FDA may determine is unnecessary. Otherwise, FDA should establish a Center-wide policy for timely review and feedback for sponsor protocols. FDA is now able to enforce compliance with study/trial schedules for PMRs created under FDAAA, and should issue Dunner letters when sponsors miss a final study/trial report date to remind and encourage them to complete their non-FDAAA PMRs/PMCs on time.

- Ensure that updates to the PMR/PMC database occur when final report submissions are received. FDA should proactively facilitate the timely review of submitted study/trial reports.

- Establish specific study/trial start and final report submission milestone dates. FDA should consider creating a new mechanism to allow sponsors to notify FDA of study/trial initiation. This new reporting strategy would allow sponsors and FDA to streamline the reporting process and improve the accuracy and compliance of PMR/PMC status updates. FDA should record the actual dates of study/trial milestone progress and completion in the PMR/PMC databases to facilitate tracking with relative milestone dates.

2. Evaluation of How Best to Communicate with Healthcare Providers about the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women: A Mental Models Research Report

**Purpose** FDA's Office of Women's Health and Office of Policy and Planning believed that it was important to better understand the factors used by physicians and other healthcare professionals (HCPs) when making treatment decisions for pregnant and nursing women who have chronic health conditions, especially decisions about whether to use prescription drugs. Further, these offices wanted to know when and how such professionals use the official prescription information associated with prescription drugs.

**Findings** The HCPs interviewed described the need to take a team-based approach to managing these patients' treatments, stressing the need to include the patient as the ultimate decision maker. Most asserted that the need for continuing to treat most chronic conditions requires finding the most appropriate drug. Primary influences on what the HCPs characterize is a highly complex decision include: treatment needs, risks of inadequate treatment, risks of drug impact on fetus/baby, the drug's labeled pregnancy category, familiarity with the condition and drug, benefits of current treatment, patients' preferences, and the degree of scientific understanding of the drug's impact.

Many HCPs cited the problem of what they believe is an unnecessary lack of human data on the effects of drugs on pregnant and nursing women. They are looking for data from studies with humans and that the lack of these data is a primary barrier to sound decision-making. They are generally ambivalent about animal study data, many believing that such evidence does not easily translate to humans and as such is not relevant or helpful. HCPs are looking for trusted, conclusive, and easily accessible information. Their own teams and HCP colleagues are most trusted. Also highly trusted are certain electronic sources of information.

Many are not clear on what sources they use are based on FDA-approved prescribing information (PI, package insert, labeling), and, aside from the labeled pregnancy categories, do not use approved prescribing information as a primary source. They are more likely to use the PI when they are unfamiliar with the drug, when the PI is easily available, or when they are using it as a patient communication tool. They believe that PI is currently inadequate to fully inform treatment decisions, because of lack of clinical relevance, availability at point of decision-making, and accessibility (including readability). HCPs consider pregnancy categories an important source of information – this is a critical gap between the HCPs and the FDA experts, who believe that the categories are often misleading and should not be used in making treatment decisions. To improve the PI they suggest: providing more clinical guidance, summarizing and simplifying the information, adding more clinically-relevant information, including more analysis of evidence, centralizing data gathering and output, increasing timeliness as new information emerges, and making it more accessible to patients.

**Recommendations**

No recommendations were presented in the study.

3. Report to the FDA Science Board: Research Planning, Program, and Facilities of the Center for Veterinary Medicine (CVM)

**Purpose** The review of the CVM Office of Research (OR) research planning process and program was initiated under the auspices of the FDA Science Board. The purpose of the review was to make recommendations on improving the planning process CVM implemented for developing its Three-Year Research Plan and to increase OR's capacity in support of CVM's mission.

**Findings** OR has a well-developed internal consultative process for developing the Three-Year Research Plan and has initiated an environmental scan to further assist in identifying emerging scientific and technological issues related to CVM's mission.

Research resources and IT infrastructure are not commensurate with current responsibilities and the gap is growing.

OR is the world's leader in animal feed, drug, and regulatory science, and US global leadership in this regulatory science is at risk.

External communications beyond the scientific community are limited; therefore, the overall visibility of research conducted within OR is limited, relative to other Federal laboratories, by several factors even though the research itself may be of high impact.

Balance in the OR research portfolio needs to be maintained.

**Recommendations**

- To provide the anticipatory, fundamental and applied regulatory research that CVM needs to fulfill its mission, OR's planning process needs to be more open and inclusive, actively seek engagement with leading scientists and organizations in academia and industry, and be benchmarked against other organizations.

- OR's research program deserves better financial and IT support.

- Build capacity to advance and lead new regulatory science.

- CVM and OR should develop a public face and communicate the value of their work in public health and animal health.

- OR should strive to maintain a balanced portfolio of mission-relevant research responsive to stakeholders' regulatory science needs and cognizant of the changing external environment.

4. Safety and Transparency of Pediatric Drug Trials

**Purpose** Medication adverse events in children often differ from those in adults, particularly those that were neuropsychiatric in nature. Although this information is provided to FDA, it may not be disseminated in reputable journals. Therefore, FDA decided to quantify the frequency and type of new safety information arising from studies performed under the auspices of the Pediatric Exclusivity Program, to describe the dissemination of these findings in the peer-reviewed literature and compare this with the FDA review, and to describe their effect on pediatric labeling.

**Findings** Thirty-three products (26 percent) had pediatric safety information added to the labeling. Of these, 12 products had neuropsychiatric safety findings and 21 had other important safety findings. Only 16 of 33 of these trials (48 percent) were reported in the peer-reviewed literature; however, 7 of 16 focused on findings substantively different from those highlighted in the FDA reviews and labeling changes.

Labeling changes for pediatric use demonstrate that pediatric drug studies provide valuable and unique safety data that can guide the use of these drugs in children. Unfortunately, most of these articles are not published, and almost half of the published articles focus their attention away from the crucial safety data.

**Recommendations**

No recommendations were presented in the study.

# GAO High Risk Issue - Transforming Federal Oversight of Food Safety

Each year, about 76 million people contract a foodborne illness in the United States; about 325,000 require hospitalization; and about 5,000 die. The fragmented US system of oversight has caused inconsistent oversight, ineffective coordination, and inefficient use of resources.

**Overall Goal:** Reduce illnesses caused by contamination of the food supply.

**Challenge:** Prevent or deter intentional and unintentional contamination of food supply through risk-based, cost-effective allocation of resources.

**FDA Actions:**

- Fully implement the Salmonella Initiative Program to provide incentives for meat and poultry plants whose processes control foodborne pathogens.

**Challenge:** Early detection of contamination of the food supply.

**FDA Actions:**

- Build a quality public health infrastructure with data that is readily accessible to key decision-makers and front-line personnel.
- Improve Food and Drug Administration (FDA) detection systems and improve risk-based annual import activities.

**Challenge:** Protect human health and mitigate impact of food supply contamination by responding rapidly to food supply contamination through risk-based, cost effective allocation of resources.

**FDA Actions:**

- Enhancement of the Food Emergency Response Network (FERN) to ensure better geographic coverage.
- Implement Supply Chain Source Verification Requirements to accelerate both the response and the return to normalcy.
- Initiate the development of new Rapid Response Teams built on California Food Emergency Response Team (CalFERT) model.

More information about specific milestones the agency will accomplish to achieve this goal, including identification of the agency official responsible for each milestone can be found here (http://www.whitehouse.gov/omb/expectmore/issue_summary/issue_31.html) and here (http://www.whitehouse.gov/omb/expectmore/issue_summary/issueDetailedPlan_31.pdf)

# Discontinued Goal Table

| Measure | FY | Target | Result |
|---|---|---|---|
| 214102: Percentage of the enrolled jurisdictions which meet 2 or more of the Standards *(Outcome)* | *2011* | N/A | N/A |
| | *2010* | N/A | N/A |
| | *2009* | 32% | 36%<br>(Target Exceeded) |
| | *2008* | 32% | 32%<br>(Target Met) |
| | *2007* | 26% | 32%<br>(Target Exceeded) |
| | *2006* | N/A | 24%<br>(Target Not In Place) |
| 223101: Number of Written Requests (WRs) issued for drugs that need to be studied in the pediatric population and number of drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity. *(Output)* | *2011* | N/A | N/A |
| | *2010* | N/A | N/A |
| | *2009* | 5/7 | 17/15<br>(Target Met) |
| | *2008* | 8/8 | 5/19<br>(Target Not Met) |
| | *2007* | 7/7 | 30/13<br>(Target Met) |
| | *2006* | N/A | 18/12<br>(Historical Actual) |
| 223206: Percentage of Rx-to-OTC Switch applications within 10 months of receipt in which there was a complete review action and the number of OTC Drug Monographs on which there was significant progress. *(Output)* | *2011* | N/A | N/A |
| | *2010* | N/A | N/A |
| | *2009* | 100%/5 | 100%/10<br>(Target Met) |
| | *2008* | 100%/5 | 100%/9<br>(Target Met) |
| | *2007* | 100%/5 | 100%/9<br>(Target Met) |
| | *2006* | NA | 100%/8<br>(Historical Actual) |
| 222301: Improve the Safe Use of Drugs in Patients and Consumers by identifying priority postmarketing safety reviews and acting upon those reviews within an established timeframe. *(Output)* | *2011* | N/A | Nov 30, 2011 |
| | *2010* | N/A | Nov 30, 2010 |
| | *2009* | Act upon 50% of issues within timelines | 72% (Target Exceeded) |
| | *2008* | Conduct pilot and act upon 50% of issues within timelines | Conducted pilot and acted upon 50% of issues within timelines<br>(Target Met) |
| | *2007* | Implement safety issue tracking system | Implemented<br>(Target Met) |
| | *2006* | N/A | Standardized communication processes<br>(Target Met) |

| Measure | FY | Target | Result |
|---|---|---|---|
| 223102: Number of medical countermeasures in which there has been coordination and facilitation in development. *(Output)* | *2011* | N/A | N/A |
| | *2010* | N/A | N/A |
| | *2009* | 4 | 5<br>(Target Exceeded) |
| | *2008* | 5 | 6<br>(Target Exceeded) |
| | *2007* | 4 | 4<br>(Target Met) |
| | *2006* | N/A | 6<br>(Historical Actual) |
| 291401: The number of Commercial Activities that will be reviewed for competitive sourcing per "Green Plan". *(Efficiency)* | *2011* | N/A | N/A |
| | *2010* | N/A | N/A |
| | *2009* | 154 FTE by Sept 15 | No studies were conducted in FY2009 as per the 2009 Omnibus Appropriations Bill, signed March 2009, which prohibits the use of funds government-wide to study or hold public-private job competitions in FY2009. In October 2009, HHS informed OPDIVs that the OMB would continue the moratorium through FY2010. |
| | *2008* | 130 FTE by Sept 15 (target changed by HHS) | 152 FTE by Sept 15<br>(Target Met) |
| | *2007* | 308 by Sept 15 | 354 FTE by 9/15/07<br>(Target Met) |
| | *2006* | N/A | Study cancelled in February 2007 with the approval of the CSO.<br>(Target Met) |