# FIELD ACTIVITIES – OFFICE OF REGULATORY AFFAIRS

The FY 2009 program level budget request for FDA's Field Activities – Office of Regulatory Affairs (ORA) Program is $608,307,000.

The following table shows a three-year funding history for the Office of Regulatory Affairs Field activities.

**FDA Program Resources Table**

| | FY 2007 Actual | FY 2008 Enacted | FY 2009 Estimate | FY 2009 +/- FY 2008 |
|---|---|---|---|---|
| **Program Level** | **$522,658,000** | **$575,883,000** | **$608,307,000** | **$32,424,000** |
| **Program Level FTE** | **3,290** | **3,338** | **3,499** | **161** |
| **Budget Authority** | **$505,753,000** | **$551,817,000** | **$580,561,000** | **$28,744,000** |
| *Food Protection (non-add)* | $330,637,000 | $370,956,000 | *$395,103,000* | $24,147,000 |
| *Med. Prod. Safety & Devel. (non-add)* | $173,176,000 | $178,551,000 | *$184,215,000* | $5,664,000 |
| *Admin. Savings & Man. Efficiencies (non-add)* | | | *-$1,067,000* | -$1,067,000 |
| **Budget Authority FTE** | **3,224** | **3,271** | **3,425** | **154** |
| **User Fees** | **$16,905,000** | **$24,066,000** | **$24,811,000** | **$1,487,000** |
| *PDUFA* | *$6,266,000* | *$10,178,000* | *$10,178,000* | $0 |
| *MDUFMA* | *$1,182,000* | *$1,434,000* | *$1,556,000* | $122,000 |
| *MQSA* | *$9,457,000* | *$12,454,000* | *$13,077,000* | $623,000 |
| **Proposed User Fees** | | | ***$2,935,000*** | ***$2,935,000*** |
| *Generic Human Drugs* | | | *$2,792,000* | $2,792,000 |
| *Animal Generic Drugs* | | | *$143,000* | $143,000 |
| **Total User Fee FTE** | **66** | **67** | **74** | **7** |

**Legal Authorities:** ORA operates under the following legal authorities that allow the Office of Criminal Investigations (OCI) to conduct criminal investigations, execute Search Warrants, make arrests, and carry firearms:

1944 – Public Health Service Act (42 USC 262)*
1965 – Food, Drug, and Cosmetic Act (21 USC 372)*
1983 – Federal Anti-Tampering Act (18 USC 1365)*
2007 – Food and Drug Administration Amendments Act (21 USC 505)*

Allocation Method: Direct Federal/intramural; contract

* Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

# Program Description and Accomplishments

FDA's Office of Regulatory Affairs is the lead office for all FDA Field activities and provides leadership on imports, inspections, and enforcement policy. ORA's Field Program supports the five FDA Product Centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States. ORA also develops FDA-wide policy on compliance and enforcement, executes FDA's Import Strategy and Food Protection Plans, and directs and coordinates FDA's emergency preparedness and response programs.

ORA's staff are dispersed throughout the United States. Over 85 percent of ORA's staff works in five Regional Offices, 20 District Offices, 13 Laboratories, and 168 Resident Posts and Border Stations. As a separate entity within ORA, the Office of Criminal Investigations (OCI) personnel are located throughout the field organization in 30 Field Offices, Resident Offices, and Domiciles, which are located throughout the U.S. FDA maintains offices and staff in Washington, D.C., the U.S. Virgin Islands, Puerto Rico, and in all States except Wyoming.

Besides executing its mission through its Federal workforce, ORA also works with State and local governments to further FDA's mission. ORA funds grants and cooperative agreements to perform State inspections and provide technical assistance to the States in such areas as milk, food, and shellfish safety. State inspection staffs attend and participate in ORA-sponsored training courses.

While ORA's Field Programs are presented in the five product programs (Foods, Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health), the ORA program description and accomplishment section will highlight several of ORA's cross-cutting areas addressing imported products, enforcement activities, leveraging States, public health emergencies, and laboratory capability.

<u>Assuring the Safety of Imported Products – Field Activities</u>
ORA coordinates import activities with the Department of Homeland Security's Customs and Border Protection (CBP) Agency. The number and complexity of FDA-regulated imported products is increasing exponentially. Even if security concerns were not taking an ever increasing role, this would challenge FDA's ability to provide an appropriate response. In FY 2009, FDA projects a total of 18.2 million import lines, which will be comprised of 57 percent food products, 9 percent cosmetic products, 3 percent human drugs and biologic products, 1 percent animal drugs and feeds products, and 30 percent medical device and radiological health products. ORA uses a combination of electronic information technology for risk-based screening and Field staff for intensive surveillance, physical examinations, and laboratory analysis to make import entry decisions.

ORA conducted 5,510 import field examinations of FDA refused entries in FY 2007. These are performed to ensure that FDA refused articles are being exported to eliminate the potential of these goods making their way into domestic commerce. This is an agency-wide goal and includes activities and resources from all five Program areas.

To support the Field Import Program, the Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002. 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. In FY 2007, the PNC performed 84,088 import security reviews on food and animal feed entries considered to be at risk for bioterrorism and/or to present the potential of a significant health risk.

During the FDA Protein Surveillance Assignment (PSA), the PNC reviewed data on imported plant proteins and finished food products containing plant proteins and issued forty nine (49) import examination and sampling assignments on shipments considered to be of higher risk for contamination with melamine including products from China, Taiwan, and Mexico. The results of these assignments contributed significantly to the general surveillance and emergent risk analysis of the quality of imported products containing or consisting of plant proteins.

OCI has initiated a system to record and track import related criminal cases by noting the country where the product or item was manufactured and the country of shipment. Compiling this data allows OCI to better target investigative efforts and focus limited resources. Since the inception of this tracking system in March 2007, OCI opened 99 investigations that have an import nexus.

Enforcement of FDA Laws – Field Activities

A strong, effective, and efficient enforcement of FDA laws and regulations is essential to FDA's mission of protecting and promoting public health. OCI was officially established in March of 1992 in response to the growing caseload of criminal activities involving FDA regulated products. The role of OCI is to provide an additional enforcement resource to enhance ORA's regulatory efforts. OCI concentrates its resources on investigations of significant violations of the Federal Food, Drug, and Cosmetic Act and Federal Anti-Tampering Act which pose a danger to the public health.

The following table shows a three-year funding history for OCI:

| Fiscal Year | Total |
|---|---|
| 2007 (Actuals) | $37,802,938 |
| 2008 (Enacted) | $41,608,000 |
| 2009 (Estimate) | $42,411,154 |

In FY 2007, OCI initiated 31 counterfeit drug investigations and had 75 arrests and 53 convictions with fines and restitutions in excess of $25,225,126. In addition, OCI continued to coordinate counterfeit drug investigations with several foreign counterparts, especially those in China, Israel, Canada and the United Kingdom. These efforts continue to produce positive outcomes for both OCI and its foreign counterparts. OCI will continue to aggressively pursue counterfeit drug investigations with law enforcement partners in foreign countries as well as with federal, State, and local law enforcement here in the U.S.

The OCI also aggressively investigates potential criminal violations regarding the nation's food supply. During 2007, OCI initiated 102 food safety related cases and had 62 arrests and 38 convictions. An example of such a case occurred in FY 2007, when OCI was among several federal agencies involved in the largest steroid enforcement action in U.S. history— "Operation Raw Deal." This international case targeted the global underground trade of performance enhancing drugs, human growth hormone (HGH), and insulin-like growth factor, most of which was produced in and imported from China. "Raw Deal" was a joint investigation with the U.S. Drug Enforcement Administration, U.S. Postal Inspection Service, Internal Revenue Service, Immigration and Customs Enforcement, Federal Bureau of Investigation, and the National Drug Intelligence Center that resulted in 124 arrests and the dismantling of underground networks dealing in illegal performance-enhancing substances. Over 11.4 million dosage units of performance enhancing drugs and hundreds of kilograms of non-controlled active pharmaceutical ingredients of Chinese origin were seized.

Leveraging With the States – Field Activities

ORA awards and manages State contract programs that provide resources to States to conduct inspections and report their findings to FDA. These contract programs benefit States with technical training, familiarity with federal requirements, and more uniform enforcement of consumer laws through cooperation and coordination with FDA. The State contract program has food safety contracts with 40 States and allows ORA to increase inspectional coverage and redirect resources to other priority activities.

ORA awarded 217 contracts/grants and Cooperative Agreements to State and local governments to implement the Mammography Quality and Standards Act (MQSA), feed/BSE, tissue residue, food, and medical device inspections and Food Emergency Response Network (FERN) laboratory projects. ORA made its electronic State Access to FACTS (eSAF) database available to all 41 State food programs and conducted training for FDA and State personnel to learn the system. State inspection data complements FDA's food protection efforts, and today over 10,000 State food contract inspections have been added into the eSAF system. ORA began expanding the design of eSAF to include the feed and BSE programs, which was piloted in FY07.

Training remains a top priority of the Field to ensure expertise and encourage collaboration with external stakeholders. In FY 2007 five courses were offered to approximately 250 FDA/ORA investigators, compliance officers and analysts; and, five FERN courses were offered to approximately 100 regulators for FDA and State laboratories.

Rapid Response to Public Health Emergencies – Field Activities

Field personnel play a lead role in response to foodborne illness outbreaks by conducting tracebacks of implicated foods. FDA initiates an outbreak investigation when surveillance identifies disease clusters or outbreaks that implicate an FDA regulated product. In foodborne outbreak investigations, ORA investigates multistate outbreaks, performs tracebacks of implicated foods, monitors all recalls of products linked to the outbreak, and evaluates data from investigations to identify trends and make recommendations to prevent similar problems. Information gathered in traceback investigations is used to identify ways to make produce safer and prevent future outbreaks from occurring.

In February 2007, more than 600 people were sickened by Salmonella-tainted Peter Pan and Great Value Peanut Butter manufactured by the ConAgra Foods at a plant in Georgia. FDA, together with public health officials in multiple states and the Centers for Disease Control and Prevention, investigated this large multi-state outbreak of Salmonella serotype Tennessee infections. FDA conducted an extensive inspection of ConAgra's Sylvester, Georgia processing plant which revealed that the probable cause of the Salmonella contamination was a leaky roof and a sprinkler system that moistened peanuts or dust in the plant, creating conditions that allowed Salmonella to grow.

To prepare for larger public health emergencies, ORA participated with FDA's Office of Crisis Management, the product centers, the Office of the Commissioner, DHHS, the Department of Homeland Security, CDC, and other federal agencies in the fourth national federal exercise, TOPOFF4. The purpose of the exercise was to test the federal response in the event of a radiological dispersal device, to identify the strengths and weaknesses or our response plan and activities, to build and improve partnerships with federal partners, and to gain valuable knowledge for national security in the event of a terrorist or natural disaster. The TOPOFF4 exercise involved more than 15,000 participants at all levels of the government, as well as international and industry sectors. ORA Headquarters also actively participated in the planning and development of the TOPOFF4 exercise.

Enhancing ORA Laboratory Capability – Field Activities

The laboratory analytical function of ORA is conducted in 13 laboratories located throughout the country. The ORA laboratory structure consists of five Regional Labs, four District Labs, and four Specialty Labs. Regional Labs are large general purpose laboratories that participate in most major analytical programs. District Labs participate in several analytical programs and have specialties in specific areas. Specialty labs conduct analyses in specific areas of laboratory service including engineering, biological, and chemical hazards associated with medical devices, electronic products, and radiopharmaceuticals; and forensic analysis of samples related to criminal activities that fall under FDA jurisdiction, including drug counterfeiting. To complement the analytical work of FDA labs, ORA developed and supports the Food Emergency Response Network (FERN), a network of State and local labs that perform laboratory analysis for FDA in the event of a public health emergency. During their participation in the Protein Surveillance Assignment, FERN laboratories provided critical analytical capacity during the melamine in pet food and ingredients emergency event.

The ability to rapidly test large numbers of samples of potentially contaminated food products is a critical component of controlling threats from deliberate foodborne contamination. In FY 2007 FERN laboratories added capacity for 1,000 radiological samples per week and maintained 1,200 chemical samples per week. Through an Interagency Agreement with the USDA Food Safety and Inspection Service, six Microbiological Cooperative Agreements were awarded to State FERN laboratories to increase the Network's capacity and capability 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 tribunal regulatory bodies.

During a two-month period, ORA laboratories analyzed more than 1,500 samples of finished products and raw materials, of which 583 tested positive for melamine and analogs. Hundreds of consumer complaint samples were collected by investigators for shipment to labs. Approximately 450 lots of wheat gluten were found positive for melamine. Additionally, FDA, USDA, and State labs, through coordination by Division of Field Science (DFS), developed methods for low-level detection of melamine, cyanuric acid and other melamine analogs in various animal tissues. Testing was performed on fish and pork samples from animals to be used for human consumption.

In response to the diagnosis of several leukemia cases, the U. S. Geological Survey (USGS) began collecting and analyzing water samples from wells in Nevada's Lahontan Valley. These wells provide water for human and/or domestic animal consumption including a number of dairy farms, and 17 were found to contain elevated levels of radioactivity. In August 2007, ORA's Winchester Engineering and Analytical Center (WEAC), the only federal regulatory agency capable of analyzing food samples for Polonium-210, was requested to conduct an analysis of samples of food and well water from the area. Samples analyzed included products regulated by both FDA and USDA, including milk and meat samples from area cattle. The analytical results obtained by scientists at the WEAC laboratory were provided to DHHS, USDA, USGS and the State of Nevada for an assessment of the impact of the detection of Polonium-210 in the wells.

**Five Year Funding Table**

| Fiscal Year | Program Level | Budget Authority | User Fees | Program Level FTE |
|---|---|---|---|---|
| 2005 Actual | $493,258,000 | $477,568,000 | $15,690,000 | 3,633 |
| 2006 Actual | $499,853,000 | $482,361,000 | $17,492,000 | 3,460 |
| 2007 Actual | $522,658,000 | $505,753,000 | $16,905,000 | 3,290 |
| 2008 Enacted | $575,883,000 | $551,817,000 | $24,066,000 | 3,338 |
| 2009 Estimate | $608,307,000 | $580,561,000 | $27,746,000 | 3,499 |

# Budget Request

The FY 2009 President's Budget requests $608,307,000 in program level funding for the Office of Regulatory Affairs (ORA), including the support of 3,499 FTE. The request represents an increase of $32,424,000 (or six percent) over the FY 2008 enacted in budget authority and user fee amounts. The overall increase provides additional budget authority to implement Agency-wide initiatives established in FY 2008 aimed at improving prevention, intervention, and response activities. Such activities include targeted increases aimed at improving the safety of FDA-regulated food, feed, and medical products in order to protect consumers by minimizing associated risks.

Protecting America's Food Supply Initiative

The FY 2009 budget request for the Field component of the Protecting America's Food Supply Initiative is $395,103,000, which includes a $22,615,000 increase in the Field Foods Program and a $1,532,000 increase in the Field Animal Drugs and Feeds Program over FY 2008 enacted levels. ORA will use base funding to continue to perform high-risk food and feed inspections and laboratory analyses. Base funding will also be used by ORA to fund State contract inspections and Rapid Response team Cooperative Agreements leveraging FDA resources with State partners.

The funding increase in the Field Foods Program will fund additional staff allowing ORA to perform increased inspections in the domestic food safety program, on domestic low acid canned foods/acidified foods, and conduct more import field exams and tests. Supplementary funds will also allow ORA to conduct increased laboratory analyses of food to protect American consumers from intentional and unintentional threats to the food supply.

The additional Food Protection funds will also support Cooperative Agreements with the States to develop and maintain Rapid Response Teams, joint State and FDA member teams trained to respond within hours to an implicated foodborne outbreak.

Finally, increased funds in the Food Protection program area will be used to support implementation of Memorandums of Agreement (MoA's) to enhance the safety of food and feed imported into the United States from China.

Medical Product Safety and Development

The FY 2009 budget request for the Field Medical Product Safety and Development Program is $184,215,000, which includes a $3,144,000 increase in the Field Drugs Program and a $1,912,000 increase in the Field Device and Radiological Products Program over FY 2008 funding levels. ORA will use base funding to continue to perform high-risk drug and device inspections and laboratory analyses. Base funding will also be used by ORA to fund State contract inspections in the device area.

The Medical Product Safety increase in the Field Drugs Program will increase the Office of Criminal Investigations (OCI) capacity to enhance the ability of OCI to investigate criminal import violations. The volume of drugs imported into the United States is estimated to increase by 12 percent in FY 2009, heightening the need for import surveillance activities.

Funding increases in the Field Device Program under the Medical Product Safety initiative will be directed towards the improvement of strategic information-sharing between FDA and regulatory partners, such as U.S. Customs and Border Protection. This activity directly supports intervention recommendations made by the Interagency Working Group on Import Safety in the Import Safety Action Plan.

Cost of Living Pay Increase

The Office of Regulatory Affairs portion of FDA's requested pay increase is $10,510,000 across all five Field Program areas. Payroll funding is especially integral to ORA given that nearly 80 percent of ORA's budget supports employee salary costs. Without these funds ORA must

reduce FTE in order to adequately cover payroll, which will lead to corresponding reductions in inspections and laboratory analyses and decrease FDA's ability to protect the public health.

Administrative Savings and Management Efficiencies

The FY 2009 budget request includes a $1,067,000 reduction across the Field Drug, Field Biologics, Field Animal Drugs and Feeds, and Field Device Programs. This proposed reduction reallocated resources from lower priority activities to higher priority FY 2009 budget initiatives. Recent hires of administrative and support staff allow ORA to increase inspectional time previously lost to administrative duties and increase the efficiency of time spent on administrative tasks. Increases in efficiency as a result of these recent hires will allow ORA to reallocate $1,067,000 in savings to activities of a higher priority.

User Fees Inflationary Increases

The request also includes a total of $14,633,000 in user fees for the Field Medical Devices and Field Biologics programs, an increase of $745,000 over FY 2008 funding levels. The Field Medical Devices and Field Biologics programs receives user fee resources for medical device review—the Medical Device User Fee and Modernization Act (MDUFMA). Additionally, the Field Medical Device program receives user fee resources for mammography facilities inspections and certification— Mammography Quality and Standards Act (MQSA). FDA is requesting an increase in MDUFMA user fee collection authority that will provide an additional $122,000 for Field activities to improve the review process. This request also includes an increase in MQSA user fee collection authority that will provide $623,000 to Field Devices Program to cover the cost of inflationary increases to the program.

The requested level of MDUFMA user fee authority supplements the Field Devices and Radiological Health and the Field Biologics Program's inspection activities.

The requested level of MQSA user fee authority funds annual MQSA inspections of non-government facilities to ensure that mammography facilities remain in compliance with established quality standards.

**Proposed User Fees**

Generic Drugs User Fee

Applications to market generic drugs, Abbreviated New Drug Applications (ANDAs), are critical to lowering public and private spending on pharmaceuticals. Since 2002, the number of ANDAs has more than doubled. This proposal is to modify the Food, Drug, and Cosmetic Act to establish user fees for each new application and annually for approved generic products. The additional $2,792,000 and six FTE by the proposed generic user fees would allow FDA to reduce the time to conduct reviews of ANDAs and respond to the growing number of generic drug applications.

Reinspection User Fee

This proposal for $13,014,000 and 102 FTE in Reinspection User Fees supports reinspection costs incurred when FDA conducts follow-up inspections to verify that a firm implements action

to correct violations discovered during an inspection or stemming from a warning letter. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations.

Generic Animal Drug User Fee

The Animal Drugs and Feeds program proposes receiving user fee resources for new Animal Generic Drug User Fees (AGDUFA) thus generating resources that will allow FDA to improve product review performance and reduce review time. FDA is requesting an increase for AGDUFA user fee collection authority that will provide an additional $143,000 and 1 FTE will go to the Field Animal Drugs and Feeds Program.

Increasing costs for the review of Abbreviated New Animal Drug Applications (ANADAs) along with inadequate resources has resulted in a significant increase in review times and a backlog of generic animal drug applications for review. Despite several management initiatives already implemented to make this process more efficient, reduced resources have led to a significant increase in review times. Increasing review staff through user fee revenues will shorten the time to approval, thereby making lower cost medications available to the food animal production industry, veterinary practitioners, companion animal owners, and the general public sooner.

## ORA Outputs / Outcomes Table

(These goals are repeated here to give a cohesive look at ORA)

| # | Key Outcomes/Outputs | FY 2004 Actual | FY 2005 Actual | FY 2006 Target | FY 2006 Actual | FY 2007 Target | FY 2007 Actual | FY 2008 Target | FY 2009 Target |
|---|---|---|---|---|---|---|---|---|---|
| **Long-Term Objective 1:** Improve the medical product review process to increase the predictability and transparency of decisions using the best available science. | | | | | | | | | |
| 1 | Number of Medical Device Bioresearch Monitoring (BIMO) inspections (253201) (output) | 354 | 335 | 295 | 336 | 295 | 323 | 300[†] | 300 |
| **Long-Term Objective 2:** Detect safety problems earlier and better target interventions to prevent harm to consumers. | | | | | | | | | |
| 2 | Number of prior notice import security reviews. (214201) (output) | 33,111 | 86,187 | 45,000 | 89,034 | 60,000 | 84,088 | 80,000[‡] | 80,000 |
| 3 | Number of import food field exams. (214202) (output) | 70,926 | 84,997 | 73,376 | 94,545 | 71,000 | 94,743 | 85,000[§] | 105,000 |
| 4 | Number of Filer Evaluations. (214203) (output) | 1,745 | 1,407 | 1,000 | 1,441 | 1,000 | 1,355 | 1,000 | 1,000 |
| 5 | Number of examinations of FDA refused entries. (214204) (output) | 4,905 | 5,655 | 3,000 | 5,846 | 3,000 | 5,510 | 4,000[**] | 4,000 |
| 6 | Number of high risk food inspections. (214205) (output) | 7,597 | 7,568 | 5,963 | 6,795 | 5,625 | 6,421 | 5,700 | 6,100 |
| 7 | Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214303) (outcome) | NA | NA | NA | NA | NA | NA | 5 data entry labs | 5 data entry labs |
| 8 | Number of foreign and domestic high-risk human drug inspections. (224201) (output) | 481 | 600 | 483 | 510 | 500 | 583 | 500 | 600 |
| 9 | Number of high risk registered domestic blood bank and biologics manufacturing inspections. (234202) (output) | NA | NA | NA | NA | NA | NA | 870[††] | 870 |
| 10 | Number of highest priority human tissue establishment inspections. (234203) (output) | NA | NA | 250 | 354 | 325 | 427 | 325 | 370 |
| 11 | Number of domestic and foreign high risk animal drug and feed inspections. (244202) (output) | NA | NA | NA | NA | NA | NA | 233[‡‡] | 233 |

[†] FY 2008 target increased to 300 to better align with recent historical actual data.
[‡] FY 2008 target increased to 80,000 to better align with recent historical actual data.
[§] FY 2008 target increased to 85,000 to better align with recent historical actual data.
[**] FY 2008 target increased to 4,000 to better align with recent historical actual data.
[††] This new FY 2008 goal is the result of a concerted effort to develop a better high risk measure for Biologics. While the overall number of inspections in this program are not decreasing, this goal guarantees that the riskiest establishments are inspected, better protecting the public health.
[‡‡] This new FY 2008 goal is the result of a concerted effort to develop a better high risk measure for Animal Drugs and Feeds. This new goal guarantees that the riskiest establishments are inspected, thus better protecting the public health.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 12 | Number of targeted prohibited material BSE inspections (244203) (output) | 647 | 588 | 516 | 516 | 490 | 523 | 490 | 490 |
| 13 | Number of domestic and foreign Class II and Class III device inspections. (254201) (output) | 1,709 | 1495 | 1,234 | 1,506 | 1,195 | 1,468 | 1,270 | 1,300 |
| 14 | Establish and maintain accreditation for ORA labs. (214206) (outcome) | 1 lab | 6 labs | 13 labs | 13 labs | 13 labs | 13 labs | 13 labs | 13 labs |
| 15 | Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week) (214305) (outcome) | NA | 0 | 1,200 chem | 1,200 chem | 1,000 rad & 1,200 chem | 1,000 rad & 1,200 chem | 2,500 rad & 1,200 chem[§§] | 2,500 rad & 1,200 chem |

**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 2009, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach. The FY 2008 and FY 2009 targets have been increased slightly to 300 inspections to better reflect recent actuals. However, they are slightly lower than the FY 2007 actuals because the number of applications under review that may require BIMO inspections can only be estimated.

**Performance:** In FY 2007, FDA exceeded this goal of 295 by conducting 323 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. The FY 2008 and FY 2009 targets have been increased to 80,000 security reviews to better reflect recent historical actuals for this goal. However, they are still lower than the FY 2007 actuals since it is unknown how many entries will be flagged for review as a potential security or public health risk in a given year. 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.

[§§] The FY 2008 target was reduced to 1,200 chemical samples per week because the FY 2007 RCR funding level did not fund the three new Chemical Labs.

**Performance:** In FY 2007, FDA exceeded this goal of 60,000 by conducting 84,088 import security reviews. The FDA Prior Notice Center collaborated with Customs and Border Protection to direct field personnel to hold and examine five (5) suspect shipments of imported foods; refused 390 lines of imported food for prior notice violations; conducted 333 informed compliance calls, responded to 29,490 phone and e-mail inquiries; and conducted the 84,088 intensive security reviews of the 9,804,001 Prior Notice submissions received in order to detect and intercept contaminated products before they enter the food supply. Explanation of why this goal was significantly exceeded: This goal is a difficult goal to set targets for because it is not known in advance how many food/feed entry lines will require an import security review, but FDA is required to review all of them. Therefore, FDA must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed the goal even if the number of lines requiring an import security review in a given year decreases from historical averages. FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years. The change in target should have minimal impact on FDA's ability to identify and prevent imported food and feed products that may be intentionally contaminated with biological, chemical or radiological agents, or which may pose a significant health risk to the American Public from entering the US.

**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 9.3 million line entries of imported food out of an estimated 15.9 million lines of FDA regulated products in FY 2007. In FY 2009, FDA expects approximately 10.4 million line entries of imported food within a total of more than 18.2 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. The FY 2008 target is lower than the FY 2007 actuals because the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that may not occur in the next year. In FY 2009, FDA will use additional Food Protection resources to increase the number of import food field exams by 20,000 exams.

**Performance:** In FY 2007, FDA exceeded this goal of 71,000 by completing 94,743 field examinations of imported food lines. Explanation of why this goal was significantly exceeded: It's difficult to estimate the target for this goal because there are several different risk factors that affect how many exams will be done in a certain year, including unplanned agency initiatives and emergencies. Therefore, FDA must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed the goal. However, FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years.

**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 2009 target is being maintained even though it is lower than the FY 2007 actuals because the historical accomplishments for this goal have decreased every year.

**Performance:** In FY 2007, FDA exceeded this goal of 1,000 by performing 1,355 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 2008 and FY 2009 targets have been increased to 4,000 examinations to better reflect the recent historical actuals for this goal.

**Performance:** In FY 2007, FDA exceeded this goal of 3,000 by performing 5,510 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 will include activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program.

**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 2008 and FY 2009 targets have been increased over the FY 2007 target but are lower than the FY 2007 actuals because the available inventory of firms for this goal is highly variable. Also, the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that may not occur in subsequent years.

**Performance:** In FY 2007, FDA exceeded this goal of 5,625 by performing 6,421 inspections of high-risk domestic food establishments.

**7. Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange.** (214301)

**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. To date, 135 laboratories representing multiple government agencies and all 50 states are contributing data into the eLEXNET system allowing the program to successfully populate its database with valuable information for use in threat detection, risk assessment, inspection planning, and traceback analysis. eLEXNET plays a crucial role in the Nation's food testing laboratory system and is an integral component of the Nation's overall public health laboratory information system. FDA anticipates that increasing data exchange participation will enhance the utility of the data, improve data quality, and increase the effectiveness of the nation's food security efforts.

**Performance:** FDA exceeded the previous FY 2007 goal by creating informational reports on 8 specific analytes and 5 select agents. eLEXNET automatically sends recurring reports regarding 8 analytes including salmonella in peanut butter, colors in all products, pesticide residue in all products, elemental analysis in all products, antibiotic residues in all products, E. coli in spinach, Shigella in all products, and results of FDA's protein surveillance assignments. eLEXNET also routinely sends reports to FERN laboratories on 5 select agents including Bacillus anthracis, clostridium botulinum, clostridium perfringens, aflatoxin, and ricin. The FY 2008 target reflects the new goal to convert manual data entry to automated for which accomplishment data will not be available until the end of FY 2008.

**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 2009. 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.

**Performance:** FDA exceeded the FY 2007 goal of 500 by inspecting 583 high-risk foreign and domestic drug manufacturers.

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

**Context:** FDA will increase risk-based compliance and enforcement activities by inspecting the highest priority registered manufacturers of biological products. The highest priority firms will be those whose operations are determined to be the highest risk, new product types in need of an inspectional history to evaluate and stratify risk, and, emergency response situations. Inspections for the goal are conducted to ensure compliance with Current Good Manufacturing Practices (CGMPs), and to ensure, as appropriate, the safety, purity and potency of biological products. There are currently an estimated 2,450 establishments in the Biologics program inventory covered under the cGMP regulation. The biologics inventory includes high-risk establishments such as blood collection facilities, plasma fractionator establishments, and vaccine manufacturing establishments, especially seasonal and pandemic influenza vaccines.

**Performance:** In FY 2007, FDA exceeded the previous statutory inspection goal of 1,138 by inspecting 1,256 blood banks, source plasma and biologics manufacturing establishments. The FY 2008 target reflects the new high-risk prioritized goal for which accomplishment data will not be available until the end of FY 2008.

**10. Number of highest priority 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 will increase this goal by 45 additional tissue inspections in order to cover more of the firms that registered as a

result of the new regulations. However, the FY 2008 and 2009 targets are lower than the FY 2007 actuals because the FY 2007 actuals reflect a one-time Agency blitz of US companies to look for problems related to tissue recovery issues uncovered in FY 2006.

**Performance:** In FY 2007, FDA exceeded the human tissue goal of 325 by conducting 427 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 will be 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 will focus on pre-market approval inspections and implementing risk-based cGMP inspection plans for animal drug and feed manufacturing facilities that will utilize risk modeling to identify the highest risk firms to be inspected. The FY 2008 target is being maintained into FY 2009 because this is a new, risk-based goal for which we have no historical experience, and are unsure how the new site-selection methodology will evolve.

**Performance:** In FY 2007, FDA exceeded the previous registered animal drugs and feed establishments' statutory inspection goal of 620 by inspecting 671 registered establishments. The FY 2008 target reflects the new high-risk prioritized goal for which accomplishment data will not be available until the end of FY 2008.

**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. The FY 2008 target is being maintained into FY 2009 because this goal is a 100% accomplishment goal; therefore, the target is set to the number of known manufacturers at the beginning of the fiscal year.

**Performance:** In FY 2007, FDA completed the inspection of all 523 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 inventory of Class II and Class III foreign and domestic firms is approximately 10,900 firms. 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. The FY 2008 and FY 2009 targets have been increased over the FY 2007 target to better reflect recent actuals. However, they are lower than the FY 2007 actuals because the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that cannot be estimated in advance.

**Performance:** FDA exceeded the FY 2007 medical device performance goal of 1,195 by inspecting 1,468 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.

**Performance:** In FY 2007, 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. Philadelphia District Lab underwent a renewal assessment in November 2007.
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.

**Performance:** In FY 2007, FDA met this performance goal when the 2 State Radiological Laboratories funded in FY 2006 were provided equipment and training to support their analytical surge capacity of 1,000 radiological samples per week. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week. Also in FY 2007, FDA awarded Cooperative Agreements to 3 State Radiological Laboratories to increase the capacity to respond to radiological attacks on the food supply. These 3 laboratories are the basis for the increase of 1,500 radiological samples per week in the FY 2008 surge capacity goal.

## Field Foods Program Activity Data (PAD)

| Field Foods Program Workload and Outputs | FY 2007 Actual | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|
| **DOMESTIC INSPECTIONS** | | | |
| Domestic Food Safety Program Inspections | 3,148 | 4,000 | 5,057 |
| Imported and Domestic Cheese Program Inspections | 360 | 360 | 450 |
| Domestic Low Acid Canned Foods/ Acidified Foods Inspections | 448 | 450 | 542 |
| Domestic Fish & Fishery Products (HACCP) Inspections | 1,954 | 1,950 | 2,000 |
| Import (Seafood Program Including HACCP) Inspections | 408 | 500 | 500 |
| Juice HACCP Inspection Program (HACCP) | 416 | 415 | 500 |
| Interstate Travel Sanitation (ITS) Inspections | 1,112 | 1,555 | 1,755 |
| State Contract Food Safety ( Non HACCP) Inspections | 7,398 | 8,973 | 9,300 |
| State Contract Domestic Seafood HACCP Inspections | 1,103 | 1,145 | 1,010 |
| State Contract Juice HAACP | 57 | 51 | 75 |
| State Contract LACF | 0 | 60 | 75 |
| State Partnership Inspections | 634 | 700 | 700 |
| **Total Above FDA and State Inspections** | **17,038** | **20,159** | **21,964** |
| | | | |
| State Contract and Grant Foods Funding | $7,372,000 | $8,825,000 | $9,600,000 |
| | | | |
| Number of FERN State Laboratories | 13 | 13 | 13 |
| Annual FERN State Cooperative Agreements/Operations Funding | $8,385,000 | $7,435,000 | $7,480,000 |
| | | | |
| **Total State & Annual FERN Funding** | **$15,757,000** | **$16,260,000** | **$17,080,000** |
| | | | |
| Domestic Field Exams/Tests | 2,438 | 4,925 | 4,925 |
| Domestic Laboratory Samples Analyzed | 11,683 | 9,880 | 9,955 |

| | | | |
|---|---|---|---|
| **PROGRAM OUTPUTS-** | | | |
| **IMPORT/FOREIGN INSPECTIONS** | | | |
| All Foreign Inspections | 96 | 150 | 200 |
| | | | |
| Import Field Exams/Tests | 94,743 | 85,000 | 105,000 |
| Import Laboratory Samples Analyzed | 24,588 | 26,000 | 26,075 |
| Import Physical Exam Subtotal | **119,331** | **111,000** | **131,075** |
| | | | |
| Import Line Decisions | 9,356,074 | 9,853,234 | 10,376,812 |
| Percent of Import Lines Physically Examined | 1.28% | 1.13% | 1.26% |
| **Prior Notice Security Import Reviews (Bioterrorism Act Mandate)** | 84,088 | 80,000 | 80,000 |

# Field Cosmetics Program Activity Data (PAD)

| Field Cosmetics Program Workload and Outputs | FY 2007 Actual | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|
| **DOMESTIC INSPECTIONS** | | | |
| All Inspections (Domestic and Foreign) | 114 | 100 | 100 |
| | | | |
| **PROGRAM OUTPUTS-** | | | |
| **IMPORT/FOREIGN INSPECTIONS** | | | |
| | | | |
| Import Field Exams/Tests | 2,095 | 2,000 | 2,000 |
| Import Laboratory Samples Analyzed | 229 | 230 | 200 |
| **Import Physical Exam Subtotal** | 2,324 | 2,230 | 2,200 |
| | | | |
| Import Line Decisions | 1,465,113 | 1,579,607 | 1,703,048 |
| Percent of Import Lines Physically Examined | 0.16% | 0.14% | 0.13% |

# Field Drugs Program Activity Data (PAD)

| Field Drugs Program Workload and Outputs | FY 2007 Actual | FY 2008 Estimate | FY 2009 Estimate | |
|---|---|---|---|---|
| **DOMESTIC INSPECTIONS** | | | | |
| Pre-Approval Inspections (NDA) | 133 | 120 | 120 | |
| Pre-Approval Inspections (ANDA) | 83 | 132 | 177 | |
| Bioresearch Monitoring Program Inspections | 494 | 511 | 511 | 1 |
| Drug Processing (GMP) Program Inspections | 1,073 | 1,400 | 1,423 | |
| Compressed Medical Gas Manufacturers Inspections | 74 | 127 | 127 | |
| Adverse Drug Events Project Inspections | 89 | 122 | 122 | |
| OTC Monograph Project and Health Fraud Project Inspections | 32 | 48 | 48 | |
| State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections | 21 | 110 | 110 | |
| State Partnership Inspections: GMP Inspections | 15 | 50 | 50 | |
| **Total Above FDA and State Partnership Inspections** | 2,014 | 2,620 | 2,688 | |
| | | | | |
| Domestic Laboratory Samples Analyzed | 1,368 | 1,144 | 1,144 | |
| | | | | |
| **PROGRAM OUTPUTS-** | | | | |
| **IMPORT/FOREIGN INSPECTIONS** | | | | |
| | | | | |
| Foreign Pre-Approval Inspections (NDA) incl PEPFAR | 167 | 192 | 192 | |
| Foreign Pre-Approval Inspections (ANDA) incl PEPFAR | 140 | 92 | 187 | |
| Foreign Bioresearch Monitoring Program Inspections incl PEPFAR | 152 | 46 | 57 | 1 |
| Foreign Drug Processing (GMP) Program Inspections | 282 | 221 | 281 | |
| Foreign Adverse Drug Events Project Inspections | 9 | 16 | 16 | |
| **Total Above Foreign FDA Inspections** | 750 | 567 | 733 | |
| | | | | |
| Import Field Exams/Tests | 2,329 | 4,400 | 4,400 | |
| Import Laboratory Samples Analyzed | 324 | 260 | 260 | |
| **Import Physical Exam Subtotal** | 2,653 | 4,660 | 4,660 | |
| | | | | |
| Import Line Decisions | 312,392 | 348,953 | 389,792 | |
| Percent of Import Lines Physically Examined | 0.85% | 1.34% | 1.20% | |

1. The estimate for FY09 Human Drugs ANDA inspections include Proposed Generic Drug User Fee inspections.

# Field Biologics Program Activity Data (PAD)

| Field Biologics Program Workload and Outputs | FY 2007 Actual | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|
| **DOMESTIC INSPECTIONS** | | | |
| Bioresearch Monitoring Program Inspections | 116 | 175 | 175 |
| Blood Bank Inspections | 1,082 | 1,071 | 1,082 |
| Source Plasma Inspections | 168 | 182 | 182 |
| Pre-License, Pre-Approval (Pre-Market) Inspections | 23 | 11 | 22 |
| GMP Inspections | 33 | 32 | 32 |
| GMP (Device) Inspections | 12 | 11 | 13 |
| Human Tissue Inspections | 426 | 517 | 562 |
| **Total Above Domestic Inspections** | 1,860 | 1,999 | 2,068 |
| | | | |
| **PROGRAM OUTPUTS-** | | | |
| **IMPORT/FOREIGN INSPECTIONS** | | | |
| | | | |
| Blood Bank Inspections | 9 | 13 | 15 |
| Pre-License Inspections | 1 | 0 | 0 |
| GMP Inspections | 20 | 17 | 17 |
| **Total Above Foreign FDA Inspections** | 30 | 30 | 32 |
| | | | |
| Import Field Exams/Tests | 46 | 100 | 100 |
| | | | |
| Import Line Decisions | 48,949 | 53,942 | 59,445 |
| Percent of Import Lines Physically Examined | 0.09% | 0.19% | 0.17% |

## Field Animal Drugs and Feeds Program Activity Data (PAD)

| Field Animal Drugs & Feeds Workload and Outputs | FY 2007 Actual | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|
| **DOMESTIC INSPECTIONS** | | | |
| Pre-Approval/Bioresearch Monitoring Program Inspections | 36 | 79 | 79 |
| Drug Process and New ADF Program Inspections | 190 | 171 | 191 |
| BSE Inspections | 1765 | 2594 | 2594 |
| Feed Contaminant Inspections | 29 | 20 | 30 |
| Illegal Tissue Residue Program Inspections | 176 | 240 | 260 |
| Feed Manufacturing Program Inspections | 326 | 141 | 141 |
| | | | |
| State Contract/Coop Agreement Inspections: BSE | 5979 | 4684 | 4700 |
| State Contract Inspections: Feed Manufacturers | 418 | 354 | 336 |
| State Contract Inspections: Illegal Tissue Residue | 310 | 310 | 350 |
| State Partnership Inspections: BSE and Other | 346 | 600 | 600 |
| **Total Above FDA and State Contract Inspections** | 9575 | 9193 | 9281 |
| | | | |
| State Contract Animal Drugs/Feeds Funding | $2,030,000 | $2,233,300 | $2,550,000 |
| BSE Cooperative Agreement Funding | $3,000,000 | $3,000,000 | $3,000,000 |
| State Contract Tissue Residue Funding | $452,000 | $323,000 | $342,801 |
| **Total State Funding** | $5,482,000 | $5,556,300 | $5,892,801 |
| | | | |
| Domestic Laboratory Samples Analyzed | 3182 | 1775 | 1810 |
| | | | |
| **PROGRAM OUTPUTS-** | | | |
| **IMPORT/FOREIGN INSPECTIONS** | | | |
| Foreign Bioresearch Monitoring Inspections | 25 | 22 | 24 |
| Foreign Drug Processing & New ADF Program Inspections | 14 | 10 | 15 |
| **Total Above Foreign FDA Inspections** | 39 | 32 | 39 |
| | | | |
| Import Field Exams/Tests | 3656 | 4500 | 4500 |
| Import Laboratory Samples Analyzed | 717 | 655 | 690 |

| Field Animal Drugs & Feeds Workload and Outputs | FY 2007 Actual | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|
| Import Physical Exam Subtotal | 4373 | 5155 | 5190 |
| | | | |
| Import Line Decisions | 235,571 | 245,592 | 256,039 |
| Percent of Import Lines Physically Examined | 1.86% | 2.10% | 2.03% |

# Field Devices Program Activity Data (PAD)

| Field Devices Program Workload and Outputs | FY 2007 Actual | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|
| **DOMESTIC INSPECTIONS** | | | |
| Bioresearch Monitoring Program Inspections | 315 | 307 | 314 |
| Pre-Approval Inspections | 62 | 100 | 100 |
| Post-Market Audit Inspections | 59 | 66 | 66 |
| GMP Inspections (Levels I, II, III and Accredited Persons) | 1278 | 1504 | 1569 |
| **Total Above Domestic Inspections: Non MQSA** | 1714 | 1977 | 2049 |
| | | | |
| Inspections (MQSA) FDA Domestic (non-VHA) | 329 | 279 | 279 |
| Inspections (MQSA) FDA Domestic (VHA) | 30 | 30 | 33 |
| Inspections (MQSA) by State Contract | 7668 | 7920 | 7800 |
| Inspections (MQSA) by State non-Contract | 619 | 620 | 700 |
| **Total Above Domestic Inspections: MQSA** | 8646 | 8849 | 8812 |
| | | | |
| State Contract Devices Funding | $0 | $200,600 | $200,600 |
| State Contract Mammography Funding | $7,627,000 | $10,730,401 | $10,812,739 |
| **Total State Funding** | $9,802,644 | $10,931,001 | $11,013,339 |
| | | | |
| Domestic Radiological Health Inspections | 86 | 154 | 154 |
| Domestic Field Exams/Tests | 847 | 934 | 934 |
| Domestic Laboratory Samples Analyzed | 140 | 102 | 102 |
| | | | |
| **PROGRAM OUTPUTS-** | | | |
| **IMPORT/FOREIGN INSPECTIONS** | | | |
| Foreign Bioresearch Monitoring Inspections | 8 | 10 | 10 |
| Foreign Pre-Approval Inspections | 27 | 33 | 33 |
| Foreign Post-Market Audit Inspections | 30 | 26 | 31 |
| Foreign GMP Inspections | 271 | 235 | 270 |
| Foreign MQSA Inspections | 19 | 17 | 20 |
| Foreign Radiological Health Inspections | 10 | 28 | 28 |

| Field Devices Program Workload and Outputs | FY 2007 Actual | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|
| **Total Above Foreign FDA Inspections** | 365 | 349 | 392 |
| | | | |
| Import Field Exams/Tests | 4620 | 5000 | 5000 |
| Import Laboratory Samples Analyzed | 1327 | 801 | 801 |
| Import Physical Exam Subtotal | 5947 | 5801 | 5801 |
| | | | |
| Import Line Decisions | 4,567,148 | 4,984,383 | 5,439,735 |
| Percent of Import Lines Physically Examined | 0.13% | 0.12% | 0.11% |