

FIELD ACTIVITIES – OFFICE OF REGULATORY AFFAIRS

Introduction

The FY2010 program level budget request for FDA's Field Activities – Office of Regulatory Affairs (ORA) Program is \$953,731,000.

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

	FY 2008		FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
	Enacted	Actuals			
Program Level	\$650,712,000	\$573,181,000	\$725,115,000	\$953,731,000	\$228,616,000
FTE	3,552	3,314	3,775	4,336	561
Budget Authority	\$626,646,000	\$555,450,000	\$699,611,000	\$848,404,000	\$148,793,000
<i>Pay Increase (non-add)</i>				12,856,000	12,856,000
<i>Protect America's Food Supply (non-add)</i>				\$107,952,000	\$107,952,000
<i>Safer Medical Products (non-add)</i>				\$26,986,000	\$26,986,000
<i>Drug Importation (non-add)</i>				\$1,000,000	\$1,000,000
Budget Authority FTE	3,485	3,258	3,706	3,977	271
User Fees	\$24,066,000	\$17,731,000	\$25,504,000	\$105,327,000	\$79,823,000
PDUFA	\$10,178,000	\$7,259,000	\$10,478,000	\$11,795,000	\$1,317,000
FTE	50	40	50	59	9
MDUFMA	\$1,434,000	\$1,230,000	\$1,556,000	\$1,556,000	\$0
FTE	9	8	8	11	3
ADUFA	\$0	\$0	\$250,000	\$250,000	\$0
FTE	0	0	2	2	0
AGDUFA			\$143,000	\$143,000	\$0
FTE			1	1	0
MQSA	\$12,454,000	\$9,242,000	\$13,077,000	\$13,077,000	\$0
FTE	8	8	8	8	0
Proposed User Fees	0	0	0	\$78,506,000	\$78,506,000
Generic Drugs				\$6,045,000	\$6,045,000
FTE				12	12
Reinspection				\$14,446,000	\$14,446,000
FTE				112	112
Export Certification				\$3,015,000	\$3,015,000
FTE				19	19
Inspection and Facility Registration				\$55,000,000	\$55,000,000
FTE				135	135
User Fees FTE	67	56	69	359	290

Authorizing Legislation:

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

Program Description and Accomplishments

The FDA's Office of Regulatory Affairs is the lead office for all FDA Field activities as well as providing FDA 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 supports 4,366 FTE that are dispersed throughout the United States. Over 85 percent of ORA's staff works in 5 Regional Offices, 20 District Offices, 13 Laboratories, and 177 Resident Posts and Border Stations. As a separate entity within ORA, Office of Criminal Investigations (OCI) personnel are located throughout the field organization in 32 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 its State, Local, Tribal, and Territories counterparts 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.

The Office of Information Management (OIM) provides FDA's leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT

*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.

projects and resources in 2008, OIM supports the Regulatory Affairs Program by maintaining its legacy systems and databases used for managing and tracking its review programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also work with the Regulatory Affairs Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

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 ORA's cross-cutting areas addressing imported products, enforcement activities, leveraging with the States, public health emergencies, and laboratory capability.

Assuring the Safety of Imported Products – Field Activities

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 2010, FDA projects a total of 20.5 million import lines, which will be comprised of 47 percent food products, 9 percent cosmetic products, 2 percent human drugs and biologic products, 1 percent animal drugs and feed products, and 41 percent medical device and radiological health products. ORA uses a combination of electronic information technology for risk-based screening and staff intensive surveillance, physical examinations, and laboratory analysis to make import entry decisions.

ORA conducted 5,926 import field examinations of FDA refused entries in FY 2008. 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 2008, the PNC performed 80,543 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.

In July 2008, FDA published a Federal Register notice seeking volunteers for a pilot program regarding third-party certification of aquacultured shrimp. The objective of the pilot is to assess whether third-party certification can augment FDA's ability to ensure that products imported into the United States meet FDA safety and security standards. In Phase I of the pilot, FDA is evaluating documentation submitted by Certification Bodies wishing to participate in the pilot and visiting their offices to ask follow-up questions and review records. Those Certified Bodies whose programs satisfy criteria specified in Federal Register will move on to Phase II of the

pilot. During Phase II, FDA will observe the Certified Bodies as they inspect aquacultured shrimp processors and assess the operations of laboratories that sample and test the product before it is shipped. ORA field personnel who are certified as Level 2 Seafood Investigators will visit shrimp processors and ORA Laboratory Analysts experienced in analyzing seafood samples will visit laboratories used by the processors. If the pilot establishes that third-party Certification Bodies are able to certify aquacultured shrimp for compliance with FDA requirements, FDA could better target its resources on products from non-certified processors. FDA expects to complete the pilot in FY 09.

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 through FY 2008, OCI opened 371 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
2008 (Actual)	41,309,714
2009 (Omnibus)	46,559,507
2010 (Estimate)	48,138,768

In FY 2008, OCI initiated 56 counterfeit drug investigations and had 25 arrests and 45 convictions with fines and restitutions approaching \$4,000,000. 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, Local, Tribal, and Territory law enforcement here in the U.S.

The OCI also aggressively investigates potential criminal violations regarding the nation's food supply. During 2008, OCI initiated 140 food safety related cases and had 48 arrests and 61 convictions. An example of such a case occurred in FY 2008, when a dairy farmer in Louisiana

pled guilty to distributing adulterated milk. The OCI investigation disclosed that the farmer added salt and water to milk that was then sold to the Dairy Farmers of America (DFA). Adding the water and salt to the milk made the load heavier, which caused DFA to pay more for the adulterated milk. Another case involved a Florida business owner who was sentenced to 15 months incarceration and ordered to pay a \$5,000 fine for distributing adulterated and misbranded foods such as lobster dip, salmon cream cheese, chicken salad, salmon spread, and others which contained the harmful bacterium *listeria monocytogenes*.

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 218 contracts/grants and Cooperative Agreements to State and local governments to perform MQSA, feed/BSE, tissue residue, food, and medical device inspections and Food Emergency Response Network (FERN) laboratory projects. Twenty five States are enrolled in the Manufactured Food Regulatory Program Standards (MFRP) initiative, which strengthens their food safety programs by striving toward standardization and equivalency. To better share inspection data with our State partners, 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. In addition, 36 States share the eSAF data base in the BSE program. These efforts improve eSAF's ability to communicate with State IT programs so that ORA can access all available State inspection data rather than being limited to contract inspection data. 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.

Training remains a top priority of the Field to ensure expertise and encourage collaboration with external stakeholders. In FY 2008, one hundred thirty nine (139) courses were conducted with more than 3,731 participants. Courses were offered to FDA, State, local, tribal and Indian Health Service regulators in the following commodity areas: Biologics; Bioresearch; Compliance; Computers; Devices; Drugs; Food; Imports; Laboratory; Management; Multi-program areas; and Veterinary Medicine. In addition, innovative video conference technology was used to connect three different States with six different locations for a three day training event. A three-year contract with the Western Institute of Food Safety and Security (WIFSS) at the University of California/Davis went into effect during FY08 for the development and maintenance of food and feed Rapid Response Teams (RRT) composed of States and their corresponding FDA District Office personnel. A draft team development and training plan has been created along with components of the curriculum, model Standard Operating Procedures (SOPS) to assist RRT development, and self assessment tool to be rolled out as a permanent part of the program. The first teams to be trained under this model will be the six states and districts involved in pilot RRT cooperative agreements awarded in fiscal year 2008. After this pilot, the (RRT) process is expected to be introduced to the other States and their FDA District Offices.

Response to Public Health Emergencies – Field Activities

ORA is working to increase FDA presence beyond our borders by opening offices in other countries and implementing Memorandums of Agreements with other countries. ORA conducted an international investigation to identify and determine the source of an unknown contaminant in Heparin Sodium USP, the active pharmaceutical ingredient in a critical drug compound used in 1,000s of US medical facilities for a host of medical procedures. Through forensic techniques, the contaminant was identified as over-sulfated chondroitin sulfate. Multiple drug and device recalls involving approximately 74 million vials/syringes were conducted by several firms as a result of this investigation. The contaminated product was imported as an API from China and used by several different domestic manufacturers. The investigation of the cause and source of the contamination included both domestic and foreign investigations. The investigation prompted recalls which ensured that distribution of contaminated product was halted, thereby preventing additional patient exposure to contaminated product and established needed standards for manufacturers to insure that their API sources were free of contamination.

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. ORA made improvements to laboratories and regulatory science during FY 2008 including developing, manufacturing and implementing the Alternative Light Source (ALS), a Field analysis kit used to conduct visual examinations to aid in screening and sampling of suspected counterfeit drug products. Preliminary results generated by ALS Field analysis help to streamline and better prioritize lab analyses. ORA also implemented a computerized National Sample Distributor system (NSD) that analyzes laboratory capacity and routes a sample to the laboratory with the capacity and capability for analysis. The NSD directed over 35,000 samples in FY 2008, and has improved lab facility usage overall and efficiency in analytical response to emergencies, outbreak, consumer complaints as well as routine import and domestic sample collections.

To complement the analytical work of FDA labs, ORA developed and supports FERN, a network of State and local labs that perform laboratory analysis for FDA in the event of a public health emergency. FERN focused on building both capacity and capability at the State and local level by expanding to 151 laboratories representing 50 States and Puerto Rico. Three Chemical Cooperative Agreements were awarded to State FERN laboratories to begin in FY2009, adding to the eight already underway.

The FERN laboratories are increasingly providing critical analytical surge capacity during food emergency events. An FDA assignment directed samples to the FERN labs during the Salmonella outbreak in peppers, with over 150 samples tested. FERN laboratories also participated in the FDA surveillance assignment for both 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.

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 2008, FERN laboratories added capacity for 2,500 radiological samples per week and maintained 1,200 chemical samples per week.

Five Year Funding Table

The following table shows a five-year funding history for the Office of Regulatory Health program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2006 Actual	\$499,853,000	\$482,361,000	\$17,492,000	3,460
FY 2007 Actual	\$522,658,000	\$505,753,000	\$16,905,000	3,290
FY 2008 Actual	\$573,181,000	\$555,450,000	\$17,713,000	3,314
FY 2009 Omnibus	\$725,115,000	\$699,611,000	\$25,504,000	3,775
FY 2010 Estimate	\$953,731,000	\$848,404,000	\$105,327,000	4,366

Budget Request

The FY 2010 President's Budget requests \$953,731,000 in program level funding for the Office of Regulatory Affairs (ORA), including the support of 4,366 FTE. The request represents an increase of \$228,616,000 (or thirty-two percent) over the FY 2009 Appropriation in budget authority and user fee amounts. The overall increase provides additional budget authority to implement Agency-wide initiatives established in FY 2009 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.

Protect America's Food Supply

The FY 2010 budget request for the Field Food Protection Program is \$107,952,000, which includes a \$100,733,000 increase in the Field Foods Program and a \$7,219,000 increase in the

Field Animal Drugs and Feeds Program over FY 2009 Budget Authority funding levels. This request will allow ORA to continue to provide technical assistance to foreign countries, establish a presence in foreign countries, and increase laboratory capacity.

Furthermore, ORA is requesting funding in FY 2010 to acquire support and continue building its workforce for more field food and feed work. In order to do so, ORA is requesting budget authority funding to continue hiring investigators, analysts, and support staff in order to continue to increase field and food work such as:

- Increase of 20,000 food and feed import exams by the end of 2011
- Increase of 2,000 domestic food and feed inspections by the end of 2012
- Increase of 50 foreign food and feed inspections by the end of 2012.

FDA envisions establishing a new strategic framework for an integrated national food safety system. In order to efficiently and effectively establish a fully integrated national food and feed safety system, FDA must build and expand existing programs and relationships with its regulatory partners, specifically its Federal, State, local, tribal and territorial partners. FDA is requesting funding in FY 2010 to begin establishing the necessary infrastructure for the Field Food and Field Feeds Programs in the following four areas:

- Develop a National Workplan that includes the inspections of food manufacturing and distribution facilities and the collection and analyses of compliance, surveillance, and environmental samples;
- Ensure that programmatic objectives and implementation are coordinated;
- Continue to develop uniform, national standards for such subjects as manufacturing, inspections, and enforcement;
- Build training courses and a certification program to be delivered to state, local, and tribal regulatory partners;
- Increase programmatic oversight and develop a more robust audit program.

A system of this magnitude may require new authorizations such as multi-year budget authority for Federal, State, local, tribal and territorial regulatory partners and the authority to share non-public information with our regulatory partners when it is necessary to protect public health. However, this request is necessary to begin building the framework for an integrated national food safety system.

Medical Product Initiatives:

The FY 2010 budget request for the Field Medical Product Safety and Development Program is \$26,986,000, which includes a \$13,868,000 increase in the Field Drugs Program, a \$4,177,000 increase in the Field Biologics Program, a \$1,554,000 increase in the Field Animal Drugs Program, and a \$7,387,000 increase in the Field Device and Radiological Products Program over FY 2009 Budget Authority funding levels. This request will allow ORA to continue with establishing its workforce for inspections and import exams and to increase laboratory capacity. Specifically, ORA will increase inspections for the Biologics and Devices Programs:

- Increase of 25 domestic tissue inspections and 41 domestic Quality Systems (QS) GMP medical device inspections above the FY 2010 levels by the end of 2012
- Increase of 23 foreign tissue inspections and 41 foreign QS-GMP medical device inspections above the FY 2010 levels by the end of 2012

These inspections are not planned to be completed until 2012 and 2013 because ORA will invest the next one to two years in hiring and training new field staff. For FY 2010, ORA is requesting \$1,000,000 for the Field Human Drug Program. This funding will be used to begin to develop a Drug Importation User Fee for FDA.

Cost of Living Pay Increase

The Office of Regulatory Affairs portion of FDA's requested pay increase is \$12,856,000 across all five Field Program areas. 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.

User Fees Inflationary Increases

The request also includes a total of \$11,795,000 in Prescription Drug User Fee Act (PDUFA) inflationary increases for ORA. This is an increase of \$1,317,000 over the FY 2009 Appropriation, an increase of \$1,186,000 for the Field Human Drugs Program, and an increase in \$131,000 for the Field Biologics Program. In September 2007, the President signed FDAAA into law. FDAAA authorized the collection of user fees for the regulatory review of prescription drugs for the fourth time. The PDUFA IV provisions of FDAAA enhance premarket review and give FDA more resources to create a modern postmarket drug safety system that follows products across their full life cycle. For ORA, PDUFA user fees enable the Human Drugs Program to conduct premarket inspections, including bioresearch monitoring inspections.

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 \$6,045,000 and 12 FTEs 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 and Food Export Certification User Fee

This proposal for \$25,848,000 and 129 FTEs 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. ORA's request is for \$14,446,000 and 112 FTE for all field programs. 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.

The FY 2010 budget also proposes a new user fee to support export certification activities. FDA collects user fees of up to \$175 per certificate issued for export certificates for drugs, animal drugs and devices as authorized by Section 801 (e)(4)(B) of the Act. However, there is no similar authority for collection user fees for export certificates for foods or animal feed. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect the cost of food and animal feed export certificate-related activities through user fees. Private sector exporters would bear the cost of the program, but would reap its benefits through FDA's enhanced ability to facilitate exports of their products. FDA currently funds this activity through discretionary appropriations. The total proposed collections for the FDA in FY 2010 are \$4,152,000 with \$3,015,000 of the collections being allocated to the Field Foods Program.

Food Inspection and Facility Registration User Fee

The FY 2010 budget proposes a User Fee for Food Inspection and Facility Registration for \$75,000,000. This proposal allocates \$45,000,000 to the Field Foods Program and \$10,000,000 to the Field Animal Feeds Program. Food facilities would be charged user fees for inspections and registration of their establishments. These user fees would fund FDA inspection activities such as an increase in domestic and foreign inspections, an additional 3,000 sample collections and the addition of three high throughput laboratories for sample analysis and faster testing.

Office of Regulatory Affairs (ORA) Performance Measures Table

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
<u>253201</u> : Number of Medical Device Bioresearch Monitoring (BIMO) inspections. <i>(Output)</i>	2010	300	December, 2010
	2009	300	December, 2009
	2008	300	301 (Target Exceeded)
	2007	295	323 (Target Exceeded)
	2006	N/A	336 (Historical Actual)
	2005	N/A	335 (Historical Actual)

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

Measure	FY	Target	Result
<u>214201</u> : Number of prior notice import security reviews. <i>(Output)</i>	2010	80,000	December, 2010
	2009	80,000	December, 2009
	2008	80,000	80,543 (Target Exceeded)

Measure	FY	Target	Result
	2007	60,000	84,088 (Target Exceeded)
	2006	N/A	89,034 (Historical Actual)
	2005	N/A	86,187 (Historical Actual)
214202: Number of import food field exams. (Output)	2010	140,000	December, 2010
	2009	120,000	December, 2009
	2008	85,000	100,718 (Target Exceeded)
	2007	71,000	94,743 (Target Exceeded)
	2006	N/A	94,545 (Historical Actual)
	2005	N/A	84,997 (Historical Actual)
214203: Number of Filer Evaluations. (Output)	2010	1,000	December, 2010
	2009	1,000	December, 2009
	2008	1,000	1,356 (Target Exceeded)
	2007	1,000	1,355 (Target Exceeded)
	2006	N/A	1,441 (Historical Actual)
	2005	N/A	1,407 (Historical Actual)
214204: Number of examinations of FDA refused entries. (Output)	2010	5,000	December, 2010
	2009	5,000	December, 2009
	2008	4,000	5,926 (Target Exceeded)
	2007	3,000	5,510 (Target Exceeded)
	2006	N/A	5,846 (Historical Actual)
	2005	N/A	5,655 (Historical Actual)
214205: Number of high risk food inspections. (Output)	2010	6,750	December, 2010
	2009	6,100	December, 2009
	2008	5,700	6,230 (Target Exceeded)
	2007	5,625	6,421 (Target Exceeded)
	2006	N/A	6,795 (Historical Actual)

Measure	FY	Target	Result
	2005	N/A	7,568 (Historical Actual)
<u>214303</u> : Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. <i>(Outcome)</i>	2010	5 data exchange additions/conversions	December, 2010
	2009	5 data exchange additions/conversions	December, 2009
	2008	5 data entry labs	11 data entry labs (Target Exceeded)
<u>224201</u> : Number of foreign and domestic high-risk human drug inspections. <i>(Output)</i>	2010	700	December, 2010
	2009	600	December, 2009
	2008	500	534 (Target Exceeded)
	2007	500	583 (Target Exceeded)
	2006	N/A	510 (Historical Actual)
	2005	N/A	600 (Historical Actual)
<u>234202</u> : Number of high risk registered domestic blood bank and biologics manufacturing inspections. <i>(Output)</i>	2010	1,000	December, 2010
	2009	870	December, 2009
	2008	870	1,014 (Target Exceeded)
<u>234203</u> : Number of highest priority human tissue establishment inspections. <i>(Output)</i>	2010	518	December, 2010
	2009	380	December, 2009
	2008	325	383 (Target Exceeded)
	2007	325	427 (Target Exceeded)
	2006	N/A	354 (Historical Actual)
<u>244202</u> : Number of domestic and foreign high risk animal drug and feed inspections. <i>(Output)</i>	2010	250	December, 2010
	2009	233	December, 2009
	2008	233	244 (Target Exceeded)
<u>244203</u> : Number of targeted prohibited material BSE inspections. <i>(Output)</i>	2010	490	December, 2010
	2009	490	December, 2009
	2008	490	555 (Target Exceeded)
	2007	490	523 (Target Exceeded)
	2006	N/A	516 (Historical Actual)

Measure	FY	Target	Result
	2005	N/A	588 (Historical Actual)
254201: Number of domestic and foreign Class II and Class III device inspections. (Output)	2010	1,365	December, 2010
	2009	1,340	December, 2009
	2008	1,270	1,431 (Target Exceeded)
	2007	1,195	1,468 (Target Exceeded)
	2006	N/A	1,506 (Historical Actual)
	2005	N/A	1,495 (Historical Actual)
214206: Maintain accreditation for ORA labs. (Outcome)	2010	13 labs	December, 2010
	2009	13 labs	December, 2009
	2008	13 labs	13 labs (Target Met)
	2007	13 labs	13 labs (Target Met)
	2006	N/A	13 labs (Historical Actual)
	2005	N/A	6 labs (Historical Actual)
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). (Outcome)	2010	2,500 rad & 2,100 chem	December, 2010
	2009	2,500 rad & 1,650 chem	December, 2009
	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	N/A	1,200 chem (Target Met)
	2005	N/A	0

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. There are no projected changes to this goal in FY 2010.

Performance: In FY 2008, FDA exceeded this goal of 300 by conducting 301 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.

Performance: During FY 2008, FDA received 10,065,863 prior notice submissions on which the PNC conducted 80,543 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. One shipment was held for potential biosecurity concerns and another 309 shipments were refused for prior notice violations. These operations actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats. In addition, the PNC responded to 25,220 phone and e-mail inquiries, and conducted 546 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 9.4 million line entries of imported food out of an estimated 17.2 million lines of FDA regulated products in FY 2008. In FY 2009, FDA expects approximately 9.5 million line entries of imported food within a total of more than 18.7 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 brings 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.

Performance: In FY 2008, FDA exceeded the target of 85,000 by completing 100,718 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 estimates a conservative target number each year to assure that there is still a reasonable opportunity to meet 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 2010 target is being maintained.

Performance: In FY 2008, FDA exceeded this goal of 1,000 by performing 1,356 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 will be maintained.

Performance: In FY 2008, FDA exceeded this goal of 4,000 by performing 5,926 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 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.

Performance: In FY 2008, FDA exceeded this goal of 5,700 by performing 6,230 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 2008, 151 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: In FY 2008, FDA exceeded its performance goal by achieving automatic exchange of data from 11 laboratories. This goal was significantly exceeded due to a one-time opportunity to add 9 laboratories with automated data exchange capabilities through a single data network (portal).

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.

Performance: FDA exceeded the FY 2008 goal of 500 by inspecting 534 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. 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. In FY 2010, the target has been increased to 1,000 inspections to reflect historical accomplishments.

Performance: In FY 2008, FDA exceeded this high risk inspection goal of 870 by inspecting 1,014 blood banks and biologics manufacturing establishments.

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 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.

Performance: In FY 2008, FDA exceeded the human tissue goal of 325 by conducting 383 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 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 we 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.

Performance: In FY 2008, FDA exceeded this inspection goal of 233 by inspecting 244 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.

Performance: In FY 2008, FDA completed the inspection of all 555 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. The FY 2009 target was increased to 1,340 inspections due to FY 2008 Supplemental funding increases in the Field Devices Program. For FY 2010, the target has been increased to 1,365 to reflect the FY 2009 Appropriations.

Performance: FDA exceeded the FY 2008 medical device performance goal of 1,270 by inspecting 1,431 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 2008, 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 will increase 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.

Performance: In FY 2008, FDA met this performance goal surge capacity target of 2,500 rad samples per week based on the awarding of cooperative agreements to 3 state radiological labs in FY 2007 resulting in a surge capacity increase of 500 rad samples per lab (1,500 total) in FY 2008. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week.

The FERN laboratories are increasingly providing critical analytical surge capacity during food emergency events. An FDA assignment directed samples to the FERN labs in the Salmonella outbreak in peppers, with over 150 samples tested. 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.

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	6,562	7,263	7,467
Domestic Food Safety Program Inspections	3,611	3,850	4,100
Imported and Domestic Cheese Program Inspections	391	400	400
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	438	450	450
Domestic Fish & Fishery Products (HACCP) Inspections	1,827	1,850	1,850
Import (Seafood Program Including HACCP) Inspections	359	500	500
Juice HACCP Inspection Program (HACCP)	377	300	300
Interstate Travel Sanitation (ITS) Inspections	1,042	1,555	1,555
Domestic Field Exams/Tests	2,638	2,425	2,425
Domestic Laboratory Samples Analyzed	12,043	14,500	14,500
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	152	200	600
All Foreign Inspections	152	200	600
IMPORTS			
Import Field Exams/Tests	100,718	120,000	140,000
Import Laboratory Samples Analyzed	23,052	26,200	26,200
Import Physical Exam Subtotal	123,770	146,200	166,200
Import Line Decisions	9,441,024	9,526,745	9,613,245
Percent of Import Lines Physically Examined	1.31%	1.53%	1.73%

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	80,543	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	8,777	11,076	11,575
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	786	500	500
State Contract Food Safety (Non HACCP) Inspections	7,791	9,797	10,297
State Contract Domestic Seafood HACCP Inspections	914	1,148	1,148
State Contract Juice HACCP	50	75	75
State Contract LACF	37	75	75
State Partnership Inspections	786	500	500
State Contract and Grant Foods Funding	\$9,100,000	\$9,775,000	\$10,400,000
Number of FERN State Laboratories	16	19	19
Annual FERN State Cooperative Agreements/Operations Funding	\$11,535,000	\$13,450,000	\$10,988,000
Total State & Annual FERN Funding	\$20,635,000	\$23,225,000	\$21,388,000
TOTAL FOOD INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	16,277	19,039	20,142

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	92	100	100
All Inspections (Domestic and Foreign)	92	100	100
IMPORTS			
Import Field Exams/Tests	1,892	2,000	2,000
Import Laboratory Samples Analyzed	301	230	230
Import Physical Exam Subtotal	2,193	2,230	2,230
Import Line Decisions	1,588,082	1,721,372	1,865,849
Percent of Import Lines Physically Examined	0.14%	0.13%	0.12%
TOTAL COSMETICS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	92	100	100

Field Drugs Program Activity Data (PAD)

Field Drugs Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	1,774	1,960	1,960
Pre-Approval Inspections (NDA)	138	120	120
Pre-Approval Inspections (ANDA)	95	51	51
Bioresearch Monitoring Program Inspections	526	490	490
Drug Processing (GMP) Program Inspections	972	1,085	1,085
Compressed Medical Gas Manufacturers Inspections	46	159	159
Adverse Drug Events Project Inspections	88	144	144
OTC Monograph Project and Health Fraud Project Inspections	33	48	48
Domestic Laboratory Samples Analyzed	1,769	951	951
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	452	566	566
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	174	192	192
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	117	69	69
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	129	210	210
Foreign Drug Processing (GMP) Program Inspections	268	382	382
Foreign Adverse Drug Events Project Inspections	6	16	16
IMPORTS			
Import Field Exams/Tests	2,863	2,870	6,197
Import Laboratory Samples Analyzed	346	586	586
Import Physical Exam Subtotal	3,209	3,456	6,783
Import Line Decisions	321,205	330,267	339,584
Percent of Import Lines Physically Examined	1.00%	1.05%	2.00%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	166	166	166
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	135	110	110
State Partnership Inspections: GMP Inspections	25	50	50
TOTAL HUMAN DRUG INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	2,392	2,692	2,692

Estimates for FY10 Generic Drugs User Fee Inspections not reflected in the table.
Estimated timeframe for these inspections is FY 2012 and FY 2013.

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
<i>FDA WORK</i>			
DOMESTIC INSPECTIONS			
<i>UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS</i>	<i>1,678</i>	<i>2,010</i>	<i>2,034</i>
Bioresearch Monitoring Program Inspections	104	183	183
Blood Bank Inspections	991	1,093	1,093
Source Plasma Inspections	149	205	205
Pre-License, Pre-Approval (Pre-Market) Inspections	38	24	24
GMP Inspections	25	17	17
GMP (Device) Inspections	3	10	10
Human Tissue Inspections	381	494	518
FOREIGN INSPECTIONS			
<i>UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS</i>	<i>50</i>	<i>52</i>	<i>66</i>
Bioresearch Monitoring Program Inspections	6	6	6
Foreign Human Tissue Inspections	2	0	13
Blood Bank Inspections	8	12	12
Pre-License Inspections	7	10	10
GMP Inspections	23	20	20
IMPORTS			
Import Field Exams/Tests	36	100	100
Import Line Decisions	63,302	81,864	105,868
Percent of Import Lines Physically Examined	0.06%	0.12%	0.09%
TOTAL BIOLOGICS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
<i>GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS</i>	<i>1,728</i>	<i>2,062</i>	<i>2,100</i>

Field Animal Drugs & Feeds Program Activity Data

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2008 Actuals	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	2,127	2,820	2,621
Pre-Approval/BIMO Inspections	61	77	77
Drug Process and New ADF Program Inspections	190	151	205
BSE Inspections	1,794	2,594	2,306
Feed Contaminant Inspections	26	20	20
Illegal Tissue Residue Program Inspections	212	320	320
Feed Manufacturing Program Inspections	208	141	141
Domestic Laboratory Samples Analyzed	1,617	1,850	1,850
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	33	26	41
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	23	25	26
Foreign Drug Processing and New ADF Program Inspections	19	10	20
Foreign Feed Inspections	2	0	8
IMPORTS			
Import Field Exams/Tests	2,930	2,930	3,500
Import Laboratory Samples Analyzed	594	720	720
Import Physical Exam Subtotal	3,524	3,650	4,220
Import Line Decisions	244,591	253,956	263,680
Percent of Import Lines Physically Examined	1.44%	1.44%	1.60%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	5,712	5,160	5,160
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	324	300	300
State Contract/Coop Agreement Inspections: BSE	5,652	4,744	4,744
State Contract Inspections: Feed Manufacturers	322	348	348
State Contract Inspections: Illegal Tissue Residue	271	550	550
State Partnership Inspections: BSE and Other	324	300	300
State Contract Animal Drugs/Feeds Funding	\$2,300,000	\$2,550,000	\$2,725,000
BSE Cooperative Agreement Funding	\$3,000,000	\$3,000,000	\$3,000,000
State Contract Tissue Residue Funding	\$300,000	\$342,801	\$375,050
Total State Funding	\$5,600,000	\$5,892,801	\$6,100,050
TOTAL ANIMAL DRUGS AND FEEDS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	8,196	8,306	8,122

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	1,996	2,322	2,404
Bioresearch Monitoring Program Inspections	289	300	300
Pre-Approval Inspections	60	75	75
Post-Market Audit Inspections	42	58	58
GMP Inspections	1,271	1,476	1,560
Inspections (MQSA) FDA Domestic (non-VHA)	278	334	334
Inspections (MQSA) FDA Domestic (VHA)	31	30	30
Domestic Radiological Health Inspections	90	125	125
Domestic Field Exams/Tests	480	480	480
Domestic Laboratory Samples Analyzed	144	201	201
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	262	297	329
Foreign Bioresearch Monitoring Inspections	14	10	10
Foreign Pre-Approval Inspections	38	34	34
Foreign Post-Market Audit Inspections	10	21	21
Foreign GMP Inspections	208	251	288
Foreign MQSA Inspections	15	14	14
Foreign Radiological Health Inspections	11	5	5
IMPORTS			
Import Field Exams/Tests	6,566	8,770	13,180
Import Laboratory Samples Analyzed	1,110	1,141	1,141
Import Physical Exam Subtotal	7,676	9,911	14,321
Import Line Decisions	5,567,469	6,786,886	8,273,385
Percent of Import Lines Physically Examined	0.14%	0.15%	0.17%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	8,272	8515	8513
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	71	71	71
Inspections (MQSA) by State Contract	7,639	7,382	7,380
Inspections (MQSA) by State non-Contract	620	1,120	1,120
GMP Inspections by State Contract	13	13	13
State Contract Devices Funding	\$75,000	\$85,000	\$120,000
State Contract Mammography Funding	\$9,000,000	\$9,500,000	\$10,000,000
Total State Funding	\$9,075,000	\$9,585,000	\$10,120,000
TOTAL DEVICES INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	10,601	11,205	11,317