FIELD ACTIVITIES - OFFICE OF REGULATORY AFFAIRS

Introduction

FDA's Field Activities – Office of Regulatory Affairs (ORA) Program summarizes the budget program requirements that justify a $546,232,000 request for FY 2008. The Field Activities program narrative has four sections:

- summary of FDA's program resources, historical funding and FTE levels
- description of the Office of Regulatory Affairs program functions
- effects of the full year FY 2007 Continuing Resolution on the Office of Regulatory Affairs
- description of the program resources changes, base resource activities, program accomplishments, program activity data, and performance plan analysis.

The Field Activities funding table shows a three year span of program level resources, budget authority resources, and proposed user fees enacted in FY 2006, displayed in the FY 2007 President's Budget and FY 2007 Continuing Resolution, and proposed in the FY 2008 budget request.

	FY 2006 Actuals	FY 2007 Continuing Resolution	FY 2007 Pres. Budget	FY 2008 Pres. Budget	Increase or Decrease
Program Level	**$499,853,000**	**$501,373,000**	**$527,018,000**	**$546,232,000**	**$19,214,000**
FTE	**3,460**	**3,242**	**3,460**	**3,472**	**12**
Budget Authority	**$482,361,000**	**$482,435,000**	**$504,029,000**	**$520,567,000**	**$16,538,000**
Foods	*$285,251,000*	*$285,153,000*	*$301,324,000*	*$312,138,000*	*$10,814,000*
Human Drugs	*$79,923,000*	*$79,919,000*	*$79,794,000*	*$81,488,000*	*$1,694,000*
Biologics	*$27,075,000*	*$27,161,000*	*$28,776,000*	*$29,310,000*	*$534,000*
Animal Drugs and Feeds	*$34,756,000*	*$34,842,000*	*$35,778,000*	*$35,774,000*	*($4,000)*
Medical Devices	*$55,356,000*	*$55,360,000*	*$58,357,000*	*$61,857,000*	*$3,500,000*
Pay Increases	--	--	--	*$9,210,000*	*$9,210,000*
Strengthening Food Safety	--	--	--	*$5,500,000*	*$5,500,000*
MDUFMA Trigger	--	--	--	*$2,421,000*	*$2,421,000*
Outreach, Coordination, Research Reduction	--	--	--	*($593,000)*	*($593,000)*
Total FTE	**3,400**	**3,191**	**3,397**	**3,403**	**6**
User Fees	**$17,492,000**	**$18,938,000**	**$22,989,000**	**$25,665,000**	**$2,676,000**
PDUFA	*$7,389,000*	*$7,077,000*	*$9,833,000*	*$9,169,000*	*-$664,000*
MDUFMA	*$1,123,000*	*$0*	*$1,295,000*	*$1,406,000*	*$111,000*
MQSA	*$8,980,000*	*$11,861,000*	*$11,861,000*	*$12,454,000*	*$593,000*
Proposed Generic Drugs	--	--	--	*$2,636,000*	*$2,636,000*
Total FTE	**60**	**51**	**63**	**69**	**6**

The historical funding and FTE levels table shows a five year history of program level funding, budget authority funding, user fee funding, and program level FTE.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2004 Actuals	$528,853,000	$513,906,000	$14,947,000	3,872
2005 Actuals	$493,258,000	$315,562,000	$15,690,000	3,633
2006 Actuals	$499,853,000	$482,361,000	$17,492,000	3,460
2007 Continuing Resolution	$501,373,000	$482,435,000	$18,938,000	3,242
2007 President's Budget	$527,018,000	$504,029,000	$22,989,000	3,460
2008 President's Budget	$546,232,000	$520,567,000	$25,665,000	3,472

Statement of the Budget Request

The ORA Field Activities is requesting $546,232,000 in program level resources for accomplishing its mission activities:

- conducting investigational, inspectional, and laboratory functions to ensure that FDA-regulated products comply with the laws and regulations that FDA is charged with enforcing
- responding rapidly to emergencies and redirecting field efforts, as necessary, to respond to unforeseen events
- managing and conducting criminal investigations within the Agency’s jurisdiction, including advising and assisting the Commissioner and other key officials on legislation and policy involving criminal justice matters
- monitoring clinical research and conducting inspections of FDA-regulated products before they are marketed to ensure that manufactured products will be safe and effective
- performing prior notice import security reviews on food and animal feed imports considered to be at risk for bioterrorism and field examinations of all types of imported products to determine compliance with FDA regulations

- serving as FDA's primary liaison with consumers, health professionals, the media, States, and the regulated industry and trade associations to disseminate information on the products the Agency regulates.

Program Description

Please note: The Office of Regulatory Affairs supports the Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health Programs. The narratives for these programs include a Field component.

ORA is the lead office for all FDA field activities. ORA supports five FDA Centers (CFSAN, CDER, CBER, CDRH and CVM) by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, reviewing imported products offered for entry into the United States, and advising key officials on regulatory and compliance-oriented matters that have an impact on policy development and execution, and on long-range program goals. ORA protects consumers and enhances public health by maximizing the compliance of FDA-regulated products and minimizing the risks associated with those products.

ORA staff is dispersed throughout the United States. Over 85 percent of ORA's staff works in five Regional Offices, 20 District Offices, 13 Laboratories, and 157 Resident Posts and Border Stations. The Office of Criminal Investigations (OCI) personnel are located throughout the field organization in Field Offices, Resident Offices, and Domiciles, which are located in 25 cities 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. FDA also monitors imported products traveling through 12 international mail facilities and 20 courier ports.

ORA's work involves conducting foreign and domestic pre-market and post-market inspections. Pre-market activities include bioresearch monitoring of clinical research, pre-approval inspections and laboratory method validations needed for premarket application decisions, and inspections of manufacturing facilities to determine if the factory is able to manufacture the product to the specifications stated in their application. The largest portion of ORA's work involves post-market inspections of foods, human drugs, biologics, animal drugs and feeds, and medical device manufacturers. These post-market inspections assess the manufacturers' compliance with Good Manufacturing Practice (GMP) requirements. ORA's radiological health activities include inspecting certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA). ORA also inspects radiological health products such as lasers, sunlamps, and x-ray equipment to ensure they are in compliance with performance standards. In addition, ORA monitors and samples imports to ensure the safety of the food supply and medical products.

ORA works with its State counterparts on safety activities. ORA funds grants and cooperative agreements to perform State inspections, and to provide technical

assistance to the States in such areas as milk safety, food safety, and shellfish safety. State inspection staffs attend and participate in ORA-sponsored training courses.

In addition to overseeing regulated products on a surveillance or "for cause" basis, ORA staff also respond to emergencies and investigate incidents of product tampering, as well as terrorist events or natural disasters that may impact FDA regulated goods. To complement the regular field force, the Office of Criminal Investigation (OCI) investigates instances of criminal activity in FDA-regulated industries.

FDA relies heavily on ORA's post-market investigation, inspection, and compliance activities to assure the safety and quality of the products the Agency regulates. ORA's Counter Terrorism (CT) program role includes ensuring the safety and security of the food and feed supply; supporting the development and manufacturing of vaccines and medical counter measures; assessment of drugs and other medical products included in the Strategic National Stockpile Program; and participation in and support for exercises and security preparations for public events such as the Olympics and National political conventions. FDA's responsibilities for radiation safety and health requires assessing x-rays used for security screening of packages and other radiation emitting products with medical or CT uses. ORA provides emergency responses to illness and injury potentially linked to FDA-regulated products and coordinates its activities with the Centers for Disease Control and Prevention (CDC). In addition, ORA inspections and investigations are essential to human tissue safety; BSE feed contamination prevention; counterfeit drug, infant formula, and other product investigations; and dietary supplement safety enforcement.

ORA coordinates import activities with the Department of Homeland Security's Customs and Border Protection (CBP) Agency. The number 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 2008, FDA projects a total of 17.9 million import lines, which will be comprised of 52 percent food products, 11 percent cosmetic products, 2 percent human drugs and biologic products, 2 percent animal drugs and feeds products, and 33 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's information technology systems allow Field personnel to respond to an ever increasing number of imports through electronic screening. ORA also uses information technology to track domestic inspections and allocate resources to identify and inspect the highest risk program areas.

Effects of Full Year FY 2007 Continuing Resolution

The analysis in this section assumes funding levels for FY 2007 based on the enactment of the President's FY 2007 budget for the Fields Program. For comparison purposes, the FDA budget tables include a column that reflects the FY 2007 Continuing

Resolution (CR) funding level in the event that Congress enacts this level of appropriations for the remainder of FY 2007.

If FDA receives the CR rather than the FY 2007 President's budget request, this will have a significant impact on FY 2007 performance for ORA and each of the field program areas.

All ORA Program Areas will be affected by the FY 2007 Continuing Resolution:

- ORA will have to modify normal operations to cope with reduced operating funds by instituting a hiring freeze, reducing FTE, and reducing operating expenses to cover the payroll shortfall.

- ORA's investigator vacancies will increase and inspections will be reduced; ORA will not be able to perform its projected number of inspections and other activities, which places the public health at risk.

- With reduced operating funds for travel to high risk inspections, ORA staff will be out of geographical balance with establishment workload; and, districts will be forced to conduct lower risk inspections.

- ORA will not be able to apply modern IT solutions to public health problems or improve risk based targeting, mission accountability or reduce operating costs**.**

- ORA's reduced training resources will limit specialized training for existing staff, resulting in a gap between the existing staff's skill set and the skill set needed for sophisticated risk based inspections, investigations and laboratory analyses.

Field Foods Program

The FY 2007 Continuing Resolution has six major impacts on the Field Foods Program:

- ORA will limit its Food Emergency Response Network (FERN) funding to the maintenance of the ten State laboratories; FDA's resources to support training, proficiency testing and planned expansions of the FERN system will be limited by reduced operating funds and fewer experienced analytical staff in ORA laboratories.

- The number of high risk foods performance goal inspections planned for FY 2007 will be reduced by almost 20 percent [-1,015 inspections] from the President's budget proposal; firms making high risk products that received annual inspections in previous years will be inspected on a biennial schedule instead.

- Routine Cosmetics inspections will be eliminated and ORA will perform cosmetics inspections only on a "for cause" basis, where a product or firm is suspected of being out of compliance.

- ORA will not be able to fund inflationary increases in State inspection costs and the number of State inspections will decline from the President's budget level, possibly damaging FDA's relationships with the States.

- Domestic and Import Laboratory Samples Analyzed will decline by 2,000 samples below the President's budget level.

- Funding under the continuing resolution causes a loss of 120 FTE for the Field Foods Program.

Field Human Drugs Program

The FY 2007 Continuing Resolution has five major impacts on the Field Human Drugs Program:

- ORA will reduce the number of Good Manufacturing Practice inspections by 277, reducing the inspection interval for moderate risk firms from every three years to every four years.

- Foreign Pre-approval and Good Manufacturing Practice (GMP) inspections will be reduced due to reduced numbers of investigators with the necessary specialized skills and the inability to fund inflationary increases in its foreign travel budget.

- ORA will continue to place a high priority on PEPFAR inspections for foreign establishments preparing to manufacture AIDS drugs for distribution outside the U.S. and will ensure that these inspections receive foreign inspection priority.

- "For Cause" and investigation activities will be limited to the highest risk situations where there is an ongoing risk to public health.

- Funding under the continuing resolution causes a loss of 39 FTE for the Field Human Drugs Program.

Field Biologics Program

The FY 2007 Continuing Resolution has four major impacts on the Field Biologics Program:

- ORA Blood Bank inspections will be reduced by 85 inspections, causing the inspection interval for blood banks to fall below the statutory inspection requirement of inspecting 50 percent of the inventory a year for the first time.

- ORA will only meet the performance goal of 325 Human Tissue establishment inspections allowing for firms in the human tissue industry to continue operating without in-depth ORA oversight.

- ORA will have to decrease the number of Bioresearch Monitoring inspections from 180 to 169, limiting FDA's ability to provide needed research oversight for integrity and the protection of human subjects.

- Funding under the continuing resolution causes a loss of 14 FTE for the Field Biologics Program.

Field Animal Drugs and Feeds Program

The FY 2007 Continuing Resolution has five major impacts on the Field Animal Drugs and Feeds Program:

- The animal drugs and feeds establishments performance goal will decline by 106 establishment inspections with FDA not meeting its statutory inspection requirement of biennial inspections for the first time.

- Domestic and Foreign Pre-approval and Bioresearch Monitoring inspections will be reduced by 75 inspections as a result of reduced travel funds, reduced numbers of investigators, and the elimination of the Anima Drug User Fee Act program.

- Maintaining State funding for BSE inspections will severely limit flexibility in operating funds for travel, training, and coordination with States and industry.

- Resources for investigation of suspect products and firms will be limited to those presenting the highest risk.

- Funding under the continuing rate causes a loss of 13 FTE for the Field Animal Drugs and Feeds Program.

Field Medical Devices and Radiological Health Program

The FY 2007 Continuing Resolution has six major impacts on the Field Medical Devices and Radiological Health Program:

- The medical device Class II and III manufacturers performance goal will decline by the reduction of 258 inspections from the President's budget level.

- Since the MDUFMA program will be eliminated, ORA will reduce Domestic and Foreign Pre-approval Inspections by 119, an 80% reduction in the Pre-Approval Inspection program.

- Foreign Post Market Audit and Good Manufacturing Practice (GMP) inspections will be reduced by 65 inspections because the number of

investigators will be reduced and travel funding will not keep pace with inflationary increases.

- ORA will not be able to fund inflationary increases in State inspection costs and the number of State inspections will decline from the President's budget level, possibly damaging FDA's relationships with the States.

- Funding under the continuing resolution causes a loss of 32 FTE for the Field Medical Device and Radiological Health Program.

If FDA receives the continuing resolution of funding rather than the FY 2007 President's budget request, this will have significant impact on FY 2008 performance for ORA's program:

- Any new hires are unlikely to exceed 25 percent of typical productivity which means that FY 2008 inspection and laboratory analysis targets may not be met and ORA work will include a higher proportion of entry level tasks than in FY 2006.

- Despite ORA's desire to pursue risk based activities, newly hired employees will require intensive coaching and supervision and may need to assist an experienced ORA specialist for several months before assuming responsibility for complex risk based activities.

- Although ORA should be able to award contracts and grants for the increased sums authorized in the FY 2008 budget, reduced staffing will delay activities funded by the contracts and grants.

Program Resources Changes

Budget Authority

Pay Increase: +$9,210,000

The FDA request for pay inflationary costs is essential to accomplish our public health mission. Eighty percent of FDA's budget authority supports the agency workforce. Of this, payroll costs account for almost sixty percent of our budget authority. The increase will allow FDA to maintain staff levels, including a national cadre of specially trained scientific staff. Maintaining the FDA workforce provides stability for the organization and allows FDA to maintain the current level of coverage for its premarket and postmarket activities. Without these funds, FDA must reduce FTE levels in order to have adequate resources to cover it payroll, which will lead to corresponding reductions in programs that protect public health. The total request for cost of living pay increases in FY 2008 is $21,773,000. The Office of Regulatory Affairs portion of this increase is $9,210,000. These resources are vitally important for FDA to fulfill its mission to protect the public health by helping safe and effective

products reach the market in a timely way, and by monitoring products for continued safety after they are used.

Strengthening Food Safety: +$5,500,000 and +6 FTE
FDA proposes a total of $10,644,000 for food safety activities, $5,500,000 of which is for ORA, to enhance FDA's ability to help industry mitigate the risks of increased foodborne outbreaks. The resources would also improve FDA's ability to protect the public health by enhancing our ability to respond to possible foodborne outbreaks. The request would help ORA develop the capacity for more rapid traceback of produce-related outbreaks, and improve the capacity to more quickly determine the root cause of an outbreak. The request would also allow FDA to accelerate the development of an integrated import decision making IT system capable of detecting high-risk shipments of FDA regulated products before they are admitted or released into U.S. commerce. In addition, ORA would begin formal integration of this technology into the Mission Accomplishment and Regulatory Compliance Services (MARCS) system.

Medical Device Safety and Review: +$2,421,000
The funding request for the Medical Device User Fee and Modernization Act (MDUFMA) Trigger of $7,164,000 is necessary for FDA to meet the statutory requirements for collecting user fees in FY 2008. The ORA portion of this amount is $2,421,000. Under the MDUFMA law, a significant feature of this program is the requirement that the Federal government appropriate and spend a minimum amount on the process for reviewing medical devices. The flow of new potentially life saving medical devices will slow, limiting the availability of safe products, including those for untreated conditions. The resources requested allow for program continuation and for FDA to meet its performance commitments under the Act.

Outreach, Coordination, and Research Reduction: -$593,000
This proposed reduction reallocates resources from lower priority activities to higher priority activities proposed in the FY 2008 budget. FDA must ensure its resources are used for maximum public health impact. This requires FDA to make funding decisions based on risk-based prioritization of needs. FDA diligently assessed research and outreach activities under ORA and proposes a reduction of $593,000 in FY 2008. This reduction contributes to the FDA's ability to fund cost of living pay increases, medical product and food safety initiatives, and rent increases in FY 2008.

User Fees

Current Law User Fees

Prescription Drug User Fee Act (PDUFA): -$664,000
In FY 2007, PDUFA collections included a one time increase of $31,600,000 for the final year adjustment under PDUFA III. For FY 2008, adjustments include increases for inflation and other increases authorized by the PDUFA statute. The net decrease in FY 2008 for the Field program is due to this one-time, non-recurring FY 2007 Final Year adjustment. Because FDA has not completed the public comment period

regarding FDA's proposed recommendations for PDUFA reauthorization, the FY 2008 PDUFA estimate is based on straight reauthorization of PDUFA III with no programmatic enhancements or adjustments.

In the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress renewed FDA's authority to the collect PDUFA user fees. This authority is effective for five years and directs FDA to strengthen and improve the process for the review of human drugs and to improve risk management for drugs approved under PDUFA. The authority to collect fees under PDUFA expires on September 30, 2007.

Proposals to reauthorize PDUFA are currently under discussion. The PDUFA user fee is expected to bring in $339,195,000 in FY 2008 collections, with the Field Program request totaling $9,169,000. These FY 2008 amounts assume that the current authorities in effect for PDUFA III continue in FY 2008. FDA may need to amend its budget request when Congress reauthorizes PDUFA IV and establishes new performance goals and fee levels.

PDUFA user fees allow ORA to perform three activities:

- conduct domestic and foreign pre-market inspections
- ensure compliance with drug manufacturing practices
- monitor and inspect manufacturing facilities to ensure that drug products are safe and effective.

Medical Devices User Fee and Modernization Act (MDUFMA): +$111,000

Enacted in 2002, MDUFMA improves the quality and timeliness of the medical device review. It authorizes FDA to collect user fees to supplement appropriations for the medical device review program. FDA collects fees from device manufacturers that submit premarket applications and premarket notifications. The authority to collect fees under MDUFMA expires on September 30, 2007.

Proposals to reauthorize MDUFMA are currently under discussion. The MDUFMA user fee is expected to bring in $47,500,000 in collections, with the Field Program increase being $111,000, for a total of $1,406,000. These FY 2008 amounts assume that the current authorities in effect for MDUFMA continue in FY 2008. FDA may need to amend its budget request when Congress reauthorizes MDUFMA and establishes new performance goals and fee levels.

MDUFMA user fees allow Field activities to perform four activities:

- allow establishment inspections to be conducted by third parties
- conduct domestic premarket inspections

- conduct foreign premarket inspections

- conduct Bioresearch Monitoring inspections to inspect the integrity of data and to protect human subjects.

Mammography Quality Standards Act (MQSA): +$593,000
Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. Experts estimate that one in eight women will contract breast cancer during their lifetime. MQSA, which Congress reauthorized in October 2004, addresses the public health need for safe and reliable mammography. MQSA requires that FDA certify mammography facilities by October 1994, and inspect facilities annually to ensure compliance with national quality and safety standards.

MQSA user fees allow ORA to perform two activities:

- fund over 8,000 state contract inspections of mammography facilities annually

- fund FDA conducted foreign inspections to ensure the safety of mammography facilities in foreign countries.

FDA and state inspections combined ensure high quality mammography exams which allow for early breast cancer detection and/or treatment.

Proposed User Fees

Proposed Generic Drugs User Fee: +$2,636,000 and +6 FTE
Applications to market generic drugs, Abbreviated New Drug Applications (ANDAs), are critical to lowering federal 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 resources generated by the proposed generic drug user fees would allow FDA to reduce the time to conduct reviews of ANDAs and respond to the growing number of generic drug applications.

Proposed Reinspection User Fee (Mandatory): $13,014,000 and 102 FTE (Non-Add)
The FY 2008 budget includes $23,276,000 in budget authority for reinspection related activities. The Budget also proposes a new mandatory user fee to support reinspection activities. Once legislation is enacted, which authorizes FDA to collect this user fee, the Administration will work with Congress to recategorize these fees as discretionary.

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. Under this proposal, FDA reclassifies these activities as mandatory user fees in FY 2008. The total proposed collections for the Agency in FY 2008 are $23,276,000, with $13,014,000 of the collections being allocated to the Field program.

Proposed Food and Animal Feed Export Certification User Fee: $2,716,000 and 17 FTE (Non-Add)

The FY 2008 budget includes $3,741,000 in budget authority for export certification related activities. The Budget also proposes a new mandatory user fee to support export certification activities. Once legislation is enacted, which authorizes FDA to collect this user fee, the Administration will work with Congress to recategorize these fees as discretionary.

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 collecting 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 the Agency's enhanced ability to facilitate exports of their products. FDA currently funds this activity through discretionary appropriations. The total proposed collections for the Agency in FY 2008 are $3,741,000, with $2,716,000 of the collections being allocated to the Field program.

Justification of Base

In FY 2008, FDA will direct its resources to support the highest risk, highest impact, and highest priority initiatives. ORA supported 3,460 FTE, including Office of Shared Services (OSS) FTE in FY 2006. ORA will reallocate resources to recruit a small number of new hires and to move staff around the country to distribute staff relative to the location of its regulated industry and to address evolving Agency priorities. Additional internal resource reallocations will fund travel costs so that foreign and domestic investigational activities, inspections, and sample collections can be based on risk instead of the close proximity to staff locations.

ORA protects consumers and enhances public health by maximizing the compliance of FDA-regulated products and minimizing the risks associated with those products. As the front-line field force supporting the five FDA Centers, ORA reviews imported products being offered for entry into U.S. commerce to ensure their safety and performs laboratory analyses of imported, as well as domestic products. ORA partners with States to increase inspectional coverage of regulated industry and maximize consumer health protection. ORA is also responsible for the enforcement of FDA laws and regulations and the Office of Criminal Investigations is an important part of these

efforts. Along with performing traditional inspections of regulated industry, ORA also responds to public health emergencies, such as foodborne illness outbreaks. Information gathered in traceback investigations is used to identify ways to make produce safer and prevent future outbreaks from occurring. Finally, information technology systems allow ORA to track import, inspectional, and analytical work and more efficiently allocate resources towards the highest risk program areas. The FDA Strategic Goals table below illustrates eight Program Areas that represent the core functions of ORA.

	FDA Strategic Goals			
	Enhance Patient and Consumer Protection and Empower Them With Better Information about Regulated Products	Increase Access to Innovative Products and Technologies to Improve Health	Improve Product Quality, Safety and Availability Through Better Manufacturing and Production Oversight	Transform Administrative Systems and Infrastructure to Support FDA Operations
Program Area				
Imports			X	
Health Fraud			X	
Office of Criminal Investigations & Enforcement			X	
Leveraging With the States			X	
Rapid Response to Emergencies			X	
Laboratory Capability			X	
Shelf Life Extension Program (SLEP)			X	
Information Technology				X

As illustrated in the table, ORA work provides support to FDA's public health mission. The majority of ORA program areas support the improve product quality, safety, and availability through better manufacturing and production oversight strategic goal.

Imports

The United States is part of an ever increasing global marketplace. FDA processed approximately 15 million import lines in FY 2006, over six times as many as it did in FY 1994. These entries include every type of FDA-regulated product including complex and highly processed goods, and come from more than 230 countries and more than 300,000 manufacturers. This rapid growth, combined with ever present security concerns, has increased the need to assess the status of imported products. FDA electronically screens imports through its Operational and Administrative System for Import Support (OASIS) electronic data system. FDA's electronic screening of

imports will be enhanced by the completion of the Mission Accomplishment and Regulatory Compliance System (MARCS). Imports include other program objectives:.

- review more than 17 million import lines for admissibility into domestic commerce by the end of FY 2008
- continue to use information on manufacturer, supplier, source country, and past violations to make enhanced risk-based admissibility decisions
- continue to perform laboratory analysis on products offered for import into the United States
- continue to conduct inspections of foreign establishments as part of the Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health programs
- perform periodic filer evaluations to ensure that the data being provided to FDA is accurate.

Prior Notice Security Reviews and Compliance Actions

In FY 2006, the Prior Notice Center conducted 89,034 import security reviews. FDA collaborated with Customs and Border Protection to direct field personnel to hold and examine two suspect shipments of imported food; refused 424 lines of food for prior notice violations; conducted 105 informed compliance calls, responded to 29,220 phone and e-mail inquiries; and conducted 89,034 intensive security reviews of Prior Notice submissions out of 9,194,082 submissions in order to intercept contaminated products before they entered the food supply.

Health Fraud

Dietary Supplements: The Consumer Health Information for Better Nutrition initiative is designed to foster two complementary goals concerning the labeling of food and dietary supplements:

- encourage makers of conventional foods and dietary supplements to make accurate, science-based claims about the health benefits of their products
- help to eliminate bogus labeling claims by bringing enforcement actions against those dietary supplement marketers who make false or misleading claims.

The Field will ensure that enforcement activities focus on products with the following marketing strategies: herbal products illegally promoted as alternatives to illicit street drugs; unapproved new drugs containing prosteroids and precursor steroids such as dietary supplements; products which are unapproved new drugs marketed as "natural" treatment for viruses (including the herpes virus), and for cold and flu protection; dietary supplements with unsubstantiated structure function claims (examples include treatments for autism, treatments for mental retardation and epilepsy, sports performance enhancement, and aging); and dietary supplements containing prescription drug ingredients.

Internet Drug Sales: At present, there are an escalating number of new websites marketing FDA-regulated products to the U.S. consumer and medical professionals. FDA currently conducts only minimal levels of web-based oversight. The Office of Criminal Investigations is expanding its efforts to develop cases that address the marketing of counterfeit products:

- continue to monitor potentially fraudulent websites to identify targets for investigation and sampling of products

- conduct "undercover only" purchases of prescription drugs from websites suspected of engaging in illicit drug sales, distribution, and/or marketing

- provide oversight of mail and courier packages entering the U.S. from foreign sources.

Office of Criminal Investigations and Enforcement

A strong, effective, and efficient enforcement of FDA laws and regulations is essential to FDA's mission of protecting and promoting public health. Enforcement actions also play an important part in ensuring that the American people can have confidence in the safety, quality and integrity of the U.S. food and medical supplies.

The Office of Criminal Investigations (OCI) was established to provide an additional enforcement resource to enhance ORA's inspectional, compliance, and 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 and on collecting evidence to support prosecutive actions through the Federal or State court systems as appropriate.

OCI is the FDA office responsible for the conduct and coordination of criminal investigations and, as such, maintains liaison and cooperative investigative efforts with other federal, state, local, and international law enforcement agencies. OCI has primary responsibility and is the primary point of contact for all law enforcement and intelligence issues pertaining to threats or perceived threats against FDA regulated products. OCI participates in numerous law enforcement and intelligence task forces both nationally and internationally to include a full time representative to Interpol.

Drug Safety Activities

In September 2006, an individual from China was arrested by officers of the Hong Kong Customs and Excise Department based on a federal arrest warrant issued by the U.S. District Court for the District of Colorado. The defendant was arrested in Hong Kong after meeting with an undercover OCI agent who posed as a buyer of over 400,000 counterfeit Cialis and Viagra tablets.

This investigation also involved the sale of several thousand counterfeit Tamiflu capsules that were manufactured in China and shipped to the U.S. Information developed by OCI and ICE was shared with Chinese authorities that led to the arrest of four individuals in Hong Kong, China and three defendants plead guilty in the U.S. to counterfeit drug charges.

Leveraging With the States

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 allows ORA to increase inspectional coverage and redirect resources to other priority activities:

- audit of State contract inspections to ensure consistent application of regulations during FDA and State inspections of food and animal feed establishments
- technical support, monitoring, and evaluation of State programs in milk, shellfish, food service sanitation, and radiation safety
- free training courses to State, local, and tribal regulatory partners.

Rapid Response to Emergencies

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 has four primary duties:

- investigation and coordination in multistate outbreaks
- tracebacks of implicated foods

- monitoring of recalls of products that are linked to the outbreak

- evaluation of data from investigation findings 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.

"*E. Coli* 0157:H7 Outbreak In Raw Spinach"

In September 2006, FDA quickly responded to an outbreak of *E. coli* 0157:H7 associated with contaminated raw spinach. FDA's efforts focused on the quick removal of the fresh spinach from the marketplace, working with the CDC and state investigators to conduct traceback investigations, and providing consumers with daily updates concerning the outbreak. FDA recall efforts save countless lives every year by causing the swift removal of unsafe foods and medical products from the marketplace and informing the public of the hazards posed by recalled products.

Laboratory Capability

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 specific areas of laboratory service:

- Winchester Engineering and Analytical Center (WEAC) focuses on the engineering, biological, and chemical hazards associated with medical devices, electronic products, and radiopharmaceuticals..

- Forensic Chemistry Center (FCC) specializes in forensic analysis of samples related to criminal activities that fall under FDA jurisdiction; including product tampering and drug counterfeiting.

The primary role of field scientists is the analysis of FDA-regulated products. ORA labs facilitate method validation, technical training, inspections, and public outreach. These labs are staffed by a highly-skilled cadre of professional chemists, microbiologists, biologists, entomologists, engineers, physicists, research scientists, quality assurance, and safety/ hazardous waste personnel.

Twelve of the thirteen ORA Laboratories have successfully completed A2LA's final audit assessment for ISO 17025 Laboratory Accreditation. ORA's FCC is accredited under the American Society of Crime Laboratory Directors/Laboratory Accreditation

Board. The accreditation of all of ORA's laboratories demonstrates ORA's ability to provide work products that fulfill customer needs, meet applicable regulatory requirements, and be able to withstand legal and international scrutiny.

Sample collection and laboratory analysis is a critical part of FDA's regulatory activities. A valid sample is the starting point for most administrative and legal actions. Therefore, the sample must be suitable as evidence to support FDA's charge that there has been a violation of the Act.

The Laboratory Capability includes three additional laboratory activities:

- chemical, microbiological, or physical hazards identification of food source contamination during foodborne illness outbreaks

- engineering, biological, and chemical analysis to prevent the exposure of the public to potentially unsafe or ineffective medical devices, electronic products, radionuclide, and radiopharmaceuticals

- analysis of food samples for pesticides and environmental contaminants.

Shelf Life Extension Program (SLEP)

Shelf Life Extension Program (SLEP) is a cooperative product evaluation program between FDA and the Department of Defense (DOD). It is a key component of the Medical Readiness Strategic Plan in response to Congressional concern over the conservation of military medical resources. To assure preparedness for war or other emergencies, DOD maintains significant pre-positioned stocks or war reserves of critical medical material. All drugs have expiration dates and routine replacement of these stocks can be very costly. To reduce costs, FDA and DOD participate in a cooperative product evaluation program, in which ORA laboratories test product samples, and in cooperation with FDA's Center for Drug Evaluation and Research, determine if the expiration date for the lot of the product can be extended and for how long.

FDA grants extensions to a specific lot number, with an understanding that all lots at all locations have been stored under Current Good Manufacturing Practices, including environmentally controlled storage conditions. The lot is retested annually to confirm extended expiration dating or permit further extension. Products that fail testing at any time are destroyed. All extended SLEP material is relabeled in accordance with FDA regulations. Current testing focuses on military significant pharmaceuticals; drugs that are purchased in very large quantities for specific contingency needs, such as Ciprofloxacin and antivirals, such as Tamiflu.500 samples were tested in FY 2006 at three ORA laboratories.

SLEP also assures only safe and effective drugs are provided to personnel during war or other contingencies. In 2004, the Strategic National Stockpile, managed by the CDC,

became part of SLEP and in 2005 the Department of Veterans Affairs was added to the program.

Information Technology (IT)

ORA is currently in the midst of a major realignment of its software projects. Burdened with a legacy of stove-piped systems that use outmoded technology, ORA's automated systems cannot provide the support necessary to ensure that FDA can continue to meet its performance goals. ORA's strategy to address this challenge is to combine its IT development efforts into three major programs: Automated Regulatory Management, Data Warehousing and Reporting, and Laboratory Automation. Grouping existing and new IT initiatives into just three areas helps focus resources and managements' attention on ORA's growing business needs. It also ensures that these programs will work together to capture, maintain, and report the information needed to identify and manage health and safety risks, while using resources more effectively.

Automated Regulatory Management - The Automated Regulatory Management program encompasses the Mission Accomplishment and Regulatory Compliance System (MARCS). The MARCS will establish an electronic environment that can dramatically improve the efficiency of FDA Field staff. Benefits include improved import screening, management of foreign inspections, tracking of violative products and BSE firms to improve the safety of the food supply, more sharing of information with States, better integration with FDA laboratories, efficient work-load management, the flexibility to address drug importation if required, and the ability to meet the prior notice requirements for 24/7 support.

Data Warehousing and Reporting - ORA Reporting Analysis and Decision Support System (ORADSS) is a centralized data warehouse that provides integrated decision support to help FDA identify and manage health and safety risks. This will consolidate ORA's reporting functions. When fully implemented, ORADSS will be a comprehensive repository of information about FDA regulated facilities and the enterprises that are part of the supply chain for regulated products. ORADSS' information will allow FDA Centers and management to statistically correlate and analyze multi-year data on geographic areas, firms, products, inspections, and shipments of interest to the FDA.

Laboratory Automation - The Laboratory Automation Program is an emerging ORA program designed to improve the efficiency of the FDA lab staff, the quality of the information the labs provide, and the ability of FDA to share this information with its own centers and other public health labs. In spite of their importance to critical FDA regulatory activities, ORA's laboratories currently depend on manual and semi-automated processes that limit the number and scope of the analyses FDA staff can perform. This program would enable FDA labs to improve chain-of custody tracking, including assignments and sample status, automate collection and processing of analytical data, and track calibration and scheduling to improve the quality of the data produced. The Laboratory Automation Program will also integrate eLEXNET, the

network developed jointly by USDA, CDC, and DoD, to communicate unusual findings from laboratory analyses about food-borne pathogens.

Selected FY 2006 Accomplishments

Imports

Coordination of International Humanitarian Assistance: In the aftermath of Hurricane Katrina, ORA's Prior Notice Center (PNC) worked with the Department of State's U.S. Agency for International Development (USAID), Customs and Border Protection (CBP), the Federal Emergency Management Agency (FEMA) and other federal agencies to develop an International Assistance System (IAS) Manual as part of the National Response Plan. Once the manual is implemented, the PNC will have a system in place to expedite the movement of humanitarian relief shipments to their destinations while ensuring that donated FDA-regulated articles meet regulatory, safety, and security requirements.

Prior Notice Center (PNC) Review and Compliance Actions: FDA received 9,194,082 million prior notice submissions on which the PNC conducted 89,034 import security reviews to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. These operations, in cooperation with CBP, actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats.

Risk-based Screening of Imports: ORA is developing a computerized system that will use known data and artificial intelligence to conduct risk-based screening of imported products. Starting with a system for food imports, FDA and its contractor, New Mexico State University/Physical Science Laboratory (NMSU/PSL), have made substantial progress in the design and proof of concept of the system. Once completed and implemented, this program will help identify imported shipments that pose the greatest risk to public health and will allow ORA to target its resources more effectively.

New Residue Detection Methods Developed: ORA analysts successfully used a new method developed by Canada to detect malachite green in seafood manufactured by 26 different processors. In addition, the State of Florida developed methods to test and measure fluoroquinolones (antibiotic residues) in honey.

New FDA Import Strategy: ORA serves as the lead component within FDA responsible for overseeing the implementation of a new import strategy throughout all product areas. The import strategy provides a framework for re-engineering FDA's agency-wide import operations, policies, and procedures and underscores the importance of applying a risk-based operational approach to the full life-cycle of an imported product. By analyzing data collected throughout the import life cycle, we will be better able to detect risks posed by imported products, as well as key junctures where timely intervention can reduce or eliminate those risks. Once established and emerging risks have been identified and assessed, we can more effectively allocate our resources to manage these risks. Likewise, by employing a more risk-based approach, we can better identify products requiring less FDA scrutiny at the border. This will

help speed the processing of imported products that do meet FDA requirements and free up additional resources for dealing with more risky imports or imports that require further evaluation.

Import Targeting and Intelligence Program (ITIP): OCI has implemented a new initiative intended to enhance and increase our efforts to prevent counterfeit and unapproved pharmaceutical products from entering the U.S. through the various International Mail Facilities (IMF), called the Import Targeting & Intelligence Program (ITIP).

Health Fraud

OCI Liaisons To Combat Fraud Over the Internet: OCI maintains a liaison with the Federation of State Medical Boards and the National Association of Boards of Pharmacy. In addition, OCI maintains a professional liaison with Internet businesses such as Internet Service Providers, GoDaddy, Network Solutions, eBay, and online transaction and financial services PayPal, Mastercard and CCNow, and Verisign. OCI provides training and education to internet auction and payment companies.

Development of Alternative Light Source Technology to Fight Counterfeit Drugs: The Forensic Chemistry Center (FCC) developed a new investigative tool utilizing Alternate Light Source (ALS) technology. Once fully implemented, ALS will be a powerful tool to identify potential counterfeit pharmaceuticals.

Warning Letters Issued for Illegal Promotion of Products on Internet: In October 2005, FDA issued Warning Letters to 29 companies that manufacture, market, or distribute products made from cherries or other fruits and which claimed that these products treat or prevent of a variety of diseases, including cancer, heart disease, and arthritis. These letters illustrate FDA's vigilance in monitoring the Internet for illegal promotion of fraudulent products targeted to the vulnerable -- those suffering from serious and sometimes fatal illness.

FDA Requested Drug Recall: In February, 2006, FDA requested Cytosol Laboratories of Braintree, MA to conduct a recall of all brands and sizes of its Balanced Salt Solution (BSS), a drug manufactured by the firm to irrigate a patient's eyes, ears, nose and/or throat during a variety of surgical procedures, including cataract surgery. FDA requested this recall because the product was found to have elevated levels of endotoxin. [Endotoxins, also known as pyrogens, are substances found in certain bacteria that cause a wide variety of serious reactions such as fever, shock, changes in blood pressure and in other circulatory functions.] FDA had also received reports of a serious and potentially irreversible eye injury associated with this product called Toxic Anterior Segment Syndrome (TASS) which occurs when a contaminant, such as endotoxin, enters the anterior segment of the eye during surgery and causes an inflammatory reaction. This Class I Recall resulted in the removal of over 1 million units of product from domestic and foreign markets and the firm's subsequent voluntary destruction of over 73,000 units of product.

OCI/Enforcement

Counterfeit Drug Investigation Statistics: In FY 2006, FDA's Office of Criminal Investigations (OCI) initiated 54 counterfeit drug investigations. This resulted in 41 counterfeit drug arrests and 35 convictions in FY 2006, with restitution and fines in excess of $8,000,000. In FY 2006, OCI continued to coordinate counterfeit drug investigations with several foreign counterparts, especially those in China, Israel, and Canada. These efforts continue to produce positive outcomes for both OCI and its foreign counterparts.

Counterfeit Percocet®, Viagra® and Cialis® Tablets: In September 2006, an individual in Philadelphia who purchased thousands of counterfeit drugs over the Internet from China, including Percocet®, Viagra® and Cialis®, was indicted in the Eastern District of Pennsylvania on charges related to trafficking in counterfeit goods, and other counterfeit prescription drug related charges. This OCI case, worked jointly with U.S. Immigration and Customs Enforcement (ICE), U.S. Drug Enforcement Administration (DEA), U.S. Postal Inspection Service and the Philadelphia Police Department, was part of a much larger OCI-ICE counterfeit drug investigation.

Joint Terrorism Task Force (JTTF) Investigation into Counterfeit Viagra and Stolen Infant Formula: In April 2006, an individual pled guilty in the Eastern District of Virginia to a charge of trafficking in counterfeit Viagra® and was sentenced to 14 months in prison. The defendant in this case distributed or intended to distribute more than 10,000 counterfeit Viagra® tablets to an OCI undercover agent. This case arose out of a Norfolk, Virginia JTTF investigation into stolen infant formula.

OCI Liaisons with Other Agencies: OCI has committed a headquarters agent to serve as a representative to CBP's Office of Anti-Terrorism at CBP headquarters, an office which reports directly to the Commissioner of CBP. OCI also has an agent assigned to the National Counterterrorism Center (NCTC) to serve as a liaison to the Central Intelligence Agency (CIA) and other intelligence agencies. An additional agent is assigned to serve as a liaison to the Department of Homeland Security (DHS) to work on intelligence matters with other DHS agencies, including the Bureau of Immigration and Customs Enforcement (ICE).

Internet Cases: American consumers are increasingly using the internet to purchase their medications. OCI cases involving the internet have risen significantly and represent some of the most egregious threats to the public health. Three cases during FY 2006 illustrate the seriousness of the issue.

Dextromethorphan deaths: On April 12, 2006, two men were sentenced in the Southern District of Indiana Federal Court to 77 months incarceration after pleading guilty to introducing a misbranded drug into interstate commerce. Specifically, they sold dextromethorphan (DXM), a cough suppressant, over the internet through their website. This case started in 2005 after five young people died after ordering and consuming DXM from the defendants' website. DXM is an anti-tussive (cough

suppressant) which is approved for over-the-counter cough medications. The defendants sold the DXM by falsely claiming that DXM was a chemical used for research and development rather than a drug for human consumption. DXM is often abused by some in order to experience a "high."

Clandestine Drug Manufacturing of Internet Drugs: In 2006, eleven individuals and an Atlanta, Georgia-based company were indicted by a federal grand jury on multiple felony charges relating to a scheme to sell adulterated and unapproved new drugs over the internet. The defendants in this case opened up a pharmaceutical manufacturing facility in Belize, where they made over 24 different prescription medications. The defendants marketed the drugs through "spam" email advertisements where they claimed the drugs were Canadian generic versions of name brand drugs. Some of the drugs the defendants made were unapproved versions of Ambien®, Valium®, Xanax®, Cialis®, Lipitor®, Vioxx® and others. These drugs were then purchased by and shipped to U.S. consumers and to various drug wholesalers.

Fraudulent Avian Flu and Cancer Cures: In 2006, a Florida man was indicted for failing to obey a Temporary Restraining Order (TRO) which directed him to cease and desist marketing non-FDA approved products which he touted as cures for influenza, migraines, cancer, and other ailments. The defendant marketed these products via more than 20 websites that he owned and operated. The TRO issued by the court ordered the defendant to discontinue selling the products and to shut down his websites. Subsequently, the defendant was charged in a superseding indictment for conspiracy, and multiple counts of wire fraud, mail fraud, misbranding, and distributing an unapproved new drug relating to the manufacture and sale of his products.

FDA Flu Statement: ORA/OCI proactively prepared a Press Statement that was cleared at the Agency-level and published on the FDA Website on January 20, 2006 warning the public of the significant threat posed by fraudulent products claiming to prevent/treat seasonal flu or avian flu. As a result of this proactive action, GoDaddy instituted a filtering process to identify and take action against any websites using their services for illegal activity; and made an employee available 24/7 to assist OCI with any problems it uncovers related to the potential flu pandemic.

Leveraging With the States

Electronic State Access to FACTS (eSAF): ORA expanded the number of States that have access to, and can enter data directly into, the electronic State Access to FACTS (eSAF) data system from 17 to 26 in Fiscal Year 2006. This application has conserved resources and allows the States and ORA to share firm and inspection data (including compliance information, consumer complaints, and sample analyses). It also allows ORA to issue inspection assignments directly to the States. With the addition of these nine States, 26 of the 40 states under contract now have access to eSAF.

State Contracts Program: ORA awarded 151 contracts to state and local governments to perform MQSA, feed/BSE, tissue residue, food, and medical device inspections. ORA made its electronic State Access to FACTS (eSAF) database available to 15 state food programs and conducted training for FDA and state personnel to learn the system. ORA began expanding the design of eSAF to include the feed and BSE programs, which will be piloted in FY 2007.

Strategically Manage Human Capital: As part of satisfying the "Green" Standards for Success, the Division of Human Resource and Development (DHRD) developed and implemented a training plan for ORA program staff. Training included 41 classroom courses delivered to 1,400 students, increasing the number of web-based modules to 460 in number; and, delivering 13 satellite/teleconference events. ORA has additional activities to support the strategic management of human capital:

- ORA was authorized by the International Association of Continuing Education and Training to continue to offer continuing education units for ORA courses.
- ORA developed and offered four courses regarding the capabilities of the FERN (Food Emergency Response Network) to 80 students.
- ORA offered eight courses to approximately 280 state and FDA students in response to BSE concerns.
- ORA delivered three import courses focused on risk-based screening of imports to approximately 120 attendees.

Rapid Response to Emergencies (Outbreaks, Recalls)

Hurricanes Katrina and Rita: ORA took the lead in FDA's emergency response and revitalization efforts following the hurricanes and worked with other federal, state and local officials on many efforts:

- scrutinize more than 500 food service operations in schools, nursing homes, hospitals, shelters and other establishments to make sure the food supply was safe
- inspect 417 pharmacies to ensure that the drugs, medical devices and biologics held and distributed by them continued to be safe and effective
- supervise the reconditioning or destruction of regulated products that were no longer deemed suitable for consumption or their intended use
- identify and examine 53 shipments of humanitarian aid supplies donated by foreign relief agencies to make sure they met FDA requirements

- dispatch two mobile laboratories to Thibodeaux, Louisiana to assist Louisiana health officials in the collection and analysis of 417 water samples so that the quality and safety of shellfish growing waters could be assessed.

Laboratory Capability

Laboratory Accreditation: Twelve of 13 ORA Laboratories have successfully completed A2LA's final audit assessment for ISO 17025 Laboratory Accreditation. ORA's Forensic Chemistry Center (FCC) was accredited under the American Society of Crime Laboratory Directors/Laboratory Accreditation Board, resulting in all ORA laboratories being appropriately accredited. Accreditation against these quality management systems demonstrates ORA's ability to provide work products that fulfill customer needs, meet applicable regulatory requirements, and able to withstand legal and international scrutiny.

Mobile Laboratory Program: In June, 2006, ORA's Mobile Chemistry Lab was deployed to Fort Sam Houston, San Antonio, TX to assist FDA's Southwest Import District in the analysis of samples collected in response to work plan and counterterrorism assignments.

Shelf-Life Extension Program

Shelf Life Extension Program (SLEP): ORA continued its participation in SLEP, a joint FDA/Department of Defense product evaluation program. To reduce replacement costs of critical medical material in war/emergency reserves, ORA laboratories test product samples, and in cooperation with CDER, determine if the expiration date for the lot of the product can be extended and for long. In FY 2006, ORA laboratories tested 500 product samples, including samples of Oseltamivir and Rimantadine. These antiviral drugs are an important component of the federal government's pandemic influenza response.

Information Technology

ORA Web Content Management: ORA implemented the Vignette Web Content Management System and succeeded in standardizing the ORA intranet web site, streamlining more than 6,500 pages of information, making the retrieval of information more user-friendly, and establishing a tool for rapid communication. The Content Management System has facilitated the publication of electronic versions of official ORA reference documents and manuals such as the Investigations Operations Manual, as well as other regulatory information and guidance documents.

ORADSS Upgrades: FDA completed its upgrade of the enforcement data warehouse, the ORA Reporting Analysis and Decision Support System (ORADSS), by consolidating its FACTS reporting system into a single ORADSS user interface. This integration will significantly improve the ability of field, ORA headquarters, and

Center offices to conduct in-depth, customized analyses of compliance programs and enforcement initiatives and to detect patterns of violations.

Mission Accomplishment and Regulatory Compliance System (MARCS): An upgrade of user access capabilities using the Web for the legacy systems, OASIS, FACTS, and Recall Enterprise System was completed in June 2006. In addition the upgrade provides an operational environment and infrastructure in support of the larger MARCS Program strategy. A prototype application to support import examinations at International Mail Facilities was completed and is in use; work to finalize its design and fully implement it is underway.

Prior Notice System Interface (PNSI): During FY 2006, usability and performance was improved by developing features such as personal address books, reusable information from past submissions, and copying and pasting of web entries. With the added benefit of addressing discrepancies related to Section 508 of the U.S. Rehabilitation Act, the process of submitting Prior Notices via the web has been simplified and streamlined.

Electronic Laboratory Exchange Network (eLEXNET): Of the 131 laboratories in the eLEXNET system, 107 are actively submitting data, an increase of 12 laboratories from the previous year. The interface of eLEXNET with the Department of Homeland Security's National Biosurveillance Integration System (DHS/NBIS) facilitates the submission to DHS of bio surveillance reports that could adversely impact the food supply. In addition, the version 5.0 SOA Methods Module was released, improving rapid sharing of validated methods between states, USDA, FDA, and Canada.

Expand Electronic Government: ORA has commitments to expanding electronic government:

- Nearly 8,000 state, local and tribal regulators have now registered with ORA's e-learning source offering 125 technical web-based training modules.

- In collaboration with CDC, ten national food safety associations and others within FDA, developed and delivered a national satellite program on food defense to over 10,000 participants.

- ORA facilitated the development of a web based training tool for state and local food regulatory personnel to initiate discussions with food producers, retailers and service organizations on food defense.

- In collaboration with the Association of Food and Drug Officials and CDC, developed a "course in a box" entitled "The Application of the Basics of Inspection/Investigation FD170" intended to be delivered on site locally to state/local/tribal new hires.

- ORA developed a course for the Shellfish Patrol Officers who police coastal waters for illegal harvesting of shell stock in collaboration with CFSAN and the ISSC (Interstate Shellfish Sanitation Conference)

- ORA developed a new course called “Food Emergency Response FD217" for Commission Corps Officers on rapid deployment teams responding to disasters.

- ORA provided up-to-date training materials on the FDA/ORA internet site for state/local/tribal regulatory employees.

- ORA facilitated the development of the web-based A.L.E.R.T. initiative for FDA, the Centers for Disease Control and Prevention, and USDA to help State and local food regulatory personnel initiate discussions with food producers, retailers, and service organizations on food defense.

- ORA developed and delivered four "eSAF" (electronic State Access to FACTS) courses to approximately 80 students to train State employees who supervise, manage, and/or perform FDA inspections work under State food contracts.

ORA Transformation Leadership Team Support: A customized, interactive website was created to provide FDA personnel with up-to-date information regarding ORA’s Transformation Initiative. The site also allows ORA personnel to submit questions, comments and feedback concerning the transformation to ORA management.

Combined Field Activities – ORA
Program Activity Data

FOODS FIELD

PROGRAM OUTPUTS- **DOMESTIC INSPECTIONS**	**FY2006** **Actual**	**FY2007** **CR Estimate**	**FY2007** **PB Estimate**	**FY2008** **Estimate**
Domestic Food Safety Program Inspections	3,833	3,000	3,400	3,400
Imported and Domestic Cheese Program Inspections	401	200	300	300
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	477	300	400	400
Domestic Fish & Fishery Products (HACCP) Inspections	2,308	2,000	2,330	2,330
Import (Seafood Program Including HACCP) Inspections	529	250	500	500
Juice HACCP Inspection Program (HACCP)	441	100	300	375
Interstate Travel Sanitation (ITS) Inspections	1,175	1,000	1,550	1,550
State Contract Food Safety (Non HACCP) Inspections	6,680	7,780	8,400	8,400
State Contract Domestic Seafood HACCP Inspections	1,006	1,010	1,010	1,010
State Contract Juice HAACP	58	47	47	47
State Partnership Inspections	822	900	900	900
Total Above FDA and State Inspections	**17,730**	**16,587**	**19,137**	**19,212**
State Contract and Grant Foods Funding	$6,378,774	$6,378,774	$6,825,288	$7,303,058
Number of FERN State Laboratories	10	10	16	16
Annual FERN State Cooperative Agreements/Operations Funding	$7,105,000	$7,195,000	$12,535,000	$10,285,000
Total State & Annual FERN Funding	**$13,483,774**	**$13,573,774**	**$19,360,288**	**$17,588,058**
Domestic Field Exams/Tests	2,455	2,500	2,500	2,500
Domestic Laboratory Samples Analyzed	11,706	9,965	10,465	10,465
All Foreign Inspections	125	100	100	100
Import Field Exams/Tests	94,545	71,000	71,000	71,000
Import Laboratory Samples Analyzed	20,662	26,980	28,480	28,480
Import Physical Exam Subtotal	115,207	97,980	99,480	99,480
Import Line Decisions	8,883,999	9,101,004	9,101,004	9,323,310
Percent of Import Lines Physically Examined	1.30%	1.08%	1.09%	1.07%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	89,034	60,000	60,000	60,000

COSMETICS FIELD

PROGRAM OUTPUTS- DOMESTIC INSPECTIONS	FY2006 Actual	FY2007 CR Estimate	FY2007 PB Estimate	FY2008 Estimate
All Inspections	151	25	100	100
PROGRAM OUTPUTS- IMPORT/FOREIGN INSPECTIONS				
Import Field Exams/Tests	2,441	2,000	2,000	2,000
Import Laboratory Samples Analyzed	280	230	230	200
Import Physical Exam Subtotal	2,721	2,230	2,230	2,200
Import Line Decisions	1,358,918	1,611,326	1,611,326	1,910,616
Percent of Import Lines Physically Examined	0.20%	0.14%	0.14%	0.12%

DRUGS FIELD

PROGRAM OUTPUTS- DOMESTIC INSPECTIONS	**FY2006 Actual**	**FY2007 CR Estimate**	**FY2007 PB Estimate**	**FY2008 Estimate**
Pre-Approval Inspections (NDA)	139	112	112	112
Pre-Approval Inspections (ANDA)	80	110	110	155
Bioresearch Monitoring Program Inspections	498	555	555	555
Drug Processing (GMP) Program Inspections	1,222	1,100	1,377	1,377
Compressed Medical Gas Manufacturers Inspections	106	158	158	158
Adverse Drug Events Project Inspections	105	133	133	133
OTC Monograph Project and Health Fraud Project Inspections	28	32	32	32
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	63	110	110	110
State Partnership Inspections: GMP Inspections	50	50	50	50
Total Above FDA and State Partnership Inspections	**2,291**	**2,360**	**2,637**	**2,682**
Domestic Laboratory Samples Analyzed	1,706	1,587	1,587	1,587
PROGRAM OUTPUTS- IMPORT/FOREIGN INSPECTIONS				
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	123	125	190	190
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	79	42	42	87
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	124	44	44	44
Foreign Drug Processing (GMP) Program Inspections	164	134	174	209
Foreign Adverse Drug Events Project Inspections	10	16	16	16
Total Above Foreign FDA Inspections	**500**	**361**	**466**	**546**
Import Field Exams/Tests	3,525	4,400	4,400	4,400
Import Laboratory Samples Analyzed	277	275	275	275
Import Physical Exam Subtotal	3,802	4,675	4,675	4,675
Import Line Decisions	279,662	295,627	295,627	312,504
Percent of Import Lines Physically Examined	1.36%	1.58%	1.58%	1.50%

Note:

1. The increase in Human Drugs ANDA inspections for FY08 above FY07 are attributed to the Proposed Generic Drugs User Fee.

BIOLOGICS FIELD

PROGRAM OUTPUTS- **DOMESTIC INSPECTIONS**	**FY2006** **Actual**	**FY2007 CR** **Estimate**	**FY2007 PB** **Estimate**	**FY2008** **Estimate**
Bioresearch Monitoring Program Inspections	88	169	180	180
Blood Bank Inspections	1,139	1,045	1,130	1,130
Source Plasma Inspections	145	174	174	190
Pre-License, Pre-Approval (Pre-Market) Inspections	22	6	6	6
GMP Inspections	26	30	30	30
GMP (Device) Inspections	6	16	16	32
Human Tissue Inspections	354	385	484	484
Total Above Domestic Inspections	**1,780**	**1,825**	**2,020**	**2,052**
PROGRAM OUTPUTS- IMPORT/FOREIGN INSPECTIONS				
Blood Bank Inspections	0	12	12	24
Pre-License Inspections	1	4	4	4
GMP Inspections	15	15	15	15
Total Above Foreign FDA Inspections	**16**	**31**	**31**	**43**
Import Field Exams/Tests	66	100	100	100
Import Line Decisions	44,418	49,350	49,350	54,829
Percent of Import Lines Physically Examined	0.15%	0.20%	0.20%	0.18%

ANIMAL DRUGS & FEEDS FIELD

PROGRAM OUTPUTS- DOMESTIC INSPECTIONS	FY2006 Actual	FY2007 CR Estimate	FY2007 PB Estimate	FY2008 Estimate
Pre-Approval /BIMO Inspections	64	65	125	125
Drug Process and New ADF Program Inspections	209	168	194	194
BSE Inspections	2,510	2,594	2,594	2,844
Feed Contaminant Inspections	19	10	10	10
Illegal Tissue Residue Program Inspections	218	180	233	233
Feed Manufacturing Program Inspections	333	170	220	220
State Contract/Coop Agreement Inspections: BSE	5,410	4,527	4,844	4,844
State Contract Inspections: Feed Manufacturers	383	314	336	336
State Contract Inspections: Illegal Tissue Residue	276	285	706	635
State Partnership Inspections: BSE and Other	1,036	900	900	900
Total Above FDA and State Contract Inspections	**10,458**	**9,213**	**10,162**	**10,341**
State Contract Animal Drugs/Feeds Funding	$1,785,384	$1,785,384	$1,910,361	$2,044,086
BSE Cooperative Agreement Funding	$3,000,000	$3,000,000	$3,000,000	$3,000,000
State Contract Tissue Residue Funding	$281,031	$281,031	$697,500	$320,375
Total State Funding	**$5,066,415**	**$5,066,415**	**$5,607,861**	**$5,364,461**
Domestic Laboratory Samples Analyzed	2,053	1,725	1,725	1,880
PROGRAM OUTPUTS- IMPORT/FOREIGN INSPECTIONS				
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	31	30	45	45
Foreign Drug Processing and New ADF Program Inspections	11	10	10	10
Total Above Foreign FDA Inspections	**42**	**40**	**55**	**55**
Import Field Exams/Tests	4,063	4,500	4,500	4,500
Import Laboratory Samples Analyzed	510	1,075	1,075	1075
Import Physical Exam Subtotal	4,573	5,575	5,575	5,575
Import Line Decisions	225,959	240,549	240,549	256,081
Percent of Import Lines Physically Examined	2.02%	2.32%	2.32%	2.18%

DEVICES FIELD

PROGRAM OUTPUTS- **DOMESTIC INSPECTIONS**	**FY 2006** **Actual**	**FY2007 CR** **Estimate**	**FY2007** **PB Estimate**	**FY2008** **Estimate**
Bioresearch Monitoring Program Inspections	319	300	300	300
Pre-Approval Inspections	76	20	119	139
Post-Market Audit Inspections	50	65	65	65
GMP Inspections (Levels I, II, III and Accredited Persons)	1,472	1,300	1,458	1,558
Total Above Domestic Inspections: Non MQSA	**1,917**	**1,685**	**1,942**	**2,062**
Inspections (MQSA) FDA Domestic (non-VHA)	367	335	335	335
Inspections (MQSA) FDA Domestic (VHA)	31	31	31	31
Inspections (MQSA) by State Contract	7,620	7,838	7,838	7,838
Inspections (MQSA) by State non-Contract	607	790	790	790
Total Above Domestic Inspections: MQSA	**8,625**	**8,994**	**8,994**	**8,994**
State Contract Devices Funding	$225,000	$225,000	$240,750	$257,603
State Contract Mammography Funding	$8,868,100	$9,754,910	$9,754,910	$10,730,401
Total State Funding	**$9,093,100**	**$9,979,910**	**$9,995,660**	**$10,988,004**
Domestic Radiological Health Inspections	85	133	133	133
Domestic Field Exams/Tests	800	1,575	1,575	1,575
Domestic Laboratory Samples Analyzed	237	173	173	203
PROGRAM OUTPUTS- **IMPORT/FOREIGN INSPECTIONS**				
Foreign Bioresearch Monitoring Inspections	17	10	10	10
Foreign Pre-Approval Inspections	37	12	32	32
Foreign Post-Market Audit Inspections	21	7	27	27
Foreign GMP Inspections	209	155	200	200
Foreign MQSA Inspections	10	15	15	15
Foreign Radiological Health Inspections	24	19	19	19
Total Above Foreign FDA Inspections	**318**	**218**	**303**	**303**
Import Field Exams/Tests	5,063	5,000	5,000	5,000
Import Laboratory Samples Analyzed	1,162	1,340	1,340	1,340
Import Physical Exam Subtotal	6,225	6,340	6,340	6,340
Import Line Decisions	4,184,839	5,026,091	5,026,091	6,036,455
Percent of Import Lines Physically Examined	0.15%	0.13%	0.13%	0.11%

PERFORMANCE ANALYSIS

During FY 2006, which was the latest performance period for which FDA has complete data, ORA successfully achieved or exceeded all 15 targets for its FY 2006 performance goals. For more information about these performance goals and results, please see the Performance Detail section.

For the FY 2007 President's Budget, the Import Food Field Exams goal was decreased by 4,000 exams as a result of redeployment of funds to other food defense priorities. In addition, three additional performance goals were reduced including the high risk foods goal (reduction of 75 inspections); high risk blood banks and source plasma goal (reduction of 37 inspections); and, the medical device Class II and III manufacturers goal (reduction of 75 inspections). The targets for the animal drugs and feeds establishment and BSE inspection performance goals were reduced due to a reduction in firm inventory.

Due to the impact of the FY 2007 Continuing Resolution, four performance goals were reduced. ORA will not have the staff to meet performance commitments made in the FY 2007 President's Budget. Outputs were reduced for the high risk foods goal (reduction of 1,015 inspections); high risk blood banks and source plasma goal (reduction of 85 inspections); animal drugs and feeds establishment goal (reduction of 106 inspections); and, the medical device Class II and II manufacturers goal (reduction of 258 inspections). The FY 2007 Continuing Resolution will also not allow for additional laboratory surge capacity in FY 2008 because ORA will be unable to fund new Food Emergency Response Network (FERN) cooperative agreements in FY 2007.

In FY 2007 and continuing in FY 2008, ORA worked with counterparts in each of the five program Centers to revise performance goals to be more risk-based and outcome oriented. Specifically, five performance goals have been revised to improve the risk-based selection process when determining specific firms to target for performance goal inspections. These include medical device protection of human subjects; foods; human drugs; biologics; and, medical device manufacturing performance goals.

These efforts will continue in FY 2008 as ORA strives to strengthen its risk-based approach and outcome orientation in field performance goals. In FY 2008, the Field will increase performance in the high risk foods goal; high risk blood banks and source plasma goal; and, the medical device Class II and III manufacturers goal.