DEVICES AND RADIOLOGICAL HEALTH

Introduction

FDA's Devices and Radiological Health Program summarizes the budget program requirements that justify a $285,376,000 request for FY 2008. The Devices and Radiological Health program narrative has four sections:

- summary of FDA's program resources, historical funding and FTE levels
- description of program functions of the Center for Devices and Radiological Health and related Field support from the Office of Regulatory Affairs
- effects of the full year FY 2007 continuing resolution on the Devices and Radiological Health Program
- description of the program resources changes, base resource activities, program accomplishments, program activity data, and performance plan analysis.

The Devices and Radiological Health Program 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 President's Budget	FY 2008 President's Budget	Increase or Decrease
Program Level	**$255,041,000**	**$237,870,000**	**$271,571,000**	**$285,376,000**	**$13,805,000**
Center	*$189,829,000*	*$170,649,000*	*$200,480,000*	*$210,117,000*	*$9,637,000*
FTE	*1,085*	*888*	*1,107*	*1,112*	*5*
Field	*$65,212,000*	*$67,221,000*	*$71,091,000*	*$75,259,000*	*$4,168,000*
FTE	*413*	*381*	*427*	*427*	*0*
Total FTE	**1,498**	**1,269**	**1,534**	**1,539**	**5**
Budget Authority	**$220,563,000**	**$220,564,000**	**$229,334,000**	**$240,122,000**	**$10,788,000**
Center	*$165,207,000*	*$165,204,000*	*$170,977,000*	*$178,265,000*	*$7,288,000*
Field	*$55,356,000*	*$55,360,000*	*$58,357,000*	*$61,857,000*	*$3,500,000*
Pay Increase	--	--	--	*$3,624,000*	*$3,624,000*
Device Safety and Review	--	--	--	*$7,164,000*	*$7,164,000*
Total FTE	**1,328**	**1,235**	**1,356**	**1,359**	**3**
User Fees	**$34,478,000**	**$17,306,000**	**$42,237,000**	**$45,254,000**	**$3,017,000**
MDUFMA	*$20,714,000*	*$0*	*$24,931,000*	*$27,083,000*	*$2,152000*
MQSA	*$13,764,000*	*$17,306,000*	*$17,306,000*	*$18,171,000*	*$865,000*
Total FTE	**170**	**34**	**178**	**180**	**2**

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	$221,506,000	$191,143,000	$30,363,000	1,515
2005 Actuals	$244,282,000	$214,962,000	$29,320,000	1,516
2006 Actuals	$255,041,000	$220,563,000	$34,478,000	1,498
2007 Continuing Resolution	$237,870,000	$220,564,000	$17,306,000	1,269
2007 President's Budget	$271,571,000	$229,334,000	$42,237,000	1,534
2008 President's Budget	$285,376,000	$240,122,000	$45,254,000	1,539

Statement of the Budget Request

The Devices and Radiological Health Program is requesting $285,376,000 in program level resources in order to complete mission-critical activities:

- promote and protect public health by ensuring the safety and effectiveness of medical devices and the safety of radiological products
- meet statutory responsibilities for review of new medical devices
- assure medical product safety by monitoring the use of all medical devices and the function and use of radiological products
- manage emerging hazards to prevent widespread health and safety threats and ensure safe and effective new medical devices and radiological health products.

Program Description

The Center for Devices and Radiological Health (CDRH) administers the program, with the assistance from the Office of Regulatory Affairs' Field offices nationwide.

CDRH adopted a Total Product Life Cycle (TPLC) for applying its regulatory oversight over medical devices and radiological health products. The TPLC spans from product concept to its obsolescence.

CDRH promotes scientific innovation in product development by focusing laboratory research on cutting edge science, and by modernizing the application review process through contracts to develop electronic submission, review, and tracking systems. Through its Postmarket Transformation action plan, CDRH monitors the safety of

medical devices after they reach the marketplace and improves risk communications to all stakeholders.

The medical device user fee program (MDUFMA) provides resources for program activities that improve the availability of products by increasing the predictability and timeliness of premarket reviews, the post-approval monitoring of innovative devices, and the implementation of establishment inspections by third parties. Under employment contracts, Medical Device Fellowship fellows supplement CDRH staff by providing expertise in all areas of the device program.

CDRH ensures the safety of devices by monitoring marketed medical products, manufacturers, and adverse events. The Medical Product Surveillance Network (MedSun) network is an example of CDRH's postmarket activities. MedSun uses contractor data collected from clinical sites to provide targeted surveillance of device use problems. In addition, CDRH's numerous websites, publications, and notifications communicate product risk-benefit information to consumers and the medical community.

Under the Mammography Quality Standards Act (MQSA), user fees fully cover the cost of inspections of non-government facilities by state inspectors; the cost of inspections of government-operated facilities is covered by appropriated funds.

Field Devices and Radiological Health Activities

ORA's Field force supports CDRH in the initial phases of the total product life cycle by conducting preapproval inspections of both foreign and domestic establishments. ORA engages in bioresearch monitoring of clinical research studies, laboratory method validations needed for premarket application decisions, and preapproval quality manufacturing facility inspections to determine if the factory is able to manufacture products according to the specifications stated in their application.

After a product is marketed, ORA conducts risk-based domestic and foreign postmarket surveillance inspections, field exams, and sampling of medical device manufacturers to assess their compliance with Good Manufacturing Practice requirements. This effort includes conducting inspections of reprocessors of single-use devices and radiological health products. ORA's radiological health activities include inspecting certified mammography facilities for compliance with the MQSA and inspection of radiation emitting products such as lasers, sunlamps, and x-ray equipment to ensure they are in compliance with performance standards. To complement the regular Field force, the Office of Criminal Investigations investigates instances of criminal activity in FDA regulated industries.

Effects of Full Year FY 2007 Continuing Resolution

The analysis in this justification assumes funding levels for FY 2007 based on the enactment of the President's FY 2007 budget for the Devices and Radiological Health program. For comparison purposes, FDA budget tables also include a column in the FDA budget tables that reflects an FY 2007 Continuing Resolution (CR) 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 the Devices and Radiological Health Program.

- Elimination of MDUFMA funding for the devices program will result in the loss of more than 140 FTE.
- CDRH will fail to meet user fee goals for PMAs and 510(k)s, causing delays and backlogs in the review process.
- CDRH will limit opportunities for pre-submission meetings and consultations with industry.
- CDRH will scale back guidance development and limit outreach and communication efforts.
- Reduced employee training and professional development, and reduced use of outside expertise will undermine CDRH's ability to keep pace with technological change and medical advancements.

<u>Field Devices and Radiological Health Program</u>
If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2007 performance for the Field 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.

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2008 performance for the Devices and Radiological Health:

- The Devices Program will be understaffed by more than 140 user fee-supported FTE at the beginning of FY 2008 due to MDUFMA's termination in FY 2007 and the loss of $24,931,000 in user fees.

- MDUFMA's termination in 2007 will increase the average review time for device applications, slowing the availability of safe products to market.

- Postmarket surveillance of product safety will decline, leading to greater public health risks.

- Prior premarket performance commitments will not be met, eliminating or severely restricting the number of premarket meetings with industry to review application status or develop review guidances.

- There will be severely limited participation in outside training and workshops for industry.

- The Devices Program will fail to continue with the current outreach and communication efforts with industry and consumers, reducing the Agency's ability to lead the development of safe products and communicate risk information.

- The Devices Program will fail to further modernize its IT infrastructure, delaying critical systems for successful premarket review, postmarket monitoring, inspectional, and document management activities.

- The Devices Program will fail to continue performing current levels of applied research activities to support regulatory decisions on new, innovative devices and safety of marketed products for consumers.

- The Devices Program will fail to maintain the Radiological Health Program at its current level; reduced monitoring and assessment of radiation-emitting products may expose consumers and security workers to unnecessary levels of radiation.

<u>Field Devices and Radiological Health Program</u>

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2008 performance for the Field Devices and Radiological Health 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 Resource Changes

Budget Authority

Pay Increase: +$3,624,000

The FDA request for pay inflationary costs is essential for FDA to accomplish its public health mission. Eighty-three percent of FDA's budget supports the agency workforce. Of this, payroll costs account for over sixty-percent of the total budget. The increase will allow FDA to maintain staff levels, including a national cadre of specially trained scientific staff. The total estimate for pay increases is $21,773,000. The Device and Radiological Health Program's portion of this increase is $3,624,000. These resources are vitally important for FDA to fulfill its mission to protect the public health by helping safe and effective devices reach the market in a timely way, and by monitoring devices and radiological products for continued safety after they are used.

Device Safety and Review: + $7,164,000 and +3 FTE

FDA is requesting an increase of $7,164,000 to improve the safety of marketed medical devices and ensure the consistency of review performance so that safe and effective medical devices are available to consumers. FDA will direct $4,743,000 on its medical safety and review program and $2,421,000 on its Field Device inspectional program. The requested increase will ensure that FDA maintains the ability to collect and spend user fees on the review process under the Medical Device User Fee and Modernization Act (MDUFMA) by meeting the requirements for the fees, including the third party inspection provision. The increase will also enable FDA to strengthen device safety program by improving FDA's ability to identify, analyze and act on postmarket safety information. This information drives improvements in the quality of new products coming to market, ensures the safety of products currently on the market, and provides timely device safety information to consumers.

Providing the appropriated funds in this request will allow FDA to collect $47,500,000 in medical device user fees. These appropriated funds, supported by user fees, ensure that FDA will meet the challenging performance goals for device review, modernize its information technology infrastructure to improve premarket and postmarket capabilities, provide outreach to industry that improves product safety, ensure that staff has the skills to keep pace with rapidly advancing new technology, increase risk management and communications capabilities, and improve recall processing.

User Fees

Current Law User Fees

MDUFMA: +$2,152,000 and +2 FTE

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. CDRH's increase of $2,1252,000, for a total FY 2008 fee collection of $27,083,000, assumes that the 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. FDA bases the increase on inflation for the device review program.

MDUFMA user fees allow CDRH to improve the review process in three areas:

- bringing safe and effective innovative new products to market as quickly as possible by reducing device review time

- improving review quality through the Medical Device Fellowship Program, which brings subject experts to FDA to supplement staff expertise

- improving the quality of device submissions by increasing the opportunities for pre-submission meetings and consultations with industry, guidance development, and outreach and communications efforts.

Mammography Quality Standards Act (MQSA): +$865,000

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 CDRH to perform the following activities:

- fund annual MQSA inspections; inspections of mammography facilities deemed to be governmental entities are funded through budget authority (approximately 9 percent), the other 91 percent of the annual facility inspections are funded through user fees
- maintain the inspection program through training and equipment calibration to ensure that mammography facilities remain in compliance with established quality standards
- improve accessibility to MQSA-related data by modernizing and enhancing the Mammography Program Reporting and Information System (MPRIS).

Proposed User Fees

Proposed Reinspection User Fee (Reclassified as Mandatory): $2,768,000 and 22 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 $2,768,000 of the collections being allocated to the Field component of the Devices and Radiological Health program.

Justification of Base

The Justification of Base describes the activities FDA plans to accomplish under the FY 2008 request that assumes the enactment of the President's FY 2007 budget.

Medical devices and radiological products are critical to the delivery of health care in the United States. The safety and efficacy of medical devices are driving improvements in medical outcomes for patients across the United States, and innovations in the medical device industry are leading advances in clinical care, treatment, and rehabilitation. The Devices and Radiological Health Program is responsible for establishing reasonable assurance of the safety and effectiveness of these devices. The Program also ensures the safety of radiological products to minimize unnecessary exposure to radiation, which is a major cause of cancer. The Devices and Radiological Health Program is administered by the CDRH with assistance from FDA's field offices based across the United States.

The Devices and Radiological Health Program's four key areas, detailed in this justification, are Premarket, Patient Safety, Mammography Quality Standards (MQSA), and Risk Communications and Outreach:

- Premarket focuses on bringing innovative medical devices to market as quickly as possible.
- Patient Safety focuses on assuring the safety of marketed devices.
- MQSA's focus is the public health need for safe and reliable mammography.
- Risk Communications and Outreach focuses on getting accurate information about regulated products to consumers.

The chart below displays the four program areas of the Medical Device and Radiological Health Program, and shows their broad support for FDA's strategic goals.

	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
Program Area			
Premarket		X	X
Patient Safety	X		X
MQSA	X		
Risk Communications and Outreach	X		

CDRH's four program areas support three of FDA's strategic goals:

- The Premarket program area supports FDA's strategic goal of increasing access to innovative products and technologies to improve health.
- The Premarket and Patient Safety program areas support FDA's goal of improving product quality, safety and availability through better manufacturing and production oversight.
- The Patient Safety, MQSA, and Risk Communication and Outreach program areas support FDA's goal of enhancing patient and consumer protection and empowering them with better information about regulated products.

Base activities within the four program areas support the accomplishment of the program's nine program performance goals that are described in the Performance Detail chapter.

Premarket

Through the Premarket program, CDRH is committed to bringing to market as quickly as possible, safe and effective new products—including products for untreated conditions, emerging infectious diseases, and counterterrorism.

The Premarket program supports the Secretary's health priority to transform health with improved regulatory processes that safely make technology available in less time, and with research objectives that reflect health care needs. To achieve these priorities and goals, the Devices and Radiological Health Program intends to:

- expand current efforts to promote scientific innovation in product development, promoting the Critical Path to market, focusing device research on the cutting-edge science needed to assess new technologies, and developing standards and guidance that improve the quality of industry product submissions

- modernize the review of innovative devices through activities that include development of electronic submission, review, and tracking systems

- implement the emergency use authorization program enabling review and access to critical new technology during times of national crisis

- maintain premarket approval (PMA) inspections, assisting firms to get innovative devices to market by identifying deficiencies early, resulting in long-term cost savings to firms and ensuring that products are safe and effective and perform as intended.

Under the Premarket area, CDRH plans to conduct critical activities in the following:

- review premarket applications and focus resources on breakthrough medical device products and unmet needs, and work to achieve review goals

- determine whether more effective but "least burdensome" regulatory mechanisms can be implemented to assist industry in bringing to market new devices to test, monitor, and administer medications for managing and treating diabetes

- encourage industry's use of 510(k) third party reviews by outside scientific and technical experts to increase these submissions from 7 percent (current) to 65 percent (eligible); provide training to ensure quality and consistency of the reviews

- continue to monitor, evaluate, and collaborate with other Federal government entities to develop new technologies that may be used in the event of a biological emergency, pandemic event, or for counterterrorism preparedness and response

- enhance workforce readiness and the development of a highly skilled workforce by providing scientific and technical development opportunities for all staff to ensure that CDRH reviewers possess the skills necessary to understand and keep pace with rapidly developing and increasingly complex technologies;

- use the special expertise of Advisory Committees, MDFP fellows, and academic, clinical and military consultants to provide scientific and technical information to CDRH workforce in accomplishing mission-related activities.

- continue to encourage new biomarker development in the medical device area and create regulatory mechanisms that promote medical innovation under the Critical Path initiative to make product development more predictable and efficient

- maintain an effective, Bioresearch Monitoring program to assure the quality and integrity of research data and to assure the protection of human research subjects through the prompt evaluation and investigation of allegations of research misconduct

- work with industry and international stakeholders to develop best practice, policy, and guidance documents to enhance the speed and quality of reviews, make premarket applications more consistent and complete, reduce multi-cycle reviews, and improve the quality of regulatory decision making.

Field Devices and Radiological Health Program

ORA provides inspectional oversight to the Medical Device PMA Program to assure that the manufacturer has the capability of manufacturing the device in accordance with the conditions outlined in the application. Inspections also verify that the manufacturer conforms to GMPs. In addition, ORA performs bioresearch monitoring inspections to assure the quality and reliability of data supporting device applications and to ensure that human subjects taking part in clinical trials are protected from undue risks.

Patient Safety

The Patient Safety area ensures that devices and radiological products currently on the market remain safe and effective. Patient Safety supports the Secretary's health priorities of transforming health and securing the homeland.

Patient Safety activities focus on improving problem detection capabilities through active surveillance systems like the MedSun network and by using analytical tools to detect signals of adverse events in marketed device products. Through the use of product recalls and enforcement actions, the program also focuses on reducing the occurrence of adverse events from user errors through activities like human factor risk analysis. Program efforts to develop scientific and technical standards maximize medical product quality.

This area also includes efforts to minimize and prevent the transmission of BSE (mad cow) related diseases during the use of and reuse of medical devices; and efforts to protect the public from excessive radiation exposure and radiological terrorism through scientific assessment of postmarket risk.

Under the Patient Safety area, the Devices and Radiological Health Program plans to conduct nine activities:

- explore active surveillance methodologies and strengthen MedSun by expanding the number of specialized sub-networks (such as cardiac, pediatric) and the use of focus groups to gather information about selected post-market safety problems from real-world users

- receive, process, and review adverse event reports, including those from other governments, to provide FDA, health care professionals, consumers, and other state and federal agencies with the information to make faster and better risk management decisions

- identify safety issues for further postmarket evaluation, actively review postmarket annual reports, and improve the quality of reviews by providing feedback on post-approval data to premarket reviewers

- improve research methods and analysis skills of field investigators and headquarters staff to facilitate problem identification related to quality systems such as corrective and preventive actions, and complaint files

- develop a pilot for a nationwide dose monitoring system, intended to reduce adverse events from user error and the health effects from ionizing radiation exposure, by educating professionals and the public on collected dose information from imaging procedures and devices, and by encouraging use of dose optimization techniques

- analyze inspection data to identify potential public health problems, develop outreach strategies to correct recurring problems, or take regulatory action as needed to bring the industry into compliance

Assuring Postmarket Safety

During 2006, FDA accomplished two objectives in strengthening its postmarket safety program:

1. FDA established a publicly available website that provide information on the progress of manufacturers' postmarket studies and how well they are meeting the submission dates for their postmarket reports.

2. FDA published the guidance document, *Procedures for Handling Post-approval Studies Imposed by PMA Order*. This guidance outlines the format, information and process that firms are asked to follow when submitting post-approval reports. These two accomplishments allow FDA to better track, evaluate and guarantee that post-approval studies meet the highest scientific rigor so that the agency can continue to assure the safety of marketed medical devices.

- use risk management to target inspection coverage for 20 percent of highest risk manufacturers, inspect 10 percent of an estimated 1,500 foreign and domestic electronic product manufacturers, and review approximately 6,000,000 device and electronic product import lines

- prioritize and leverage FDA's radiation protection efforts with states, professional societies, and other federal agencies; and encourage federal agencies to develop consistent policies aimed at reducing exposure for the public

- assist Department of Homeland Security's Transportation Security Administration and Customs and Border Protection Service, and the CDC's National Institute for Occupational Safety and Health in assuring worker safety during the use of non-intrusive search products, cargo x-ray, and electromagnetic screening and scanning products, all of which help guard against terrorism and secure the homeland.

Field Devices and Radiological Health Program

ORA ensure the safe manufacture and use of radiation-emitting products through three activities:

- conducting inspections of laser manufactures to determine if laser products are in compliance with radiation emissions requirements

- performing import entry reviews to assure that imported electronic products presented for entry into the U.S. meet performance standards

- testing diagnostic x-ray equipment to control unnecessary radiation associated with its use.

Mammography Quality Standards Act (MQSA)

The MQSA program addresses the public health need for safe and reliable mammography. MQSA supports the Secretary's health priority of transform health through early detection strategies that increase healthy life potential.

The MQSA program develops national quality standards and regulations for mammography facilities and the accrediting bodies. The program focuses on facility inspections to ensure that only facilities that remain in compliance with established quality standards are performing mammograms. MQSA activities also center on providing accessible MQSA data to consumers.

Under the MQSA area, the Devices and Radiological Health Program plans to conduct the following activities in FY 2008 to advance the MQSA program:

- certify new mammography facilities and recertify one third of the more than 8,900 existing facilities

- analyze and act on inspection results to ensure compliance with quality standards

- enhance the MPRIS by migrating subsystems to the Web framework and improving accessibility to MQSA-related data for inspectors and FDA

- amend the MQSA regulations to better address Congressionally mandated studies (Institute of Medicine and General Accountability Office) and the changes that occurred in the mammography area since previous regulations were published.

Digital Mammography to Screen for Breast Cancer

CDRH provided the laboratory science to support the recent NIH-sponsored $30 million clinical trial on digital mammography. Initially, the laboratory demonstrated that digital mammography performance should be equivalent or better than older technology; then it developed the methodology for clinical trials to conclusively demonstrate this. Trial findings showed that digital accuracy was significantly higher than film among those women with dense breasts, under 50, or pre- and peri-menopausal. This knowledge allows women to select the mammography technology most likely to detect cancer in its small and most curable stage.

Field Devices and Radiological Health Program

ORA support the MQSA program in two ways:

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

- conducting foreign inspections to ensure the safety of mammography facilities in military facilities located in foreign countries.

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

Risk Communications and Outreach

The Risk Communications and Outreach area helps the public get science-based, accurate information about medical devices and radiological products that they need to improve their health. The Risk Communications and Outreach area support the health priority of the Secretary to transform health by proactively communicating with providers and patients.

The Risk Communications and Outreach area focuses on improving risk communications activities by maximizing its ability to communicate information in a clear and timely way to practitioners, industry, patients and consumers through an array of products and methods. These products include Public Health Notifications, Advice to Patients Documents, consumer-friendly recall summaries, and print and electronic communications. Risk Communications and Outreach methods include websites and website subscription services that target audiences of health care professionals, consumers, and regulated industry.

Under the Risk Communications and Outreach area, the Devices and Radiological Health program plans to conduct six activities during FY 2008:

- expand the Home Health Care Initiative to devices specifically labeled for home use by establishing a repository for brochures, references, and links to government and private agencies working on home care issues

- improve communication of risks with FDA's stakeholders and consumers by redesigning the CDRH Internet and CenterNet to best meet the needs of customers, healthcare professionals, manufacturers, and FDA staff

- conduct usability and audience analysis research on how to best provide the public with web-based safety information, which offers the most efficient and cost-effective method to publish up-to-date information

- improve postmarket communication to mitigate risk from medical device problems through Public Health Notifications, Advice to Patients Documents, consumer-friendly recall summaries, topic specific websites, and other print and electronic communications

- support the vision of healthy life potential by maintaining FDA's Diabetes Information and Heart Health Online websites and developing improved content and delivery of risk/benefit information on implantable cardioverter defibrillators for consumers and physicians

- work with other Federal government partners, such as CDC, CMS and Federal Trade Commission, to ensure that consumers have access, including via the CDRH website, to information about the nature of genetic tests available online and over-the-counter.

Research, Development and Evaluation Activities

Research, development, and evaluation activities support the Devices and Radiological Health's regulatory activities. Research findings improve the predictability, efficiency and effectiveness of premarket reviews and the development of new device technologies. The research also provides for a knowledgeable assessment of postmarket risks and performance issues. Importantly, CDRH's laboratory research supplies the understanding of future technology, such as nanotechnology, that CDRH must be prepared for. Research activities support CDRH's four program areas. The list below summarizes CDRH's applied research activities by primary program area:

Premarket – These activities advance the premarket and GMP inspection programs, and the scientific understanding, standards and guidance development, and experimental capabilities CDRH needs to assess new technologies and speed reviews:

- Biological research promotes improvement of medical devices in the areas of biological risk assessment, biosensors/nanotechnology, genomic and genetic technologies, infection control and sterility, tissue-device interactions, toxicity/biocompatibility, and radiation bioeffects.

- Chemistry and materials science research develops data related to the safety and performance of implanted and externally used medical devices and their impact on public health.

- Imaging and applied mathematics research provides scientific expertise in support of radiation-emitting products, medical imaging systems, and devices using computer-assisted diagnostics.

- Physics research supports many specialties including optical physics and metrology, sensors, fiber optics, electromagnetics (compatibility and interference), electrophysics, electrical stimulation, electrophysiology, and radiofrequency/microwave.

- Solid and fluid dynamics research supports the Center's enforcement activities in ultrasound and blood flow, and develops measurement methods, instrument

calibration capabilities, and analytical procedures to characterize and evaluate devices, device materials, and products.

Patient Safety – These activities significantly advance CDRH's understanding of the root causes of medical device failures and user errors, enabling CDRH to knowledgeably assess performance issues and risk throughout the product life cycle:

- Electrical and software engineering activity supports the application of electronics, software engineering, and systems engineering to medical devices.

- Human factors studies support design practices that minimize or eliminate use errors. Research supports guidance, better error reporting, use-related health hazard evaluations, and industry outreach.

MQSA
Ionizing Radiation Measurements Laboratory provides metrology support to the Center's safety mission. The ISO 17025-compliant laboratory provides traceability in support of both MQSA and P.L 90-602 (Radiation Control for Health and Safety Act).

Risk Communication – Outreach
Usability and audience analysis research determines how to best provide web-based patient safety information to the public.

Selected FY 2006 Accomplishments

The Devices and Radiological Health Program is highlighting selected accomplishments in the order of the area provided in the Justification of Base narrative.

Premarket Accomplishments

MDUFMA – Medical Device User Fee and Modernization Act of 2002, P.L. 107-250 – CDRH continued implementing MDUFMA in FY 2006 by consulting with its stakeholders, developing guidance documents, and building the new review processes and process improvements required to meet MDUFMA's progressively challenging performance goals. In support of MDUFMA, CDRH made key accomplishments during FY 2006:

- *Steady progress in meeting performance goals* - CDRH met or is on track to meet, most of the MDUFMA performance goals for FY 2003 through FY 2006 receipt cohorts and maintained review performance in areas not covered by official performance goals.

- *Guidance documents* - CDRH issued six MDUFMA guidance documents during FY 2006. The guidances addressed reprocessed single-use medical devices, combination products, small business qualifications, Section 301 compliance (mark of manufacturer on single-use devices), premarket approval application (PMA) inspections, and the Bioresearch Monitoring (BIMO) Program. (See http://www.fda.gov/cdrh for specific guidances.)

- *Stakeholder communications* - CDRH held stakeholder meetings to discuss and receive input on MDUFMA implementation and qualitative performance goals for FY 2007.

Innovations in Patient Care – CDRH approved and cleared the following devices that exemplify advanced device technologies that have a valuable impact on patient care:

Olympic Cool-Cap. – This is a first-of-a-kind device to treat babies born with a potentially fatal brain injury caused by moderate to severely low levels of oxygen. Olympic Medical Corp's system is designed to prevent or reduce brain damage by keeping the head cool while the body is maintained at a slightly below-normal temperature. Prior to this approval, there was no effective treatment for the 5,000 to 9,000 U.S. babies affected annually. Up to 20 percent of patients died, and 25 percent suffered permanent disability because of neurological deficits.

AbioCor® Implantable Replacement Heart – AbioMed, Inc.'s electrically powered pump replaces the ventricles (lower part) of the heart to circulate blood for patients with severe heart failure who are not candidates for transplant. An implanted *controller* and rechargeable implanted battery allow the patient to be free from all external connections.

LeadCare II - FDA expanded the availability of the first simple and portable lead test system to make testing and treating children and adults for lead poisoning much easier and faster. ESA Biosciences, Inc.'s LeadCare II Blood Lead Test System, is now available to more than 115,000 certified point-of-care locations nationwide, including healthcare clinics, mobile health units and schools. The system produces test results in as little as three minutes. The rapid result means a second, confirmatory test can be obtained quickly, reducing the chance for lost-to-follow up—especially for children, at risk for high levels.

Avian Influenza A /H5 (Asian Lineage) Virus Real-Time RT- The PCR Primer and Probe Set, manufactured by CDC, provides preliminary results on suspected H5 influenza samples within four hours. Previous testing technology required at least two to three days to render results. If the presence of the H5 strain is identified, then further testing is conducted to identify the specific H5 subtype, such as H5N1.

Xpert GeneXpert™ Dx Test For Group B Streptococcus, - This device, from Cepheid, Inc., is a qualitative in vitro diagnostic test designed to detect Group B Streptococcus (GBS) DNA from vaginal and rectal swab specimens. The test rapidly identifies a GBS infection before and during labor and delivery. If passed from mother to child during birth, GBS can cause sepsis, pneumonia, meningitis, neurological damage and, in a small percentage of newborns, even death.

DexCom™ STS® Continuous Glucose monitoring System – This device from DexCom, Inc., is a short-term sensor that wirelessly transmits glucose readings to a hand-held receiver to provide real-time continuous measurements. The system, used by adult diabetic patients at home and in health care facilities, detects trends and tracks patterns. The device aids in detecting episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize high and low blood sugar levels.

Leveraging External Expertise – Industry use of the Third Party Review Program for 510(k) submissions increased 18 percent in FY 2006 over FY 2005. CDRH received 287 510(k) submissions reviewed by Accredited Persons and made final decisions on 268, up from 250 in FY 2005. This review option may be faster than reviews performed exclusively by FDA staff and gives manufacturers access to specialized expertise by third parties.

Premarket Critical Path - CDRH's Critical Path initiative addresses the recent slowdown in innovative medical therapies and supports product development that is more predictable, efficient, and less costly:

- established a collaboration with the Juvenile Diabetes Research Foundation to promote the development of an artificial pancreas

- established collaborative interactions with other government entities and external stakeholders to advance the development of new biomarkers for diseases

- developed guidances to foster the development of new technologies in the area of genetics, pharmacogenomics, and drug/device co-development; and to reduce the development cost of in vitro diagnostic devices that require clinical studies that use leftover human specimens.

Electronic submission, review, and tracking systems development – CDRH improved its electronic submission, review and tracking systems in the following areas:

- CDRH expanded "Turbo 510(k)", its voluntary electronic submissions program for the in vitro diagnostic device industry after a very successful pilot.

- CDRH improved the new version of the submission software, called CeSub (CDRH electronic submission) eSubmitter, enabling use with a variety of submission types, improving the review process and reducing review times.

Staff Training – CDRH provided expanded continuing education opportunities through its Staff College to create and maintain an excellent work force by presenting a total of 126 different courses in Science (36 percent), Professional Development (29 percent), Law & Policy (17 percent), and Leadership (18 percent).

Premarket Approval and Good Manufacturing Practice Inspections - CDRH's inspection-related accomplishments promote innovative device development:

- The Third Party Inspection Program, authorized by MDUFMA, accredits third parties (APs) to conduct inspections of eligible manufacturers of Class II and Class III medical devices. The Program helps FDA focus its resources on higher-risk inspections and gives medical device firms operating in global markets an opportunity to more efficiently schedule multiple inspections.

- During FY 2006, the FDA review board accredited one additional AP for a total of 16, and APs conducted two independent inspections.

- CDRH signed with Health Canada (HC) a protocol for the Pilot Multi-Purpose Audit Program (PMAP) that will start in 2007 and will evaluate the effectiveness of performing a single third party inspection or audit of medical device manufacturers' quality systems which would meet the needs and regulatory requirements of both countries.

Joint Center and Field Devices and Radiological Health Program Accomplishments

Bioresearch Monitoring (BIMO) Audits and Enforcement Activities – BIMO requirements include good laboratory practices (GLP) and regulations related to human subject protection and data integrity. CDRH collaborates with the ORA to conduct data audits to determine if devices should be approved. There were four major Audit-related accomplishments in FY 2006:

- conducted 108 data audit inspections, addressed data integrity concerns, and issued compliance actions related to 55 active PMAs or PMA supplements

- received and evaluated 154 allegations of research misconduct that could compromise the safety of human research subjects or undermine the quality of research data. Evaluation of the allegations resulted in the issuance of 82 inspections or investigations

- assured integrity, with three firms withdrawing pending 510(k)s due to unreliable substantial equivalence data or information, and one pediatric device sponsor withdrawing an Investigational Device Exemption (IDE) for lack of proper oversight and subject safety issues

- issued 24 BIMO Warning Letters and 13 BIMO Untitled Letters to bring non-compliant firms and researchers into compliance with the regulations, and entered into a consent agreement to restrict a device clinical investigator from participating in device research.

Field Devices and Radiological Health Program Accomplishments

Field Devices and Radiological Health Program exceeded FY 2006 inspection goals by approximately 20 percent for domestic, foreign and BIMO inspections:

- inspected 1,299 registered domestic Class II and Class III medical device manufacturers

- inspected 209 Foreign Class II and Class III medical device manufacturer

- conducted 319 BIMO inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations.

Science: Standards and Guidance – Standards and guidance improve the quality of submissions, which can reduce review time and speed life-saving medical devices to consumers. While there were many accomplishments in FY 2006 in the area of science standards and guidance, four were especially noteworthy:

- cleared 20 Regulations, reviewed and coordinated the Agency's actions with regard to 16 Citizens Petitions, and cleared 46 Guidances, which is a 59 percent increase from FY 2005

- issued draft guidance for the use of innovative Bayesian statistics in medical device clinical trials to provide a flexible alternative framework to classical clinical trial design for sponsors of innovative new devices

- issued draft guidance for industry and FDA staff on pharmacogenetic tests and genetic tests for heritable markers which is intended to shorten development and review timelines, facilitate rapid transfer of new technology from the research bench to the clinical diagnostic laboratory, and encourage informed use of pharmacogenomic and genetic diagnostic devices.

- recognized 43 new voluntary consensus standards, withdrew 80 standards and replaced them with new versions, incorporated 66 changes to the existing recognized standards, and withdrew 10 standards; these new standards address newly developing technologies to improve the quality of future submissions

- contributed to the administration and technical maintenance of the Global Medical Device Nomenclature standard for naming, defining, and coding medical device groups, an effort that should identify product world wide and reduce confusion concerning the identification of problem products.

Patient Safety Accomplishments

Surveillance – These accomplishments exemplify CDRH's efforts to advance patient safety by improving problem detection capabilities in marketed device products:

- CDRH's Medical Product Surveillance Network—MedSun—exceeded by 15 percent its 2006 goal of obtaining a 71 percent participation rate from the 350 participating user facilities.

- MedSun expanded to include interactive networks that address particular health issues, including LabNet (laboratory devices), KidNet (pediatric devices), TissueNet (human cells and tissues), and HeartNet (electrophysiology devices, such as pacemakers), and used surveys of network facilities to determine the effectiveness of recalls and the training needed to reduce adverse events.

- CDRH published a notice of proposed rulemaking and announced an FY 2007 public meeting on an initiative to require medical devices to have unique device identifiers, or UDI, similar to those for drugs which FDA anticipates reduced medical errors and improved adverse event reporting and recalls.

- CDRH received over 150,000 adverse event reports concerning medical devices. FDA's review of these reports led to follow-up actions, including Public Health Notifications, to protect the public health.

- CDRH finalized the post-approval inspection program, assuring that post approval study commitments are properly conducted and reported. Also, FDA issued the first Warning Letter, citing post-marketing surveillance violations under the Federal Food Drug and Cosmetic Action, Section 522.

Defibrillator External Collaboration – FDA formed the Defibrillator Working Group to coordinate premarket and postmarket FDA activities for defibrillators, both implantable (ICD) and external (AED) devices. Working Group accomplishments included:

- addressed specific processes related to the regulation of ICDs and AEDs

- collaborated with the Heart Rhythm Society and AdvaMed to assure a full perspective on the issues

- piloted a model for effective communication across the full device life cycle.

Compliance and Enforcement

In FY 2006, FDA made improvements in the timeliness of risk management actions. These were aimed at preventing harm to the public from regulated products:

- FDA continued grass root and collaborative efforts with eBay and FTC to ensure that unapproved products were removed and not offered for sale on the eBay website.

- FDA used the cross-center, risk-based inspection work plan prioritization process to identify public health concerns. The Center issued special emphasis inspection assignments in three areas: IV Administration Test Kits, Internal Cardioverter Defibrillators (ICD), and Automatic External Defibrillators (AED)

- FDA Issued Preliminary Public Health Notifications and updates related to the Class I recall of the Ventak Prizm® 2DR and Contak Renewal® and Renewal® 2 implantable cardioverter defibrillator (ICD) devices. These notifications provided the clinical community with information about deaths and serious injuries that can be used by patients and physicians in making treatment decisions.

- During FY 2006, the number of Class I (most serious), II, and III recall actions totaled 651 and involved 1,550 products, which is total is an increase from 571 in FY 2005 and includes 143 in vitro diagnostic device recalls.

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	Actions	Products
Class I	21	76
Class II	500	1252
Class III	130	222
Total	651	1550

- FDA improved product quality and the safety of medical devices by taking at least 55 legal actions in FY 2006.

- In order to address systemic problems, CDRH issued a Corporate Warning Letter to Boston Scientific.

- Other compliance actions included 1 Civil Money Penalty, 5 Seizures, 4 Injunctions, and 1 Prosecution.

- FDA collaborated with the CDC and the Federal Trade Commission to issue a Public Message alerting consumers about the facts surrounding the direct-to-consumers marketing of genetic tests. The message warned consumers that these tests may lack scientific validity and provide questionable results.

Patient Safety Science – CDRH research accomplishments provide for a knowledgeable assessment of postmarket risks and performance issues.

- Software Forensics Laboratory—CDRH developed a science-based capability, unique in the federal regulatory environment, and used in several high-profile compliance cases.

- Device Safety in Magnetic Resonance Imaging Environments – CDRH developed a new standard method for marking implanted medical devices and other items safe in the magnetic resonance environment, and replaces the old system whose confusing terminology may have allowed patient injuries.

- Infection Control: Reuse of Single Use Devices and Cleaning Validation –CDRH developed cleaning and disinfection-sterilization methods to insure that no microbial contamination remains on a reusable device, thus reducing misdiagnosis due to tissue contamination and toxicity from residual detergents and sterilization agents.

- Computer-Assisted Diagnostic Systems – CDRH developed new models and methods for assessing computer-assisted diagnostic (CAD) systems in the review of digital mammography systems, breast cancer screening, lung cancer screening, and CT colonoscopy.

- Effect of RFID on Drug Potency – CDRH initiated, at the request of FDA, import new research to determine whether exposure to electromagnetic fields from radiofrequency identification (RFID) systems has any effect on the potency of pharmaceuticals.

Radiological Health – CDRH's accomplishments play a critical role in securing the homeland and protecting the public from excessive radiation exposure and radiological terrorism:

- CDRH enhanced the eSubmitter and eReviewer applications, and increased the number of electronic submission templates for the Radiological Health Program.

- CDRH consulted with Federal partners on counterterrorism and radiation safety support to address radiation safety of security screening and defense products; to revise radiation safety training preparing for its security staff working with security screening products; and to evaluate the safety of air-based and ground-based laser anti-missile defense systems to protect commercial air traffic.

<u>Field Devices and Radiological Health Accomplishments</u>
Two major cases involving the safety of marketed medical devices were completed that demonstrates FDA's resolve to ensure the safety and effectiveness of medical devices and to hold those in authority who violate FDA laws accountable for their actions:

- Baxter Healthcare Corporation signed a Consent Decree of Condemnation and Permanent Injunction with FDA based on FDA's seizure of 4,000 infusion pumps because of the Baxter Healthcare Corporation's failure to meet GMP requirements.

- The Abtox Medical Company's former president and vice-president were sentenced to 10 and 6 years' imprisonment, respectively, and were ordered to pay $17 million to hospitals for selling surgical sterilizing devices that led to eye injuries in 18 patients.

MQSA Accomplishments

CDRH advanced mammography quality standards in FY 2006, especially in three areas:

Mammography Facility Information – CDRH placed MQSA's new web-based Mammography Program Reporting and Information System into production. MPRISweb provides low cost operation and maintenance, and efficient accessibility for the inspectors and FDA who use MPRIS.

Inspections – CDRH conducted annual inspections at over of 8,600 mammography facilities and ensured that 98% of those facilities met inspection standards with less than 2% having Level I (serious) problems. FDA completed over 104,000 facility inspections nationwide since the MQSA Program's inception.

Regulatory Actions – CDRH conducted mammography facility regulatory actions as needed as part of the MQSA compliance program, results include:

- FDA issued one Patient and Physician Notification (PPN).
- FDA declared a facility's MQSA certificate 'no longer in effect'.
- CDRH performed 80 of these additional mammography reviews since the MQSA program began.

Risk Communications and Outreach Accomplishments

The Risk Communications and Outreach program helps the public get science-based accurate information about medical devices and radiological products that they need to improve their health.

Health Professionals and Industry Outreach - Of the many FY 2006 accomplishments in the area of Health Professionals and Industry Outreach, six deserve particular note:

- using compliance data evaluations and analysis to develop educational material for industry workshops and consumer meetings, participated in 27 educational programs at numerous national and regional meetings throughout the country, and authored two articles on designing quality into device clinical trials for a major medical device journal
- continued its medical device safety educational outreach effort to the clinical community through biomedical audio conferences, the Device Safety Exchange (DS-X) website, newsletters, the issuance of Safety-Tips, and workshops
- produced FDA Patient Safety News (PSN), an award-winning monthly television news show and web site for communicating FDA safety messages on drugs,

devices and biologics to physicians, nurses, pharmacists, risk managers and educators

- redesigned the Medical Device Safety website to consolidate and organize all medical device safety information in one site for health care professionals

- collaborated with the National Institute of Occupational Safety and Health (NIOSH) to develop a Public Health Notification alerting users to the dangers of fires at the interface of oxygen regulators and cylinder valves

- produced 18 teleconferences for FDA and other government agencies on a variety of topics, as well as 8 hours of mission-related programming every day to CDRH staff via the CDRH fiber-optic network, including 37 educational and training programs received live via satellite and delivered simultaneously.

Risk Communications Outreach

FDA and AdvaMed, a major advocacy association for medical technology companies, co-sponsored a communications workshop entitled, "Risk Communication on Medical Devices: Sharing Perspectives." During the workshop's presentations and panel discussions, participants gained insights from senior FDA staff and industry representatives on how the government and the medical device industry communicate expected and unexpected risks to practitioners, patients and the general public. Participants also gained insights from practicing physicians, risk managers and the news media about how this information is received and transmitted to patients, hospital staff members, and the public.

Consumers Outreach - CDRH continued to reach out to consumers, keeping them informed and up-to-date. Among the accomplishments of FY 2006, five were especially notable:

- disseminated important information to consumers through fourteen Recall Notices, Seizure Notices, and Press Releases

- published the inaugural issue of Maturity Health Matters online newsletter, focused specifically on products that help people live longer, more productive lives;

- published the online newsletter, FDA & You for a third year; issued three times a year, FDA & You targets secondary school students and Health Educators and provides information on FDA topics of interest to teenagers

- testified on the regulation of IVDs before the Special Committee on Aging to address the findings of the General Accountability Office's (GAO) investigation of certain direct-to-consumer IVD tests

- responded to over 8,400 consumer inquiries (included telephone calls, letters, faxes, and emails).

Devices and Radiological Health
Program Activity Data [1]

PROGRAM WORKLOAD AND OUTPUTS	FY 2006 Actuals[3]	FY 2007 Continuing Resolution	FY 2007 President's Budget	FY 2008 President's Budget[4]
Expedited Original PMA MDUFMA Decision Goal (% of decisions within # of FDA days)	**80% in 300 days**	**45% in 300 days**	**90% in 300 days**	**90% in 300 days**
Expedited PMA Received Expedited PMA Approved	2 0	9 4	9 9	9 9
Expedited PMA – Performance	70% in 300 days	45% in 300 days	90% in 300 days	90% in 300 days
PMA original, panel track supplement and premarket report submissions MDUFMA Decision Goals (% of decisions within # of FDA days)	**80% in 320 days**	**55% in 320 days**	**90% in 320 days**	**90% in 320 days**
PMAs Received (PDP and PMA)	51	50	50	50
PMAs Approved (PDP and expedited)	19	29	43	43
Original PMA performance	95% in 320 days	55% in 320 days	90% in 320 days	90% in 320 days
PMA Supplement Panel Tracks[2] Received	23	12	12	12
PMA Supplement Panel Tracks[2] Approved	5	5	12	12
Panel track PMA Supple-Ment[2/] performance	95% in 320 days	40% in 320 days	90% in 320 days	90% in 320 days
Humanitarian Device Exemptions Received	5	6	6	6
Humanitarian Device Exemptions Approved	2	4	5	5
Average HDE FDA Review Time (FDA days approval)	86	182	140	140
180- day PMA Supplements MDUFMA Decision Goal (% of decisions within # of FDA days)	**80% in 180 days**	**60% in 180 days**	**90% in 180 days**	**90% in 180 days**
PMA Supplements Received	131	150	150	150
PMA Supplements Approved	94	90	135	135

PROGRAM WORKLOAD AND OUTPUTS	FY 2006 Actual [3]	FY 2007 CR	FY 2007 PB	FY 2008 PB
180-day PMA supplement performance	95% in 180 days	60% in 180 days	90% in 180 days	90% in 180 days
510(k) MDUFMA Decision Goal (% of decisions within # of FDA days)	**75% in 90 days**	**45% in 90 days**	**80% in 90 days**	**80% in 90 days**
510(k)s Received (Trad., Special, Abbrev., 3rd party)	3,913	4,000	4,000	4,000
510(k)s Completed (All Decisions)	2,416	1,920	3,700	3,700
510(k) performance	90% in 90 days	45% in 90 days	80% in 90 days	80% in 90 days
Investigational Device Exemptions Received	262	230	230	230
Investigational Device Exemptions Decisions	243	220	220	220
% Acted on Within 30 Days	99%	100%	100%	100%
IDE Supplements Received	4520	4,300	4,300	4,300
IDE Supplements (Approved/Total Decisions)	4464	4,300	4,300	4,300
% Acted on Within 30 Days	100%	100%	100%	100%
Total Standards Recognized for Application Review	745	745	795	795

[1/]Data represents CDRH contributions to the categories listed above and are current as of 1/05/2007. Performance totals for FY 2006 are subject to change as the cohort matures. FDA is committed to meeting the performance goals cited in the MDUFMA legislation. User fees, coupled with the increased appropriated resources for medical device review received in FY 2005, will enable FDA to meet the aggressive premarket goals agreed upon by FDA and its stakeholders.

[2/] A "Panel-Tracked" PMA supplement is a supplement to an already approved PMA and is usually for a change in the indications for use statement. The change in indications statement is usually for a new use of the already approved device (not change to the device), for use in a different disease condition, for use in a different anatomical site, or for use in a different patient population. A summary of safety and effectiveness information is prepared and made available to the public.

[3/] Includes filing decisions, review determinations, and approval decisions. Estimated performance when receipt cohorts are complete based on experience under MDUFMA through FY 2006.

[4/] Assumes we maintain FY 2007 staffing levels

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 the latest performance period, (FY 2006), the Medical Device Program has either met or expects to meet all of its Center and Field Performance Goals. For more information about these goals and results, please see the Performance Detail section.

The Food and Drug Administration Modernization Act of 1997 gives FDA the mandate to replace universal user facility reporting with the Medical Product Surveillance Network (MedSun) that is composed of user facilities that constitute a representative profile of user reports. FDA surpassed by 200 percent our long-term goal of expanding patient surveillance by 50 percent by 2008, through increasing the number of patients covered from 17 million to 53 million by 2004. This will allow for more rapid identification and analysis of adverse events. MedSun is a critical component towards achieving this long-term goal.