DEVICES AND RADIOLOGICAL HEALTH

The FY 2009 program level budget request for the FDA Devices and Radiological Health Program is $290,921,000.

The following table shows a three-year funding history for the Devices and Radiological Health Program.

FDA Program Resources Table

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate	FY 2009 +/- FY 2008
Program Level	**$267,543,000**	**$283,777,000**	**$290,921,000**	**$7,144,000**
Center	*$198,727,000*	*$210,203,000*	*$215,089,000*	*$4,886,000*
FTE	1,124	1,125	1,115	-10
Field	*$68,816,000*	*$73,574,000*	*$75,832,000*	*$2,258,000*
FTE	420	421	421	0
Program Level FTE	**1,544**	**1,546**	**1,536**	**-10**
Budget Authority	**$230,682,000**	**$237,992,000**	**$241,881,000**	**$3,889,000**
Center	*$172,257,000*	*$177,839,000*	*$180,175,000*	*$2,336,000*
Field	*$58,425,000*	*$60,153,000*	*$61,706,000*	*$1,553,000*
Med. Prod. Safety & Devel. (non-add)	*$230,682,000*	*$237,992,000*	*$242,921,000*	*$4,929,000*
Admin. Savings & Man. Efficiencies (non-add)			*-$1,040,000*	*-$1,040,000*
Budget Authority FTE	**1,358**	**1,359**	**1,349**	**-10**
User Fees	**$36,861,000**	**$45,785,000**	**$49,040,000**	**$3,255,000**
Center MDUFMA	*$22,329,000*	*$26,647,000*	*$28,911,000*	*$2,264,000*
Field MDUFMA	*$934,000*	*$967,000*	*$1,049,000*	*$82,000*
Center MQSA	*$4,141,000*	*$5,717,000*	*$6,003,000*	*$286,000*
Field MQSA	*$9,457,000*	*$12,454,000*	*$13,077,000*	*$623,000*
User Fee FTE	**186**	**187**	**187**	**0**
Mandatory User Fees:			**$2,768,000**	**$2,768,000**
Field Reinspection (non-add)			*$2,768,000*	*$2,768,000*
Mandatory User Fees FTE			**22**	**22**

The FDA Devices and Radiological Health Program operate under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Radiation Control for Health & Safety Act (21 U.S.C. 360hh-360ss)
Medical Device Amendments of 1976*
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Safe Medical Devices Act of 1990*
Mammography Quality Standards Act of 1992 (42 U.S.C. 263b)

Medical Device Amendments of 1992*
Food and Drug Administration Modernization Act*
Medical Device User Fee and Modernization Act of 2002*
Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3)
Medical Device User Fee Stabilization Act of 2005*
Food and Drug Administration Amendments Act of 2007*

Allocation Method: Direct Federal/intramural

Program Description and Accomplishments

The FDA Devices and Radiological Health Program is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products. The scope of the medical device and radiological health industry is diverse. Products range in complexity from eye glasses to heart pacemakers and from microwave ovens to medical ultrasound and x-ray machines.

The Devices and Radiological Health Program began in 1976 with the passage of the Device Amendments to the Food, Drug, and Cosmetic Act. The program operates with appropriations and user fees. The user fee program known as the Medical Device User Fee and Modernization Act (MDUFMA) was enacted in FY 2002 and reauthorized in FY 2007 as the Medical Device User Fee Amendments (MDUFA). An additional user fee program is authorized by the Mammography Quality Standards Act (MQSA), enacted in 1992. The Centers for Medicare and Medicaid Services (CMS) user fee program, authorized by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), also provides support for the Devices Program.

The Center for Devices and Radiological Health (CDRH) conducts program activities, with assistance from the Office of Regulatory Affairs (ORA). CDRH employs a Total Product Life Cycle (TPLC) approach for regulatory oversight of medical devices and radiological health products. TPLC spans from product concept to its obsolescence. DHHS's *Mission Matters: the FY 2007 Management Report to Employees* on the President's Management Agenda showcased four CDRH achievements in improved management and performance. The achievements addressed the goals of Strategic Management of Human Capital, Expanded Electronic Government, and Budget and Performance Integration.

The ORA provides FDA leadership on enforcement, import, inspection, and laboratory policies. Through its Field offices nationwide, ORA supports the CDRH TPLC strategy by conducting premarket and postmarket inspections and laboratory analyses, reviewing imported medical device and radiological health products, evaluating and taking enforcement actions, and performing data audits. ORA's Field Device Program is funded by appropriated and user fee dollars. These resources allow ORA to perform inspections and fund inspections through state contracts.

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

The Devices and Radiological Health Program executes its regulatory responsibilities in three areas: Premarket Device Safety and Effectiveness, Postmarket Device Safety and Surveillance, and MQSA.

Premarket Device Safety and Effectiveness — Center Activities

Under Premarket Device Safety and Effectiveness, the Devices and Radiological Health Program is responsible for bringing to market, innovative, high quality, and safe medical products for all consumers. Premarket Device Safety and Effectiveness supports the President's Pandemic Influenza and HIV/AIDS initiatives and the Department of Health and Human Services (HHS) priority to transform health through improved regulatory processes that safely make technology available in less time.

CDRH conducts Premarket Device Safety and Effectiveness activities with assistance from ORA Field offices. During premarket review, the program evaluates the safe manufacturing and data integrity components of premarket applications for medical devices. With support from MDUFMA user fees, the premarket review program improved the timeliness and predictability of FDA review of new devices for consumers. Under MDUFMA, FDA agreed to pursue a comprehensive set of device review performance goals. FDA's overall performance to date for the FY 2003 through FY 2007 receipt cohorts[1] indicate FDA is meeting or exceeding most MDUFMA performance goals.

CDRH reviews of Premarket Device Safety and Effectiveness improved patient care and access to health care technology and innovation. During FY 2007, CDRH approved and cleared many advanced, first-of-kind device technologies. Examples include a quick test for malaria to allow rapid, point-of-care testing; a blood vessel shunt used to save the arms and legs of critically injured soldiers and accident victims; a molecular-based test to detect metastatic breast cancer at the time of primary surgery that spares women the wait of extensive microscopic testing and follow-up surgery; and a genetic test to determine the increased likelihood of recurrent breast cancer. The genetic test allows tailoring of treatment and follow-up and is a landmark in development of new biomarkers for personalized medicine.

CDRH conducts regulatory research to support Premarket Device Safety and Effectiveness. Regulatory research allows CDRH to improve the predictability, efficiency, effectiveness, and speed of premarket reviews to ensure that consumers have access to safe medical devices. Research findings improve the development of new device technologies, such as nanoparticle-based breast and colon cancer diagnostic devices that improve the power to detect cancer cells in blood samples. CDRH laboratory research ensures greater understanding of future technology that CDRH must be prepared to regulate.

[1] MDUFMA and MDUFA calculate performance statistics for the fiscal year in which premarket submissions are received (the "receipt cohort"), regardless of when FDA acts on the submissions. As a result, the statistics shown for a particular fiscal year may change with time as FDA continues to complete work on the submissions within a fiscal year cohort. Until all submissions in a cohort receive a final decision, only a preliminary performance assessment can be provided for that cohort.

Concurrently with regulatory research efforts, CDRH is working collaboratively with product developers and the scientific community on FDA's critical path initiative to identify and resolve critical product development problems and improve FDA's regulation of new device technology. Modernizing the medical product development process makes product development more predictable and less costly. One important result of the critical path initiative is CDRH's approval in FY 2007 of the first genetic test for sensitivity to the widely used blood-thinning drug, warfarin. The nanotechnology-based, cost-effective test aids in optimizing the drug dose for patients to prevent dangerous bleeding complications.

To improve the quality of industry premarket submissions and health outcomes for consumers, the Device and Radiological Health Program's conducts outreach to industry, consumers, and others. CDRH conducts industry workshops and participates in audio conferences and educational programs at national meetings. In FY 2007, CDRH participated in 45 educational programs at national and regional meetings. Clinical community outreach also includes websites and newsletters.

Premarket Device Safety and Effectiveness — Field Activities

ORA's Field force supports CDRH in the initial phases of the total product life cycle by conducting preapproval inspections of foreign and domestic establishments. ORA also conducts bioresearch monitoring of clinical research studies, laboratory method validations 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.

The device bioresearch monitoring program assures the quality and integrity of research data and protects human research subjects through the prompt investigations of allegations of research misconduct. In FY 2007 ORA conducted 323 inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations. Through its consistently meeting its performance goal targets in this area since FY 2002, 85 percent of FDA inspections of clinical research with medical devices reveal only minor problems with research conduct. To help improve the remaining device research that may be problematic, CDRH increased outreach activities to regulated industries through meetings and by publishing articles in professional journals to improve awareness of proper clinical research practices.

Postmarket Device Safety and Surveillance — Center Activities

The Devices and Radiological Health Program is responsible for ensuring that medical devices and radiological products currently on the market remain safe and effective for consumers by monitoring medical products, manufacturers, and adverse events. Postmarket Device Safety and Surveillance support the HHS priority to transform health by proactively communicating with providers and patients, and sustaining the HHS goal of protecting the public from infectious, occupational, environmental, and terrorist threats and preventing the spread of infectious disease.

CDRH established the Medical Products Surveillance Network (MedSun) to actively collect information about device use problems from a sample of clinical sites nationwide. The MedSun program has been successful in monitoring postmarket device use. It exceeded its performance targets for each year from the program's inception through FY 2005 by increasing the number of

participating hospitals to a total of 350 facilities. It also exceeded its performance targets for FY 2006 and FY 2007 to increase the number of actively participating facilities that submit reports to FDA. MedSun's sub-networks within participating facilities provide FDA with increased knowledge of device problems occurring in targeted high-risk products and populations. During FY 2007, CDRH established new and expanded existing networks, including 26 LabNet, 22 KidNet, and 14 HeartNet sites. During the same time period, the percentage of MedSun sites stating that MedSun has improved patient safety in their hospital increased from 83 percent to 88 percent.

CDRH also employs a Medical Device Reporting system for adverse event reports. In FY 2007, the program received more than 749,000 reports concerning 1,368 medical devices. FDA review of these reports led to follow-up actions, including Public Health Notifications to communicate critical health information such as the importance of fully vaccinating cochlear implant patients to prevent life-threatening bacterial meningitis. To improve its postmarket signal detection, data analysis, and risk management action, in FY 2007 CDRH implemented electronic Medical Device Reporting (eMDR) for voluntary electronic submissions by industry and drafted a proposed rule to make electronic reporting mandatory.

CDRH provides training for industry on ways to reduce manufacturing errors and omissions. The CDRH risk communication and outreach program to health professionals and consumers provides science-based, accurate information about medical devices and radiological products to improve consumer health. CDRH publishes six audience-specific e-Newsletters, and produces FDA Patient Safety News, a 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. In August 2007 CDRH developed a consumer website on Tanning and its effects as part of the Center's ongoing commitment to provide up-to-date information and warnings about indoor and outdoor tanning.

CDRH's research activities also provide information to assess device postmarket risks and performance issues. In FY 2007, CDRH responded to the need for safe implanted medical devices for millions of patients undergoing magnetic resonance imaging (MRI) each year. CDRH developed guidance and four American Society for Testing and Materials standard test methods for marking devices for safety in an MRI environment. Additionally, CDRH is working with the international community to more appropriately address radiofrequency heating of active devices during MRI.

CDRH maintains its pandemic and emergency preparedness through enhanced functionality and reliability of emergency operations. In FY 2007 CDRH developed in-house database capabilities to rapidly support just-in-time access to reliable data on emergency medical device inventories and production capacities. Completion of this database bolsters FDA's capability to identify and secure the most critical medical products during emergencies.

<u>Postmarket Device Safety and Surveillance — Field Activities</u>
ORA's Field force supports the postmarket safety by performing 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 work includes

conducting inspections of reprocessors of single-use devices and manufacturers of radiological health products. ORA's radiological health activities include inspecting radiation emitting products such as lasers, sunlamps, and x-ray equipment to ensure they comply with performance standards. To complement the regular Field force, the Office of Criminal Investigations investigates instances of criminal activity in FDA regulated industries.

During FY 2007, the ORA Field force conducted more than 1,278 Good Manufacturing Practice inspections to evaluate the manufacturing processes of medical device manufacturers. The importance of postmarket surveillance is highlighted by a recent increase in Class I (most serious), II, and III recall actions. The number of recall actions for FY 2007 was 661, up from 651 in FY 2006, and these recalls involved 1,273 different products. This surveillance achievement is also shown in the resolution of significant enforcement actions involving the safety of marketed medical devices. In April 2007, FDA took action to seize adulterated medical devices manufactured by Shelhigh Inc. for violations of FDA regulations which seriously compromised the sterility of their tissue-based devices used in surgical settings, including open heart surgery in adults, children and infants, and to repair soft tissue during neurosurgery. Additionally, in June 2007, pursuant to a court-ordered injunction, Shelhigh agreed to stop distributing its implantable medical devices until the company brought its production processes in line with FDA standards.

GE OEC Medical Systems, Inc., its parent company, and two top executives signed a consent decree of permanent injunction related to the firm's X-ray surgical imaging systems. The accuracy of these imaging devices is critical for the successful outcomes of important diagnostic, surgical, and interventional procedures. The companies agreed to take necessary measures to ensure that these X-ray surgical imaging systems comply with FDA Quality System regulations as well as for reporting adverse events, malfunctions, device corrections and removals. Successful completion of the cases demonstrates FDA's resolve to hold those in authority who violate FDA laws accountable for their actions.

In accomplishing its mission, the postmarket area faces many of the same challenges as the premarket area, including insuring safety with limited resources as the volume of medical devices and radiological products increase. The postmarket area faces the additional challenge of ensuring safety as products of foreign origin continue to increase. ORA continue to implement improved risk-based targeting of inspection and import resources to address these new challenges.

Mammography Quality Standards Act (MQSA) — Center Activities

The Center for Devices and Radiological Health also administers the MQSA that addresses the public health need for safe and reliable mammography to detect breast cancer in its earliest and most curable stages. The MQSA supports the HHS priority to transform health through early detection strategies that increase healthy life potential.

Under the MQSA, FDA collects user fees to fully cover the cost of inspecting non-government facilities. Congress authorizes yearly fee adjustments to ensure FDA recovers the full cost of facility inspections.

CDRH's MQSA program develops national quality standards and regulations for mammography facilities and the mammography 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 provide accessible MQSA data to consumers. Through state contracts and ORA's Field force, CDRH certifies new mammography facilities and annually recertifies one-third of approximately 8,800 facilities. CDRH analyzes and acts on inspection results to ensure compliance with quality standards. CDRH met or exceeded its mammography performance goal in the past five years (from FY 2003 to FY 2007). This goal ensures that 97 percent of domestic facilities meet inspection standards, with less than 3 percent of the non-standard facilities with Level I (serious) problems. In FY 2007 only 1.8 percent of mammography facilities had Level 1 violations.

Mammography Quality Standards Act — Field Activities

The Field Device Program supports the MQSA program by managing approximately 8,000 state-conducted inspections annually and by conducting foreign inspections to ensure the safety of mammography conducted in military facilities located in foreign countries.

Five Year Funding Table with FTE Totals

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
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 Actuals	$267,543,000	$230,682,000	36,861,000	1,544
2008 Enacted	$283,777,000	$237,992,000	$45,785,000	1,546
2009 President's Budget	$290,921,000	$241,881,000	$49,040,000	1,536

Budget Request

The FY 2009 President's Budget requests $290,921,000 in program level funding for the Devices and Radiological Health Program, including the support of 1,536 FTE. CDRH's portion of the request is $215,089,000, supporting 1,115 FTE. The Field portion of the request is $75,832,000, supporting 421 FTE. The total Program request represents an increase of **$**7,144,000 (or 2.6 percent) over the FY 2008 enacted level in budget authority and user fee amounts. The overall increase provides additional user fees and budget authority to cover a targeted increase in medical product safety and development for Field Devices, and a cost of living pay increase for the entire Devices and Radiological Health Program. The budget request also reflects a decrease in the budget authority as part of the administrative savings and management efficiencies initiative that redirects savings gained by recent FDA modernization efforts to higher level priorities.

<u>Modernizing Medical Product Safety and Development Initiative</u>
The FY 2009 budget requests $242,921,000 for Medical Product Safety and Development. This reflects a $4,929,000 over the FY 2008 enacted level. Of this amount, $4,252,000 is for the pay raise and $677,000 is Device portion of the Initiative that will supporting the funding of the Field Devices Program's activities associated in the Administration's Import Safety Action Plan. The CDRH portion of the pay raise is $3,017,000 and the Field portion of the pay raise is $1,235,000. The cost of living pay raise will contribute to maintaining the Results Act performance targets and program activity estimates at the FY 2008 levels.

The Modernizing Medical Product Safety and Development Initiative will move FDA closer to realizing the promise of personalized medicine while improving the safety of medical devices and radiological health products. Base funding for medical product safety and development encompasses all of the Devices and Radiological Health program activities for ensuring the safety and effectiveness of medical devices and the safety of radiological products. These activities include research, outreach-coordination, inspection, premarket review, and postmarket surveillance. The increase to the Field Devices Program will support specific recommendations

made in the President's Import Safety Action Plan including the development of strategic information-sharing agreements to address import issues. Specifically, ORA through the Field Devices Program will improve its risk-based targeting of imports through information technology enhancements, such as integration with the Standard Establishment Data Service administered by the Department of Homeland Security's Customs and Border Protection Service. Overall, the increase will also allow Field Devices Program to maintain new investigative FTE hired during FY 2007.

These program increases plus the base funding allows the Medical Devices and Radiological Health Program to meet the statutory "trigger" for the Devices and Radiological Health Program appropriations, enabling FDA to collect the MDUFMA user fees that supplement the appropriated portion of the medical device review program. The Program will be able to retain more than 150 user fee-supported FTE to continue its efforts to improve the quality and timeliness of the device review process and promote the delivery of new technologies to the public. As a result of these supplemental resources, the Devices and Radiological Health Program will maintain its Results Act performance goals and targets at the same level as those in FY 2008. The Devices and Radiological Health Program's Activity Data show a similar level of performance for CDRH workload targets as with the FY 2008 level and targeted increases of 2 to 19 percent for Field Devices inspections.

Administrative Savings and Management Efficiencies Reduction

The request for $241,881,000 in total budget authority for the Devices and Radiological Health Program also reflects a reduction of - $1,040,000 in FY 2009. CDRH's portion of the savings reduction is - $681,000 and the Field Devices portion is - $359,000. CDRH's efficiencies flow from conversion of two large paper-based systems to electronic systems. The new systems—electronic Medical Device Reporting (eMDR), and electronic registration and listing (FURLS)—will reduce high contractor costs previously associated with processing and data entry for the paper systems.

The reduction of $ -359,000 in the Field Devices Program reflects reallocated resources from lower priority activities to fund higher FY 2009 priority items. ORA's Field programs (Foods, Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health) collective savings is $ -1,067,000. ORA will achieve administrative savings through the redirection of program staff that had handled both program and administrative duties. With the hiring and training of new support staff, ORA will improve its efficiency in providing administrative support services.

User Fees Inflationary Increases

The FY 2009 request also includes a total of $49,040,000 in user fees for the Medical Devices program, an increase of $3,255,000 over FY 2008 funding levels. The Medical Devices program receives user fee resources for medical device review (MDUFA) and for mammography facilities inspections and certification (MQSA). FDA is requesting an increase in MDUFA user fee collection authority that will provide an additional $2,264,000 for CDRH's medical device review program and $82,000 for Field activities to improve the review process. This request also includes an increase in MQSA user fee collection authority that will provide an additional $286,000 to CDRH and $623,000 to the Field Devices Program to cover the cost of inflationary increases to the program.

Beginning with FY 2008, MDUFA includes the addition of an establishment fee to ensure a more stable revenue base, a change in the CPI factor to October to better correspond to our budgeting process, and the addition of an inflation factor to reflect the five year average of FDA's salary and benefit costs. The requested level of $29,960,000 in total MDUFA user fee collection authority supplements the Devices and Radiological Health Program's device review activities. The request allows the Devices and Radiological Health Program to maintain its Results Act performance goals and targets at the same level as those in FY 2008.

The requested level of $19,080,000 in total MQSA user fee authority funds annual MQSA inspections of non-government facilities, training, equipment calibration to ensure that mammography facilities remain in compliance with established quality standards, and accessibility to MQSA-related data through the Mammography Program Reporting and Information System. These activities ensure a performance result that is key to protecting the public health. This funding level will maintain the mammography performance goal, established several years ago.

At the requested funding level, the program's target is to inspect an estimated 8,800 domestic mammography facilities, with at least 97% expected to meet inspection standards, and with less than 3% with Level I (serious) problems.

Center for Medical Devices and Radiological Health Outputs / Outcomes Table

#	Key Outcomes/Outputs	FY 2004 Actual	FY 2005 Actual	FY 2006 Target	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Target
Long-Term Objective 1: Increase the number of safe and effective new products available to patients, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism.									
1.1	Percentage of Expedited PMAs reviewed and decided upon within 180 and 280 days. (253202) (Outcome)	NA	83% of 6	80% in 300 days	1/09	90% in 300 days	1/10	50% in 180 days and 90% in 280 days[2]	50% in 180 days and 90% in 280 days
1.2	Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. (253203) (Outcome)	NA	NA	80% in 320 days	95% of 51	90% in 320 days	9/08	60% in 180 days and 90% in 295 days[3]	60% in 180 days and 90% in 295 days
2	Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. (253204) (Outcome)	NA	95% of 101	80%	95% of 131	90%	1/09	85% in 180 days and 95% in 210 days[4]	85% in 180 days and 95% in 210 days
3	Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. (253205) (Outcome)	NA	92% of 3,376	75% in 90 days	93% of 3,549	80% in 90 days	9/08	90% in 90 days and 98% in 150 days[5]	90% in 90 days and 98% in 150 days
4	Number of Medical Device Bioresearch Monitoring (BIMO) inspections (253201) (output)	354	335	295	336	295	323	300[6]	300
5	Reduction in FDA's total approval time for the fastest 50 percent of expedited PMAs approved, using the submission cohort for FYs 2005-2007. The baseline for this goal is the three year average of total FDA approval time for the fastest 50 percent approved for the applications filed during FYs 1999-2001. (253206) (Outcome)	492 days	2/08	NA	2/09	290 days	2/10	NA	NA
Long-Term Objective 2: Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.									
6	Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (254101) (Outcome)	97% of 9,100	97% of 9,100	97%	97%	97%	97%	97%	97%

[2] FY 2008 target changed to match the new format under the MDUFMA, as amended agreement.
[3] FY 2008 target changed to match the new format under the MDUFMA, as amended agreement.
[4] FY 2008 target changed to match the new format under the MDUFMA, as amended agreement.
[5] FY 2008 target changed to match the new format under the MDUFMA, as amended agreement.
[6] FY 2008 target increased to 300 to better align with recent historical actual data.

7	Number of domestic and foreign Class II and Class III device inspections. (254201) (output)	1,709	1495	1,234	1,506	1,195	1,468	1,270	1,300
Long-Term Objective 3: Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.									
8	Participation rate of facilities in the MedSun Network. (252201)	NA	NA	NA	NA	90%	90%	95%	95%

MDUFMA , and MDUFMA, as amended review goals (Goals 1, 2, and 3) are based on FDA review time only, and do not include time that elapses when the sponsor is responding to questions or issues raised by FDA. This means that FDA cannot determine exactly when all the applications in a review cohort will be completed. The actual results reported for this goal are as of the times noted, and as the final applications in the cohort are resolved, small changes to previously reported results may occur.

1. Percentage of Expedited PMAs reviewed and decided upon within 180 and 280 days and Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. (253202 and 253203)

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. PMAs involve potentially high-risk devices with the most chance of significantly improving the treatment of patients. The steps taken in MDUFMA, and MDUFMA, as amended that will reduce approval times for PMA applications are expected to reduce approval times for all filed applications, while recognizing that some applications may not ultimately meet FDA's standards for safety and effectiveness and that performance measures based on all applications will take more time to observe.

The MDUFMA, as amended expedited review performance goals will apply only when the number of submissions granted expedited review equals 10 or more in any one fiscal year. If in any one fiscal year, the number of submissions granted expedited review is less than 10, then it is acceptable to combine the submissions for the following year(s) in order to form a cohort of 10 submissions upon which FDA will be held to the performance goals.

Performance: CDRH has exceeded performance for this goal in FY 2005 and is currently on pace to exceed agreed upon performance in FYs 2006 and FY 2007. The current baseline for FDA decision time for standard PMAs is 320 days.

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

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. A decision will result in one of the following designations for each application: approval, approvable, approvable pending GMP inspection, not approvable, denial. PMAs involve potentially high-risk devices that have the highest likelihood of significantly improving the treatment of patients. Supplemental applications are generally submitted for changes in already approved products such as

technology changes or the addition of a new indication. It is essential that FDA complete the review process for these products quickly and thoroughly.

Performance: CDRH has exceeded performance for this goal in FYs 2005 and FY 2006 and is currently on pace to exceed agreed upon performance for this goal in FY 2007.

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

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. A decision will result in one of the following designations for each application: substantially equivalent or not substantially equivalent. This goal for review and decision on 510(k)s within 90 days addresses the statutory requirement to review a 510(k) within 90 days**.**

Performance: CDRH has exceeded performance for this goal in FYs 2005 and FY 2006 and is currently on pace to exceed agreed upon performance for this goal in FY 2007.

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

Context: FDA's mission includes assuring the protection of human research subjects, the quality and integrity of research, and the advancement of new medical technologies. A FDA-regulated research community that consists of Clinical Investigators, Sponsors and Monitors, and Institutional Review Boards has a shared responsibility to oversee this research in a truthful and ethical manner. For FY 2009, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach. The FY 2008 and FY 2009 targets have been increased slightly to 300 inspections to better reflect recent actuals. However, they are slightly lower than the FY 2007 actuals because the number of applications under review that may require BIMO inspections can only be estimated.

Performance: In FY 2007, FDA exceeded this goal of 295 by conducting 323 medical device related Bioresearch Monitoring inspections.

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

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

- About 25 percent of PMAs are for breakthrough technologies; and

- Over 25 percent of PMAs are from first-time submitters.

The area of expedited devices is particularly important because they are the most complex, raise new medical and scientific issues, and FDA often works with first time or small device sponsors. These devices are for uses that have not been approved yet, and could have great clinical impact. Our expedited program is the area where we have the most improvements to make.

Standard PMAs are also for the most complex (Class III) devices, and also have significant clinical impact. For example, a drug-eluting cardiac stent could, if used properly, reduce repeat angioplasty of bypass surgery by 15-30 percent.

Performance: The FDA approval time for the fastest 50 percent of Expedited PMAs approved for the FY 2002-2004 cohort is 320 days compared to 360 days for the baseline FY 1999-2001 submission cohort. *This is a reduction of 40 days versus the FY 2005-2007 target reduction of 30 days.* CDRH initially calculated the baseline data for this goal, time to approval for the fastest fifty percent of expedited PMAs, for the time period of FYs 1999 – 2001.

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

Context: This goal will ensure that mammography facilities remain in compliance with established quality standards and improve the quality of mammography in the United States. Under the Mammography Quality Standards Act (MQSA), which was reauthorized in 2004, annual MQSA inspections are performed by trained inspectors with FDA, with State agencies under contract to FDA, and with States that are certifying agencies. State inspectors conduct approximately 90 percent of inspections. Inspectors perform science-based inspections to determine the radiation dose, to assess phantom image quality, and to empirically evaluate the quality of the facility's film processing. MQSA requires FDA to collect fees from facilities to cover the cost of their annual facility inspections. FDA also employs an extensive outreach program to inform mammography facilities and the public about MQSA requirements. These include: an Internet website, collaboration with NIH to provide a list of MQSA-certified facilities, and a toll-free facility hot line. In FY 2009, FDA will ensure at least 97% of an estimated 8,800 domestic mammography facilities meet inspection standards.

Performance: FDA met this goal in FY 2007 by ensuring that 97 percent of an estimated 8,800 mammography facilities met inspection standards with less than 3 percent level 1 (serious) problems. Inspection data continue to show facilities' compliance with the national standards for the quality of mammography images. Improving the quality of images should lead to more accurate interpretation by physicians and, therefore, to improved early detection of breast cancer. FDA works cooperatively with the States to achieve this goal.

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

Context: The inventory of Class II and Class III foreign and domestic firms is approximately 10,900 firms. The ultimate goal of preventing unsafe and ineffective devices from reaching the consumer will be advanced by detecting and intercepting unsafe and ineffective product at the manufacturing level. By utilizing risk-based inspection strategies and focusing on surveillance throughout a products life-cycle FDA will be better able to protect the public health by ensuring both the quality and effectiveness of medical devices available in the U.S. marketplace. The FY 2008 and FY 2009 targets have been increased over the FY 2007 target to better reflect recent actuals. However, they are lower than the FY 2007 actuals because the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that cannot be estimated in advance.

Performance: FDA exceeded the FY 2007 medical device performance goal of 1,195 by inspecting 1,468 foreign and domestic high-risk Class II and Class III medical device manufacturers.

8. Participation rate of facilities in the MedSun Network. (252201)

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

Performance: In FY 2007, FDA expanded actively participating sites in MedSun Network to 90% and maintained a cohort of 350 facilities.

CDRH Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
Expedited PMA Received	2	9	9
Expedited PMA Approved	2	8	8
Expedited PMA – Performance	90%	90%	90%
PMAs Received (PDP and PMA)	33	50	50
PMAs Approved (PDP and expedited)	28	45	45
Original PMA performance	86%	90%	90%
PMA Supplement Panel Tracks Received	3	12	12
PMA Supplement Panel Track Approved	3	12	12
Panel track PMA Supplement performance	90%	90%	90%
Humanitarian Device Exemptions Received	6	6	6
Humanitarian Device Exemptions Approved	3	5	5
Average HDE FDA Review Time (FDA days approval)	230	140	140
PMA Supplements Received	132	150	150
PMA Supplements Approved	120	135	135
510(k)s Received (Trad., Special, Abbrev., 3rd party)	3,531	3,600	3,600
510(k)s Completed (All Decisions)[7]	2,206	3,500	3,500
510(k) performance	80%	80%	80%
Investigational Device Exemptions Received	225	230	230
Investigational Device Exemptions Decisions	223	220	220
% Acted on Within 30 Days	99%	100%	100%
IDE Supplements Received	4,376	4,300	4,300
IDE Supplements (Approved/Total Decisions)	4,288	4,300	4,300
% Acted on Within 30 Days	99%	100%	100%
Total Standards Recognized for Application Review	795	795	795

[7] MDUFMA 510(k) Performance for FY 2007 is incomplete as the cohort remains open.

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
DOMESTIC INSPECTIONS			
Bioresearch Monitoring Program Inspections	315	307	314
Pre-Approval Inspections	62	100	100
Post-Market Audit Inspections	59	66	66
GMP Inspections (Levels I, II, III and Accredited Persons)	1278	1504	1569
Total Above Domestic Inspections: Non MQSA	1714	1977	2049
Inspections (MQSA) FDA Domestic (non-VHA)	329	279	279
Inspections (MQSA) FDA Domestic (VHA)	30	30	33
Inspections (MQSA) by State Contract	7668	7920	7800
Inspections (MQSA) by State non-Contract	619	620	700
Total Above Domestic Inspections: MQSA	8646	8849	8812
State Contract Devices Funding	$0	$200,600	$200,600
State Contract Mammography Funding	$7,627,000	$10,730,401	$10,812,739
Total State Funding	$9,802,644	$10,931,001	$11,013,339
Domestic Radiological Health Inspections	86	154	154
Domestic Field Exams/Tests	847	934	934
Domestic Laboratory Samples Analyzed	140	102	102
PROGRAM OUTPUTS-			
IMPORT/FOREIGN INSPECTIONS			
Foreign Bioresearch Monitoring Inspections	8	10	10
Foreign Pre-Approval Inspections	27	33	33
Foreign Post-Market Audit Inspections	30	26	31
Foreign GMP Inspections	271	235	270
Foreign MQSA Inspections	19	17	20
Foreign Radiological Health Inspections	10	28	28
Total Above Foreign FDA Inspections	365	349	392

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