

Food and Drug Administration
FY 2012 Congressional Budget Request
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DEVICES AND RADIOLOGICAL HEALTH

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table

(Dollars in thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	\$366,900	\$369,971	\$366,900	\$394,946	\$28,046
Center	\$272,771	\$279,151	\$272,771	\$292,384	\$19,613
FTE	1,294	1,332	1,332	1,373	79
Field	\$94,129	\$90,820	\$94,129	\$102,562	\$8,433
FTE	461	469	469	511	50
Program Level FTE	1,755	1,801	1,801	1,884	129
Budget Authority	\$313,935	\$313,452	\$313,935	\$329,102	\$15,167
Center	\$233,932	\$233,584	\$233,932	\$247,726	\$13,794
Field	\$80,003	\$79,868	\$80,003	\$81,376	\$1,373
<i>Pay Increase (non add)</i>				\$753	\$753
<i>Protecting Patients (non-add)</i>				\$5,829	\$5,829
<i>Advancing Medical Countermeasures (non-add)</i>				\$8,428	\$8,428
<i>FDA Regulatory Science and Facilities (non-add)</i>				\$4,009	\$4,009
<i>Administrative and Contract Savings (non-add)</i>				-\$3,852	-\$3,852
Budget Authority FTE	1,494	1,525	1,525	1,553	59
Center	1,048	1,077	1,077	1,103	55
Field	446	448	448	450	4
User Fees	\$52,965	\$56,519	\$52,965	\$65,844	\$12,879
Center MDUFMA	\$32,836	\$41,283	\$32,836	\$38,655	\$5,819
FTE	220	232	232	244	24
Field MDUFMA	\$1,049	\$1,442	\$1,049	\$1,235	\$186
FTE	7	13	13	14	7
Center MQSA	\$6,003	\$4,284	\$6,003	\$6,003	\$0
FTE	26	23	23	26	0
Field MQSA	\$13,077	\$9,510	\$13,077	\$13,077	\$0
FTE	8	8	8	8	0
Field Medical Product Reinspection				\$3,424	\$3,424
FTE				24	24
International Courier User Fee				3,450	3,450
FTE				15	15
User Fees FTE	261	276	276	331	70

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

- Federal Food, Drug, and Cosmetic Act¹ (21 U.S.C. 321-399)
- Radiation Control for Health & Safety Act (21 U.S.C. 360hh-360ss)
- Medical Device Amendments of 1976¹
- Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
- Safe Medical Devices Act of 1990¹
- Mammography Quality Standards Act of 1992 (42 U.S.C. 263b)
- Medical Device Amendments of 1992¹
- Food and Drug Administration Modernization Act¹

Medical Device User Fee and Modernization Act of 2002¹
Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3)
Medical Device User Fee Stabilization Act of 2005¹
Food and Drug Administration Amendments Act of 2007 (FDAAA)¹
Patient Protection and Affordable Care Act, 2010

Allocation Method: Direct Federal/intramural

Program Description and Accomplishments

The Devices and Radiological Health Program (the Devices Program) began in 1976 with the passage of the Medical Device Amendments to the Food, Drug, and Cosmetic Act. In keeping with its mission, the Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health by:

- assuring the safety, effectiveness, and quality of medical devices
- assuring the safety of radiation-emitting products
- fostering innovation
- providing the public with accurate, science-based information about the products it oversees throughout the total product life cycle.

CDRH regulates medical devices that range in complexity from eye glasses and medical gloves to sophisticated implantable devices and diagnostic tests that utilize the latest in molecular biology. In addition to medical devices, the Devices Program regulates radiation-emitting electronic products — medical and non-medical — such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

A combination of appropriations and user fee programs funds the regulatory process to assure product safety and effectiveness. The Program's user fees are authorized under the Mammography Quality Standards Act (MQSA), enacted in 1992, and the Medical Device User Fee and Modernization Act (MDUFMA), enacted in FY 2002, and reauthorized in FY 2007 as the Medical Device User Fee Act (MDUFA). 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 Office of Regulatory Affairs (ORA) Field offices nationwide support Devices Program activities by assessing industry compliance with applicable regulations. ORA does the following:

- conducts premarket and postmarket inspections of domestic and foreign manufacturers

¹ Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified in scattered sections of 21 U.S.C.

- investigates medical device reports (MDR) and consumer complaints
- monitors and evaluates compliance with recalls of violative products
- performs laboratory analysis to support inspections
- reviews and evaluates imports of medical devices and radiological products to ensure products meet FDA quality standards
- conducts enforcement activities.

The Devices Program executes its regulatory responsibilities in five areas:

- Premarket Device Review
- Postmarket Safety
- Compliance, Enforcement and Radiation Safety
- Device Innovation and Regulatory Science
- Mammography Quality Standards Act (MQSA).

Premarket Device Review – Center Activities

Base Amount: \$131,595,148 (BA: \$108,933,498 / UF: \$22,661,650)

Public Health Focus

The Premarket Device Review program focuses on increased access to innovative, safe and effective products and technologies to improve public health. CDRH evaluates the safety and effectiveness of new devices and approves or clears thousands of products annually, many of which are critical to the delivery of health care in the United States. These innovative medical devices advance patient clinical care, treatment, and rehabilitation as well as provide tools for health maintenance and disease prevention.

Through CDRH's Premarket Device Review activities, FDA is able to achieve important HHS and Administration priorities:

- improving health care quality and patient safety
- transforming health care
- promoting high-value effective care.

Public Health Outcome

In the past fiscal year, CDRH's Premarket Device Review program received over 8,000 premarket submissions resulting in innovative devices and radiological products that improve public health. Recent examples of devices approvals include:

- the first heart valve approved for sale in the United States that can be implanted through a catheter in a leg vein and guided to the heart without open-heart surgery
- an artificial cervical disc that allows motion at the operated spinal level, unlike a fusion procedure

- an implantable miniature telescope used to magnify objects to improve vision in patients with end-stage, age-related macular degeneration
- the first rapid blood test for antibodies to the hepatitis C virus (HCV)
- the first test for the 2009 H1N1 Influenza Virus.

In recent years, CDRH experienced significant growth in the number and the complexity of medical device applications due to an acceleration of scientific discovery. These trends offer not only the promise of exciting, new diagnostic tools and devices to improve patient care, but pose significant public health challenges. Americans rely on an assurance from FDA that medical devices marketed for public use will be safe and effective. This assurance must be backed by rigorous and independent scientific analyses and matched with resources for CDRH scientists and engineers to keep pace with rapid growth in application volume and complexity.

CDRH is responding to the challenge by working smarter. CDRH fosters medical device innovation and enhancing device safety by improving the transparency, consistency and quality of its premarket review process. CDRH leadership directed staff to assess and provide recommendations for improvements to the premarket notification (510(k)) program. The 510(k) process is used to review most medical devices prior to marketing in the United States. The recommendations are designed to provide industry with better guidance and predictability on FDA policies, leverage outside scientific expertise, and support informed decision making. CDRH reviewed and analyzed public comments from a variety of stakeholders and announced in January 2011 plans to implement the recommendations that have widespread support. These recommendations include creating new guidance and improving staff training.

The Premarket Device Review program provides rapid response to national emergencies. CDRH worked with industry and government partners to rapidly review *in vitro* diagnostic tests for detection of the H1N1 flu virus and created a submission template and guidance to help manufacturers develop and validate diagnostic tests. CDRH approved 18 Emergency Use Authorizations for H1N1 tests. In preparation for the 2010-2011 influenza season, FDA cleared three additional tests for market release, one developed by the Centers for Disease Control and Prevention (CDC) for public health laboratory surveillance and two by commercial companies for the diagnosis of influenza infection.

CDRH also supports activities to meet the unique needs of children and youth. These activities include funding the Pediatric Device Consortia Program, which promotes development of devices for pediatric populations, and premarket device review guidance to improve the quality of marketing submissions. To date, four Pediatric Device Consortia have been established, collectively facilitating the early development of over eighty potential medical devices for children.

CDRH strives to prevent unnecessary harm to human research subjects and to assure the integrity of data collected through the Bioresearch Monitoring (BIMO) Program. In the past fiscal year, CDRH issued over 300 clinical and non-clinical inspections at medical device research sites and conducted significant outreach to Institutional Review Boards (IRB) to ensure clinical study data integrity and adherence to required human patient safety protocols. Investigations of for-profit IRBs identified more than 10 research studies that were incorrectly identified in the exempt or non-significant risk categories. Once CDRH determined that these studies involved significant risk, FDA terminated the studies to protect the research subjects. The research cannot resume until CDRH determines that the sponsors corrected the studies' problems.

Promoting Efficiency

Through its Premarket Device Review program, CDRH has been a leader in encouraging the use of innovative clinical trial designs and analyses to support regulatory approval of medical devices. CDRH has developed several improved methods that can result in smaller clinical trials and can leverage data from previous trials to support more streamlined and efficient device development.

For example, Bayesian clinical trial designs can use data from previous studies so that fewer new clinical trial subjects are required to achieve the same level of evidence to support device approvals. Adaptive clinical trials can be used to increase or decrease the number of clinical trial subjects to achieve the optimum number necessary to demonstrate a clinical trial result.

In some situations, "propensity score" methods can be used to appropriately compare outcomes between patients in a current study or establish a control group of patients from a previous study. The CDRH web page also provides data on the type and design of pivotal clinical trials necessary to support high quality premarket approval applications for devices. FDA can review high quality applications more efficiently and in less time. FDA's efforts allow industry to deploy their financial resources more efficiently and improve their competitiveness in the global market place.

CDRH also works with industry and other stakeholders to develop best practices, policies, and guidance that improve efficiency by making premarket applications more consistent and complete. These efforts result in fewer cycles of FDA review and faster results for industry. For example, CDRH provides technical assistance to manufacturers who need support for new product development.

To train researchers on FDA expectations for medical device research, CDRH implemented Academic Centers for Excellence, an educational outreach program located in public and private universities. In FY 2009 and FY 2010 CDRH conducted town-hall meetings to solicit input from industry and other stakeholders about the medical device program and released a total of 69

guidance documents to communicate up-to-date information regarding FDA's current thinking on medical devices and radiological products. The medical device industry uses the information in these guidances to innovate and stimulate economic opportunity within the medical device sector.

Premarket Device Review – Field Activities

Base Amount: \$8,448,743 (BA: \$7,451,743 / UF \$997,000)-

Public Health Focus

The ORA Field force supports the Devices Program in the initial phases of the total product life cycle by conducting preapproval inspections of domestic and foreign establishments to determine if the facility is able to manufacture products according to the specifications stated in their application. ORA also conducts bioresearch monitoring inspections of clinical research studies—including the clinical investigators, sponsors and monitors, and Institutional Review Boards—to safeguard patients and to validate laboratory methods for device premarket application decisions.

Public Health Outcome

ORA works to ensure that firms are able to manufacture products according to the specifications outlined in an application and that concerns or issues raised during review of the application are accounted for. ORA efforts help to assure that medical products, once manufactured, become a viable supply of safe commodities for U.S. consumers.

Promoting Efficiency

Through the Field activities of the Premarket Device Review subprogram, ORA collaborates with CDRH on the most efficient way to conduct bioresearch monitoring inspections. This collaboration provides ORA investigators with information on the use of the device being studied, previous clinical trials, and concerns raised during review of preapproval inspections. These Field activities allow FDA to efficiently focus its available inspection resources on significant issues related to data integrity and human subject protection. Through this subprogram, FDA helps ensure that sponsors collect data that can support a device application rather than conducting clinical trials that yield data that sponsors cannot rely upon to support device approval.

Performance Measures

The Premarket Device Review program is supported by the MDUFA user fee program. Under MDUFMA and MDUFA, FDA agreed to pursue a comprehensive set of device review performance goals.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
<u>253203</u> : Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. <i>(Outcome)</i>	FY 2009: ¹ 86% of 28 in 180 days and 93% of 28 in 295 days (Target Exceeded)	60% in 180 days and 90% in 295 days	50% in 180 days and 60% in 295 days	-10% in 180 days and -30% in 295 days
<u>253204</u> : Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. <i>(Outcome)</i>	FY 2009: 93% of 153 in 180 days and 97% of 153 in 210 days (Target Exceeded)	85% in 180 days and 95% in 210 days	75% in 180 days and 85% in 210 days	-10% in 180 days and -10% in 210 days
<u>253205</u> : Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. <i>(Outcome)</i>	FY 2009: 91% of 3,324 in 90 days and 98% of 3,324 in 150 days (Target Exceeded)	90% in 90 days and 98% in 150 days	75% in 90 days and 80% in 150 days	-15% in 90 days and -18% in 150 days
<u>253201</u> : Number of Medical Device Bioresearch Monitoring (BIMO) inspections. <i>(Output)</i>	FY 2010: 392 (Target Exceeded)	300	300	Maintain

^{1/} FY 2009 cohort is not fully complete for PMAs and 510(k)s.

Postmarket Safety – Center Activities

Base Amount: \$51,900,834 (BA: \$46,194,962 / UF: \$5,705,872)-

Public Health Focus

CDRH postmarket safety activities focus on monitoring medical devices performance, including adverse events, to ensure that devices and radiological products remain safe and effective for patients and consumers. CDRH analyzes safety signals with potential clinical impact and when an issue surfaces, it responds to quickly identify and limit potential problems with medical devices and radiological products. Additionally, CDRH's postmarket safety activities are focused on improving techniques for detecting signals of potential medical device problems and applying risk-based decision making in evaluating the need for intervention.

Through CDRH's Postmarket Safety activities, FDA is able to achieve important HHS and Administration priorities including:

- improving health care quality and patient safety
- promoting high-value effective care.

Public Health Outcome

CDRH's recent postmarket safety outcomes include advances in the Medical Product Safety Network (MedSun). MedSun is a national network of 350 hospitals designed to prevent unnecessary device-related injuries and deaths by partnering with FDA to report device-related adverse events and near misses. The number of recalls resulting directly from MedSun reporting more than doubled from 11 to 24 over the 2008 – 2009 calendar years (CY) while manufacturers' actions increased from 66 to 78. For CY 2010, MedSun-based recalls and manufacturers' actions have surpassed the previous two years with a total of 32 recalls and 101 manufacturers' actions resulting from MedSun reporting.

The Sentinel Initiative is a national electronic system that will transform FDA's ability to monitor medical products. CDRH's lead role in the initiative enables emerging medical device safety concerns to be identified sooner and appropriate responses to be provided earlier. In FY 2010, Sentinel activities included exploring capabilities for active surveillance of registries through a pilot study that addressed a statewide cardiovascular registry and a network of institutions implanting cardiovascular devices. Under the SafeRx project for safety evaluation, CDRH examined the use of Medicare data to understand device performance, initially focusing on surgical mesh and gastric banding devices.

Rapid communication to the public, clinical community and manufacturers about device problems posing a significant public health risk is essential for consumer safety. As part of its risk communication strategy, CDRH launched CDRH Learn, an online educational training tool to improve training of U.S. and international limited resources by empowering more foreign and domestic safety regulators. The medical device and radiological health regulation modules are available in multiple languages and were viewed over 180,000 times since the launch of the tool. CDRH also streamlined its risk communication processes to provide quicker communication to the public, clinical community, and manufacturers about device problems.

CDRH continues to prepare world class data systems for state-of-the-art product surveillance. Its Unique Device Identifier (UDI) initiative will enable CDRH to enhance and improve its postmarket surveillance and recall processes. UDI implementation will improve CDRH's and industry's understanding of medical devices throughout the entire product life cycle and provide valuable data to compare the performance of marketed devices. Following extensive public outreach, CDRH developed a proposed rule to require medical device manufacturers to place a UDI on a label, or on the device itself, and supply critical identifying information in a UDI database. CDRH will publish the rule in the first half of CY 2011. The Initiative will provide significant cost savings to industry including supply chain efficiency savings and reduced costs to distribute products globally by using a common UDI framework.

Other important postmarket safety activities include developing scientifically sound post approval studies to assure the safety of newly marketed devices. CDRH's staff of highly trained epidemiologists works with industry and other stakeholders to design, track, oversee, and review results for studies when they are mandated as a condition of premarket approvals.

CDRH is committed to advancing the delivery of safe and effective devices for use in the pediatric population and expanding its efforts to better understand the performance of pediatric medical devices in the postmarket surveillance period. CDRH is engaging in a number of initiatives to address pediatric device needs. For example, CDRH is collaborating with healthcare systems and hospitals to track adverse events related to pediatric patients, providing outreach to industry, and developing sophisticated systems to enhance the tracking and flagging of pediatric data.

Promoting Efficiency

CDRH strategically designs Postmarket Safety activities to operate most efficiently. For example, a program known as CDRH Learn provides on-line training on key regulatory issues. This web tool reduces the need to send CDRH experts to foreign and domestic locations.

The CDRH unique device identifier (UDI) initiative allows FDA, device manufacturers and the medical community to identify devices by batch numbers and locations, allowing FDA and industry to conduct more targeted recalls. This improvement has obvious benefits for FDA and patients but also benefits industry by preventing blanket recalls that may reduce consumer confidence in products from multiple manufacturers.

CDRH is also finalizing a rule to require electronic medical device reporting, known as eMDR. eMDR is expected to provide significant cost savings to industry and FDA related to data entry, storage, handling and reporting. This electronic submission system will replace a far less efficient manual reporting system. eMDR is designed to meet the needs of large volume reporters -- who can submit reports in batch -- and small volume reporters who can submit reports one-at-a-time. Manufacturers have electronically submitted more than 150,000 reports using the eMDR system, at great savings to FDA and manufacturers.

Likewise, CDRH increased industry's awareness of existing clinical trial data helping eliminate costly trials and duplicative data gathering and allowing manufactures to conduct more efficient post-approval studies. For example, the Interagency Registry for Mechanically Assisted Circulatory Support is a national registry that captures short- and longer-term clinical-trial quality data on patients receiving heart pump assistance devices. Device manufacturers can avoid the significant cost of developing and conducting new clinical studies by using this

registry to support applications for “de novo” classification. De novo classification is available for devices that have never been marketed in the United States but whose safety profile and technology are now reasonably well understood.

Postmarket Safety – Field Activities

Base Amount: \$819,164 (BA: \$767,164 / UF: \$52,000)

Public Health Focus

The ORA Field force supports the Devices Program in postmarket safety by conducting follow-up investigations of MDRs. These inspections of reporting medical facilities or manufacturers identify significant problems by analyzing recurring problems and performing trend analysis. ORA also collects data on complaints, significant problems and potential hazards so corrective actions can be initiated. ORA conducts bioresearch monitoring inspections of post-approval studies that monitor the postmarket safety of products already available to the public for use.

Public Health Outcome

ORA conducts inspections of both domestic and foreign medical device firms where issues or concerns have been identified. In January 2010, FDA announced a Class I recall of Huber needles and Huber Infusion sets following the receipt of MDRs and inspections of numerous Exelint International Co. manufacturing facilities. Huber needles are used to access ports implanted under the skin of chronically ill patients for repeated access to veins for withdrawing blood and infusing medication, blood products, and solutions. These needles should be designed to penetrate the port without cutting and dislodging any silicone cores (or slivers) from the ports into which they are inserted.

Investigations found that the needles cored in 60 to 72 percent of tests. These cores could cause the ports to leak and could lead to a silicone sliver entering the patient’s body, risking serious adverse events such as stroke, heart attack, organ damage and death. ORA’s inspections, investigations, sample collections and analyses into safety concerns related to Huber needles and Huber infusion sets led to the recall of more than 2 million units distributed nationwide.

In 2010, ORA investigations followed up on complaints regarding products labeled as Bard polypropylene surgical mesh. ORA worked with Bard to identify the counterfeit products and ORA laboratory analysis showed that the counterfeit mesh was not sterile, differed in weave pattern and in the size of the weave openings, and differed in the finish of the edge of the mesh, perhaps allowing it to unravel. In June 2010, FDA issued a Class I recall of the counterfeit polypropylene surgical mesh products, resulting in the recall of 15 lots of product.

Promoting Efficiency

FDA issued-press releases, guidance to industry, and alerts provide industry, health care professionals, and consumers with FDA recommendations, guidance, or warnings on specific medical devices. Examples include infusion pumps, infusion set needles, and counterfeit surgical mesh. These notices provide industry with guidance on the FDA's current initiatives and provide up-to-date information to consumers and medical professionals about device safety concerns. These FDA communications ensured efficient and timely public health response and industry and consumer awareness.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
<u>252201</u> : The minimum number of reports per year that 80 percent of MedSun hospitals, enrolled for at least 11 months in the program will submit. <i>(Outcome)</i>	FY 2010: 3 Reports (Target Met)	3	3	Maintain
<u>252202</u> : By 2013, enroll 80% of the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. <i>(Outcome)</i>	FY 2010: 47% (Target Exceeded)	40%	73%	+33%

Compliance, Enforcement, and Radiation Safety – Center Activities

Base Amount: \$32,080,819 (BA: \$32,080,819 / UF: \$0)

Public Health Focus

CDRH's Compliance, Enforcement, and Radiation Safety activities focus on protecting patient safety by assuring that manufacturers comply with laws and regulations. These efforts enable FDA to achieve important HHS and Administration priorities:

- improving health care quality and patient safety
- promoting high-value effective care.

Public Health Outcome

Compliance, enforcement, and radiation safety activities are designed to quickly identify major violations and take prompt, clear, and appropriate actions to resolve issues. Recent enforcement efforts include:

- a consent decree against STERIS Corporation following a finding that the company significantly modified the STERIS System 1 (SS1) processor without FDA approval or clearance. SS1 is used in surgical and endoscopy suites for reprocessing medical devices. STERIS agreed to destroy used SS1 devices, components, parts and accessories. This action protected patients from a device that CDRH has not determined is safe or effective for its labeled claims, including claims that it sterilizes medical devices.
- an investigation into a specific model line of fetal heart rate monitors in conjunction with a device recall. After the recall, CDRH formed a working group to look into similar issues with other monitors and track relevant signals for adverse events.
- a recall for up to 200,000 defective Baxter Colleague Volumetric Infusion Pumps due to safety risks. Baxter was required to provide replacements or refunds to purchasers of their devices. CDRH worked with Baxter to develop a transition guide for customers to switch to FDA-cleared or approved pump alternatives.

CDRH also identified accuracy, interference, and infection control problems with glucose meters – used an estimated 42 billion times annually by diabetic patients. In FY 2010, CDRH held a public meeting to gather input on appropriate meter accuracy goals. CDRH, along with CDC and CMS, issued Public Health Notifications alerting users of the risk of pathogen transmission when blood glucose testing is performed at healthcare facilities without proper cleaning and disinfection procedures. CDRH is developing guidance and working with device manufacturers to address these important issues.

To address current public health needs related to electronic product radiation, CDRH administers the Electronic Product Radiation Control Provisions of the FD&C Act through its Radiological Health Program. CDRH monitors industry for compliance with required performance standards, monitors radiation dose to the public, and balances public health safety benefits and risks. These activities identify and correct unnecessary and hazardous radiation exposure and reduce the incidence and severity of acute and chronic radiation injury. In the past fiscal year, CDRH slashed by half its average timeframe for review of field establishment inspection reports to 64 days.

CDRH is leading an initiative to reduce unnecessary radiation exposure from three types of medical imaging procedures that are the greatest contributors to Americans' total radiation exposure from medical imaging: computerized tomography (CT scan), nuclear medicine studies, and fluoroscopy. The initiative

promotes the safe use of medical imaging devices, supports informed clinical decision-making, and increases patient awareness of their own exposure. In response to this initiative, industry voluntarily committed to build dose checking safeguards into CT scanners within the coming year. CDRH is also working with the Foundation for the National Institutes of Health (FNIH), the American College of Radiology, and others to establish a national radiation dose registry for CT scans.

Promoting Efficiency

To leverage its resources, CDRH is collaborating with foreign governments to ensure that imported medical devices and radiological products are safe and effective for the American public. During FY 2009 and FY 2010, CDRH delivered 14 major regulatory workshops for key stakeholders of foreign governments including China, India and Korea.

In addition, CDRH is developing a Common Audit Program (CAP) to dramatically enhance program efficiency, stretch FDA resources, and improve patient safety. CAP will establish device quality management system requirements that are consistent with each regulator's requirements. As a result, audits performed by any regulator will meet the requirements of all foreign partners. CAP allows CDRH to stretch its inspection resources by allowing CDRH to access and review reports of inspections conducted by trusted countries that use U.S.-recognized inspection standards. CAP will also provide uniform guidelines to industry, and reduce the cost of complying with multiple regulators and a web of overlapping and possibly inconsistent requirements. FDA will implement a pilot CAP program with Canada in CY 2011 and Australia in CY 2012. Common audits and shared results will expand oversight of foreign and domestic manufacturing facilities, allowing FDA and other regulators to deploy inspection resources more efficiently and reduce duplicate inspections. CAP will also improve the quality of manufactured products.

CDRH conducts public education and outreach to both industry and the research community to foster understanding of relevant laws and regulations, and to promote voluntary compliance with FDA standards. CDRH analyzes data to determine the root cause of reported problems associated with recalls, adverse events and industry quality system problems. CDRH communicates this information to industry through direct meetings and seminars and presentations at industry-sponsored events. CDRH also works with industry to resolve systemic issues and prevent future problems – activities designed to save industry unnecessary costs associated with recalls and enforcement actions.

Compliance, Enforcement, & Radiation Safety – Field Activities

Base Amount: \$ 67,489,564 (BA: \$67,489,564 / UF \$0)

Public Health Focus

The ORA Field force supports the Devices Program by advising FDA leadership on enforcement, import, inspection, and laboratory policies. Through its nationwide field offices, ORA supports compliance and enforcement activities by conducting risk-based domestic and foreign postmarket inspections, field exams, and sampling of medical device manufacturers to assess compliance with the Quality Systems regulations. 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 that they comply with applicable performance standards. In addition to overseeing the regulated products on a surveillance or "for cause" basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated goods.

ORA works with state contractors through the inspection contract program to support the mission of assuring the safety, quality, and effectiveness of medical devices. Inspections ensure that Class I (low risk) and Class II medical device manufactures are in compliance with the Quality Systems Inspection Technique (QSIT)/Good Manufacturing Practices (GMP) regulations.

ORA conducts import entry reviews, import field exams, and import sample collections to determine if import entries comply with the medical device registration and listing requirements and other general controls. These reviews assure that import entries declared as import for export are CDRH approved and to detain all import entries that do not comply with applicable regulations.

As part of the recall program, CDRH determines the level (classification) of public health risk a product presents and makes appropriate public notification of a recall. ORA monitors recalls of medical devices that have been found to present safety concerns. This monitoring assures that a firm's recall is adequate to effectively remove the defective product from commerce.

ORA field offices investigate and build enforcement cases, which are initiated by CDRH or ORA. A number of enforcement tools bring about industry compliance with the law. Seizure removes a violative commodity from commerce. Injunction stops or prevents future violations of the law. Administrative Detention prevents distribution or use of violative devices until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action. Civil Money Penalties (CMP) serve to eliminate the profit from violative activity and to provide non-compliant firms with the financial incentive to correct violations.

Public Health Outcome

ORA successfully managed the medical devices contract with the state of Texas with a total of 20 inspections including 8 QSIT Level 1 and 12 QSIT Level 2 inspections. In addition to completing contracted inspections, ORA worked with external stakeholders to train state investigators to perform audits and joint inspections. This training strengthened state inspector qualifications in conducting inspections. Leveraging relationships with state counterparts while providing training and guidance to the states provides U.S. consumers with an integrated safety network, ensuring a greater level of regulatory oversight of the device industry and assuring the products available in the domestic market are safe and effective.

The FDA Regulatory Procedures Manual (RPM) was revised to provide a process for issuing Warning or Untitled Letters based on evidence obtained by state personnel. The process allows FDA to issue Warning or Untitled Letters if the standards and criteria used by state personnel provide reliable support for regulatory action consistent with the agency's guidance on regulatory actions and laboratory procedures. This process revision is associated with an increase in the number of enforcement actions and a decrease in the time and resources required to prevent the continued distribution of adulterated products in US commerce that could harm consumers.

In FY2010, FDA classified and issued recall numbers for 334 Class I (most serious); 2,208 Class II; and 93 Class III recalls of medical device products. In FY 2010, the agency's MARCS-Compliance Management System indicated four approved injunctions for device products. These actions helped protect patient safety by assuring that manufacturers comply with laws and regulations.

Since the Secretary's declaration of the 2009 H1N1 Flu Virus Public Health Emergency, FDA worked proactively to protect consumers by identifying, investigating, and taking regulatory or criminal action against individuals or businesses that promote illegal and fraudulent H1N1 influenza products, including test kits regulated by CDRH. FDA issued 30 warning letters to offending internet firms in FY 2010. Four of the 30 were FDA/Federal Trade Commission joint letters. As of November 2010, FDA issued a total of 95 warning letters covering 185 fraudulent H1N1 flu products, resulting in a compliance rate exceeding 80 percent.

To protect vulnerable consumers, FDA issued warning letters to eight internet firms promoting chelation (metal bonding) products with unproven claims to treat a range of diseases that include autism spectrum disorder, cardiovascular diseases, Parkinson's disease, Alzheimer's disease, macular degeneration, and other serious conditions. Three firms were also cited for promoting unapproved test kits that purported to detect the presence of heavy metals to justify the need for chelation therapy.

ORA authorized the testimony needed in a sex trafficking case when the U.S. Attorney's office needed to prove that condoms are not manufactured in the state of NY and therefore were brought across state lines and used against minors. This cooperation and coordination demonstrates the broad public health impact of medical device surveillance.

In FY 2010, ORA established a dedicated foreign device cadre consisting of 10 experienced medical device investigators to augment the existing foreign inspection program. The cadre performed more than 80 foreign device firm inspections in their first year to provide assurance that products manufactured abroad are safe for use in the United States.

In the past fiscal year, ORA began staffing the Commercial Trade Analytical Center (CTAC), a facility designed to identify safety risks in imported products by leveraging information sharing and data analysis by numerous government agencies. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA is working closely with other government agencies on several ongoing cases including Devices Program products such as lasers.

In FY 2010 ORA conducted more than 1,400 domestic inspections of class II & III (greatest risk) medical device manufacturers and more than 250 inspections of class II & III device foreign manufacturers. ORA continues to use violative findings during inspections of foreign facilities to establish pre-emptive import controls. These internal actions provide increased surveillance of regulated products in violative firms to ensure a higher level of scrutiny if products are offered for import into the United States.

A portion of ORA inspections focuses on quality systems, including Corrective Action and Preventative Actions (CAPA). The review of CAPA data reveals process and product problems from multiple sources, both from within and outside of the manufacturer. These reports demonstrate potential issues to be investigated and corrected. ORA investigators evaluate this data to target specific areas of the production process and quality system to ensure all stages of the product life cycle are in compliance with FDA regulations. These inspections assure FDA that product components used in the manufacturing process and the process itself are in compliance with FDA regulations, providing greater assurance of the finished product meeting safety and efficacy standards for use in the U.S. market.

Promoting Efficiency

ORA and CDRH recently developed a set of automated database lookup procedures for the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system. FDA is using these automated PREDICT procedures to determine the admissibility of imports of medical devices and radiological health products. With appropriate data submitted by import entry filers, the system can electronically determine the marketing status of a product during import review. This enhancement to PREDICT allows FDA to expedite the clearance of firms' low risk products, while allowing ORA to focus resources on higher risk device products. PREDICT provides both industry benefits and greater assurance that imported products are safe and effective for use by U.S. consumers. As of July 2010, this PREDICT enhancement was in use in FDA's Los Angeles, New York, San Francisco and Seattle Districts. FDA plans to expand this feature to additional districts.

The universe of FDA regulated medical devices and radiation-emitting products is diverse. Many of these devices and products have unique regulatory and performance requirements. ORA and CDRH recently implemented a joint initiative to create and issue a series of field advisories to assist ORA investigators. As a result of this initiative, ORA issued 12 field advisories in FY 2010. This effort to establish and implement nationwide guidance resulted in uniform national procedures that increase the efficiency of admissibility decisions while minimizing delays in processing import shipments. These efforts allow ORA to efficiently allow medical devices to enter U.S commerce in a timely manner, ensuring that safe and effective products are available to U.S. consumers.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
<u>254202</u> : Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters. <i>(Output)</i>	FY 2010: 66% (Target Not Met)	90%	75%	-15%
<u>254201</u> : Number of domestic and foreign Class II and Class III device inspections. <i>(Output)</i>	FY 2010: 1,659 (Target Exceeded)	1,365	1,515	+150

Device Innovation and Regulatory Science – Center Activities

Base Amount: \$47,086,810 (BA: \$42,618,332 / UF: \$4,468,478)

Public Health Focus

CDRH's Device Innovation and Regulatory Science activities focus on improving the timeliness and quality of feedback to industry and consumers regarding new technologies, and on providing critical evaluation tools that can ensure the safety and effectiveness of cutting edge innovations while speeding up the time from product development to market.

Through CDRH's Device Innovation and Regulatory Science activities, FDA is able to achieve important HHS and Administration priorities:

- improving health care quality and patient safety
- transforming health care
- promoting high-value effective care.

Public Health Outcome

CDRH's science activities are essential to assure that advances in science and technology translate into improvements in human health. CDRH relies on its scientific activities to identify the underlying mechanisms of device actions on the body and to develop the science-based questions, test methods, and tools necessary to assess the safety and effectiveness of medical products. These tests and tools are designed, validated, and provided to consensus standards organizations and industry.

CDRH develops state-of-the art computer simulations of devices to evaluate safety and effectiveness. Recent examples include developing and verifying computer models and highly accurate physical models of the head to simulate brain perfusion computed tomography (CT). These models estimate the dose to specific organs and estimate risks associated with the delivered dose. These tools improve premarket assessment of CT devices and enable industry professionals to use the dose necessary for the study without exceeding the threshold for damage.

CDRH also works with manufacturers to redesign existing devices with systematic safety problems. When device failures cause injuries, CDRH's scientific investigations provide in-depth analyses of the underlying causes. The findings from these analyses are then used to redesign the devices to ensure safe future products. CDRH engineers recently identified the cause of hazards with the Huber needle, a component of implantable ports used to give chemotherapy and other medicines to adults and children. As a result, CDRH recalled more than two million Excel Huber needles, worked with manufacturers to prevent problems in the manufacturing process, and developed test methods to enable continued monitoring.

CDRH is dedicated to adapting to the unique issues of emerging technologies while continuously improving regulatory pathways to support and foster medical product innovations. CDRH established a personalized medicine (PM) staff to address the new generation of medical products that provide patients with targeted medical treatment based on individual patient genetic attributes. The PM staff conducted a public meeting to gather input on aligning regulatory review requirements with realistic expectations and finalizing a guidance on regulatory requirements for companion diagnostics and therapeutics. CDRH announced that it is easing the pathway to market for mammography systems that produce computerized X-ray images of the entire breast. CDRH also released a “special controls” guidance for industry that describes the scientific evidence that will be needed for these systems to come to market.

CDRH is committed to quickly incorporating new science into its decision making while maintaining as much regulatory predictability as practical. In FY 2010, CDRH released a report for public comment that recommends concrete steps it can take to achieve this goal. CDRH also established a Council on Medical Device Innovation to facilitate medical device innovations that address unmet public health needs. The Council is composed of several government agencies, including Department of Defense, Defense Advanced Research Projects Agency, Center for Medicare and Medicaid Services, Federal Communication Commission, Veterans Administration, and Centers for Disease Control and Prevention. These efforts, including a public meeting to receive input from external constituencies, help ensure that reliable regulatory pathways are available to rapidly translate innovative concepts to safe and effective medical devices that address public health needs.

Promoting Efficiency

CDRH’s science activities serves as a force multiplier, generating benefits for the stakeholders that CDRH serves, including the U.S. medical device sector.

CDRH science activities

- reduce cost of research and development for device manufacturers
- foster innovation and economic growth
- support economic development in the medical device sector.

For example, CDRH develops and shares with industry reliable tests, tools and methods for evaluating key characteristics of new devices and technologies. The availability of these standardized, well-validated methods reduces ambiguity and uncertainty as industry develops and submits data to FDA. The availability of these methods also allows FDA to interpret industry data more efficiently.

CDRH also performs laboratory investigations to clarify the underlying scientific mechanisms and parameters that govern the safety and effectiveness of new

types of technologies. An early, solid scientific understanding of performance-critical factors allows industry to focus on developing data for FDA review that is truly relevant, thereby increasing the efficiency of industry research. CDRH develops state-of-the-art computer simulations of devices and their interactions with the body to efficiently provide fundamental insights into safety and effectiveness issues. CDRH and industry benefit from the ability of such models to analyze large numbers of scenarios and to determine which scenarios are meaningful for determining device performance. The CDRH models allow CDRH and industry to conduct extremely powerful assessments of device performance in a fast and efficient way.

Recent examples of laboratory investigations that promote efficiency include CDRH glucose sensing research that allows CDRH to provide prompt feedback to industry and improves industry's ability to develop products such as glucometers, continuous glucose monitor (CGM) devices, and electrochemical enzymatic biosensors. This glucose sensing research also directly advanced the development of a safe and effective "closed loop" artificial pancreas through glucose reading criteria that supports the sensor component of an artificial pancreas. The artificial pancreas is intended to ensure delivery of the appropriate amount of insulin to enable effective management of blood glucose levels.

CDRH scientists also recently developed the first phantoms (standards) for rapidly assessing Optical Coherence Tomography (OCT) image quality. OCT is currently being used in the health community at least 37,000 times per day to scan for eye diseases. The availability of standardized phantoms as test objects enhances academic and industry research and development efforts. These standards provide a more accurate, less costly, and highly efficient manner to clarify basic OCT issues and ensure the safety of American patients.

In addition, CDRH maintains laboratory collaborations with external scientific institutions and universities in the United States and around the globe. Recent collaborations include work with the National Science Foundation, National Institutes of Health, National Institute for Standards and Technology, National Institute for Disability and Rehabilitation Research, Defense Advanced Research Projects Agency, and dozens of public and private universities. Regular interactions with other scientific investigators enable CDRH's scientists and engineers to leverage expertise to meet ever-changing scientific and technical needs in a more efficient manner.

Device Innovation and Regulatory Science –Field Activities

Base Amount: \$1,533,334 (BA: \$1,533,334 / UF: \$0)

Public Health Focus

ORA's Winchester Engineering and Analytical Center (WEAC) laboratory supports Device and Radiological Health Science activities by conducting test method development, validation and evaluation activities. ORA worked closely with CDRH to identify devices posing the greatest risk to the public and subsequently developed, and will continue to develop, analytical test methods for timely and efficient analyses.

Public Health Outcome

ORA continues to make advancements in device safety for consumers by leveraging internal and external stakeholders, conducting postmarket analytical methods development activities on pressing public health risks, and developing a proactive FDA approach for post-market device testing. WEAC continues to:

- develop new and improved methodology to support regulatory analysis
- validate analytical methods to support enforcement activities
- conduct product evaluation study projections to provide comprehensive postmarket surveillance information about devices.

ORA's laboratories support the Devices Program through analysis and surveillance of samples for the Condoms and Gloves programs to assure they are safe and effective. These analyses help reduce the risk to the public and health care community of unnecessary exposure and transmission of blood-borne pathogens, particularly human immunodeficiency virus (HIV), hepatitis B, and hepatitis C infections. ORA's field laboratories have undertaken an effort to increase the number of medical gloves analyzed at an expedited rate utilizing a "high throughput" model previously adopted for food borne outbreaks. Increased equipment funding and test method development activities allowed regulatory labs to design, procure, and commission automated glove testing machines that shorten timeframes for analytical testing.

Promoting Efficiency

Increased efficiencies and capacity allowed ORA to analyze a higher volume of fundamental yet essential products such as medical gloves in reduced timeframes. These efforts support the timely release of industry products into U.S. commerce. These efficiencies also ensure that reliable medical products are available to the health care community, safeguarding medical practitioners and patients from ineffective medical devices.

ORA scientists foster communication between the public and private sectors to develop solutions that meet both the requirements of business and the broader needs of protecting the public from harmful medical devices. For example, these activities will allow manufacturers to more efficiently conduct product

development and manufacturing of billions of syringes, which will lead to savings for manufacturers while ensuring the safety of patients.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
252101: Number of technical analyses of postmarket device problems and performance. (Output)	FY 2010: 127 Analyses (Target Exceeded)	125	125	Maintain
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. (Output)	FY 2010: 1,429 Reviews (Target Exceeded)	1,175	1,175	Maintain

Mammography Quality Standards Act (MQSA) – Center Activities

Base Amount: \$10,107,389 (BA: \$4,104,389 / UF: \$6,003,000)

Public Health Focus

CDRH administers the Mammography Quality Standards Act (MQSA) to ensure the quality of mammography services. MQSA provides national quality standards for mammography and assures that mammography facilities meet these standards. These activities, combined with new and improved treatment methods, led to a decline in breast cancer morbidity and mortality in the United States.

Through MQSA activities, FDA is able to achieve important HHS and Administration priorities:

- improving health care quality and patient safety
- promoting high-value effective care
- promoting wellness and prevention.

Public Health Outcome

MQSA requires FDA-approved accreditation bodies to evaluate and accredit mammography facilities based on quality standards. Once accredited, FDA or an FDA-approved State certifying agency grants the facility a certificate so that it can legally operate. FDA, along with its State contract partners, annually inspects each of the approximately 8,700 certified mammography facilities in the United States. As a result of the MQSA program, over 80 percent of the facilities are free of violations at the time of inspection, and less than one percent of facilities are cited with the most serious Level I violations. CDRH works with facilities that are

not in compliance to bring them into compliance. If these efforts fail, MQSA allows a variety of sanctions to be imposed, such as civil money penalties and certificate revocation and suspension.

Promoting Efficiency

MQSA maximizes the efficient operation of mammography facilities and reduces health costs by ensuring the quality of mammography services that contribute to the early detection of breast cancer. CDRH improved cost-effectiveness and efficiency within the MQSA program by approving multiple, alternative standards for manufacturers of full field digital mammography devices. These alternative standards allow mammography facilities to more efficiently correct quality control test failures. The efforts of the MQSA subprogram also eliminate redundant MQSA inspection testing. Finally, actions by the MQSA subprogram will make training more efficient and less intrusive for State partners. By the spring 2011, two-thirds of MQSA inspector training will be available online.

Mammography Quality Standards Act – Field Activities

Base Amount: \$15,838,195 (BA: \$2,761,195 / UF: \$13,077,000)

Public Health Focus

To protect consumers and advance public health for women, ORA continues to focus resources on health prevention by carrying out the mammography facility inspection contract program with the states, which includes an annual audit of state inspections and FDA-provided training for state inspectors.

Public Health Outcome

The ORA Field force supports the MQSA program by managing state-conducted inspections annually and by conducting foreign inspections to ensure the safety of mammography conducted in military facilities located in foreign countries. The Field:

- inspects certified mammography facilities
- conducts follow-up inspections to determine compliance with terms of corrective action plans based on non-compliances found during prior inspections
- performs on-site quality assurance audits of FDA and State MQSA inspectors to ensure their proficiency in conducting mammography facility inspections.

In FY 2010, ORA oversaw approximately 7,300 MQSA state inspections and monitored over 90 audits to state inspectors. To ensure high quality facility inspections conducted by the states, ORA coordinated with CDRH to offer annual

MQSA inspectors training courses to new state inspectors as well as to provide continuing education units for certified state inspectors.

Promoting Efficiency

ORA works with the states to maintain MQSA contract program quality standards, which ensure that women receive high quality mammography for early breast cancer detection. Maintaining the contract program through collaboration with qualified state partners maximizes resources dedicated to MQSA and ensures that a greater number of mammography facilities are inspected each year than could be accomplished by an individual program alone.

Performance Measures

The following table lists the performance measure associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (Outcome)	FY 2010: 97% (Target Met)	97%	97%	Maintain

Information Technology Investments – Devices and Radiological Health Program Activities (Base Amount displayed as a non-add item: \$59,072,000)-

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

In addition to investments in the systems described above IT infrastructure, unique center-specific systems, and enterprise-wide systems, CDRH-specific IT development efforts support the regulation of medical devices and radiation-emitting products. CDRH has information management objectives of increasing

transparency, collaboration, integration, knowledge management, business agility and improved efficiency throughout the medical device and radiological health total product life cycle. To meet these objectives, CDRH depends heavily on modernized IT, informatics standards and the migration from paper to standardized electronic submissions. In addition to maintaining and/or enhancing existing IT systems, CDRH leverages commercial off the shelf (COTS), government off the shelf (GOTS) and FDA technologies and initiatives to help achieve those objectives. For example, CDRH will utilize COTS social networking-type tools that are transforming communication and collaboration on the internet to improve collaboration and knowledge management both internally and externally.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2007 through FY 2011 for the Devices and Radiological Health Program.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2007 Actual	267,543,000	230,682,000	36,861,000	1544
FY 2008 Actual	\$275,284,000	\$237,734,000	\$37,550,000	1,564
FY 2009 Actual	\$345,311,000	\$298,536,000	\$46,775,000	1,707
FY 2010 Actual	\$369,971,000	\$313,452,000	\$56,519,000	1,801
FY 2011 Continuing Resolution	\$366,900,000	\$313,935,000	\$52,965,000	1,801

Summary of the Budget Request

The FY 2012 budget request for the Devices and Radiological Health Program is \$394,946,000. This amount is an increase of \$28,046,000 above the FY 2010 Enacted Budget. The Center for Devices and Radiological Health amount in this request is \$292,384,000, supporting 1,373 FTE. The Field amount is \$102,562,000, supporting 511 FTE.

The base funding for the Devices and Radiological Health Program is \$366,900,000, which includes \$272,771,000 for the Center for Devices and Radiological Health activities and \$94,129,000 for the Devices and Radiological Health Program Field activities.

The Devices and Radiological Health Program (Devices Program) is requesting budget authority and user fee resources to maintain its base program in FY 2012. Base program funding allows the Devices Program to conduct mission-essential activities in support of:

- Premarket Device Review
- Postmarket Safety
- Compliance, Enforcement, and Radiation Safety
- Device Innovation and Regulatory Science
- Mammography Quality Standards Act (MQSA).

These activities are critical to protecting and promoting the public health by assuring:

- safe and effective medical devices and radiological products
- manufacturing processes and industry compliance of regulations and laws
- medical device innovation and emerging technologies
- safe, high quality mammography facilities.

Premarket Device Review

Center Activities (Base Amount: \$131,595,148)

FY 2012 increase for current law user fees (MDUFA): +\$4,016,000; 18 FTE

Initiatives

Advancing Medical Countermeasures (MCM) Initiative (+\$4,589,000; 19 FTE)

Pillar 1 – Optimizing the Review Process for MCM by Establishing Public Health and Security Action Teams (PHSATs): (+\$3,865,000; 16 FTE)

Under Pillar 1, CDRH staff will enhance its MCM review capacity and provide expertise through Public Health and Security Action Teams (PHSATs) to ensure that MCM diagnostic and medical products and technologies receive necessary support throughout the product lifecycle.

CDRH will develop a regulatory pathway for radiation injury protection devices to facilitate and promote the development of personal biodosimetry devices for estimating radiation dose from an exposure. Availability of these devices will empower people to take actions necessary to decrease or eliminate the severity of injury from radiological and/or nuclear events.

CDRH will also develop a regulatory pathway to promote more rapid development of multiplex diagnostic devices, which are a new generation of diagnostic devices designed to simultaneously detect a large number of biological threat agents. CDRH will collaborate with the Department of Defense (DOD), the Centers for Disease Control and Prevention (CDC), and other external partners to develop multiplex diagnostic testing assays. Activities will include facilitating Emergency Use Authorizations (EUA) and pre-EUAs for chemical, biological, radiological and nuclear threats.

Similarly, CDRH will develop a regulatory pathway for portable ventilators and other personal protective equipment. CDRH will work with the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response to develop a portable ventilator for adult and pediatric use.

Pillar 3 – Optimizing the Legal, Regulatory and Policy Framework for Effective Public Health Response: (+\$724,000; 3 FTE)

Under Pillar 3, CDRH will work with FDA's Office of the Commissioner to analyze gaps in regulation and optimize the legal and policy framework needed to support the activities described above, and others, to assure an effective emergency public health response.

Field Activities (Base Amount: \$8,448,743)

FY 2012 increase for current law user fees (MDUFMA): +\$186,000; 7 FTE

Postmarket Safety

Center Activities (Base Amount: \$51,900,834)

FY 2012 increase for current law user fees (MDUFA): +\$1,011,000; 4 FTE

Initiatives

Protecting Patients Initiative: Medical Device Registry (+\$1,667,000; 4 FTE)

FDA will lead an effort to develop and implement a national strategy for the best public health use of health-related electronic data that incorporates unique device identifiers (UDIs) and leverages existing procedure and device registries.

The initiative will:

- establish a national strategy for developing national medical device registries and expanding existing procedure and device registries
- develop a roadmap for the effective and efficient incorporation of UDIs into health-related electronic data, including electronic records and claims systems
- identify the best proposal(s) for incorporating UDIs
- pilot efforts to create device type attributes and reference libraries.

These activities will harness the vast amount of untapped public health information on device safety and effectiveness available in health-related electronic data. The activities will also incorporate a critical piece of information -- specific device exposure. Without this information, evaluations of device safety and effectiveness are not possible.

Protecting Patients Initiative: Pediatric Safety (+\$750,000; 3 FTE)

The funds support the integration of all available internal and external data on the pediatric population which will strengthen FDA's postmarket science base. FDA will purchase data from external sources and hire an epidemiologist to build the infrastructure to analyze pediatric postmarket device information. FDA will broaden the scope of targeted surveillance of pediatric device use and performance through the MedSun program by using Regional Representatives. FDA will hire and support travel for two Regional Representatives who will

- train staff from hospitals and home-health agencies to recognize if a device played a role in an adverse outcome
- assist staff in collecting the details of the problem so they may be reported to FDA
- conduct focus group discussions and interviews with health care providers
- work with clinical sites following a manufacturer's recall to evaluate the effectiveness of the change.

The successful integration of available postmarket information will benefit FDA, the sponsors of medical devices, and the public through an enhanced understanding of how devices move into wide-spread use in the clinical environment, and their effectiveness and safety in under-studied populations, including pediatrics.

This initiative enables FDA to:

- establish a centralized capacity to coordinate all CDRH pediatrics-related activities, including the development of devices to treat or diagnose uncommon conditions
- expand KidNet
- develop different methodological approaches to analyze data from external postmarket databases and integrate such data in FDA's post-approval decision making process, including key patient populations – children, women, and minorities.
- conduct high quality comparative effectiveness studies
- obtain increased quantity and quality reports about device problems used in the pediatric population, resulting in FDA taking actions to solve problems and improve safety in this vulnerable population
- build postmarket capabilities for the present and future monitoring of medical device safety and effectiveness, especially in the pediatric population.

Field Activities (Base Amount: \$819,164,000)

No Initiative increases

Compliance, Enforcement, and Radiation Safety

Center Activities (Base Amount: \$32,080,819)

Initiatives

Protecting Patients Initiative: Imported Medical Device Safety (+\$1,500,000; 5 FTE)

Funding the Medical Device Safety initiative will allow CDRH to continue to build the capacity to ensure the safety of products shipped to the United States. Specifically, the initiative will allow CDRH to:

- hire and train five Center staff to support an audit program of foreign government inspections and an FDA increase in foreign and domestic medical device inspections
- increase the number of foreign assignments provided to FDA's Office of Regulatory Affairs by 10% over the 2010 level to ensure the quality and safety of imported products.

With this initiative, FDA will build its import safety program capacity to protect the American public. CDRH anticipates an increase in the Center's oversight of foreign manufacturing facilities by creating an audit program for high quality

inspections conducted on behalf of foreign governments with well-developed regulatory systems. To handle the additional workload and emerging technology, CDRH will develop a compliance review staff that is:

- well versed in FDA's Quality System Regulation
- knowledgeable of the ISO 13485 requirements that are used by many foreign regulators and serve as the basis of the manufacturing information shared with FDA
- capable of integrating information from both sources into the CDRH risk-based surveillance process.

With this initiative, the CDRH compliance review staff will be more vigilant of new innovations and technologies that medical device manufacturers incorporate into their manufacturing processes and medical products.

Protecting Patients Initiative: National Imaging Dose Registry (+\$250,000; 1 FTE)

These funds will support the development of standards for safe and effective CT scanners and fluoroscopes, as well as a pilot dose registry program FDA is already actively participating in with the American College of Radiology in beginning development of a national radiation dose registry. FDA will also begin to develop an educational program to support medical imaging dose awareness. The focus will be on CT scans—the largest single contributor to public radiation dose, fluoroscopy, and nuclear medicine studies.

Funding the initiative will allow CDRH to:

- hire and train staff to support activities for standards development, dose reduction education, and support of a dose registry pilot
- establish and enhance relationships with professional organizations that collect medical imaging dose information—including the American College of Radiology and the Society of Interventional Radiology—to understand the status of their efforts and to identify areas for possible collaboration
- establish relationships with key stakeholders that advance education priorities.

With this initiative CDRH will establish design standards for safe and effective CT scanners and fluoroscopes and work with healthcare professional organizations to create a national radiation dose registry. The initiative will also support CDRH's preparation for projects to evaluate the feasibility of establishing meaningful dose metrics and capturing dose information in electronic health records. This allows healthcare providers to make better informed decisions as to which, if any, medical imaging studies a particular patient should undergo.

Field Activities (Base Amount: \$67,489,564)

Proposed user fee (Medical Products Reinspection): +\$3,424,000; 24 FTE

Initiatives

Protecting Patients Initiative: Increasing Medical Product Inspections (+\$1,662,000; 6 FTE)

ORA will expand inspections to ensure greater technical assistance and compliance. The increase in inspections will not be fully realized until the end of fiscal year 2015 due to the time it takes to hire and fully train investigators to conduct these complex inspections, especially in the foreign arena.

This initiative will permit FDA to rise to the challenge of protecting patients in the 21st century. It supports critical international efforts, important internal upgrades to scientific capacity, and essential partnerships with the private sector. With the proposed resources, the component will lead to:

- additional inspection capacity
- improved data collection and risk analysis for medical products
- enhanced postmarket safety assessment.

By September 30, 2012, ORA will complete hiring of 6 additional employees and will have begun training these employees. By September 30, 2014, once the new employees are fully trained, ORA will conduct an additional 14 domestic GMP surveillance inspections. By September 30, 2015, ORA will conduct an additional 14 foreign Radiological Health Inspections and 53 foreign GMP surveillance inspections for a total foreign inspection increase of 67 inspections.

Advancing Medical Countermeasures Initiative: (+\$218,000; 1 FTE)

Under Pillar 1, ORA Field operations will conduct enhanced inspection and compliance activities, identify problems that impede MCM product development as early and efficiently as possible and provide technical assistance to minimize risk during MCM product manufacturing. This increase will support 14 additional domestic device inspections once the investigators reach full performance in FY 2014.

Proposed User Fee: International Courier (+\$3,450,000; +15 FTE)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities. These shipments are often destined for individual consumers or for illegal distribution. The number of shipments continues to grow, and current FDA staffing does not match the growth in import volume. Federal Express and other couriers have indicated that they expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of

imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee.

User fees for this activity allow increased import surveillance of FDA-regulated products at express courier hubs. FDA will:

- conduct entry reviews
- sample collections and physical exams to determine product admissibility into the U.S.
- initiate compliance actions to prevent release of unsafe products into U.S. commerce, and establish import controls to prevent future unsafe products from entering U.S. commerce.

Device Innovation and Regulatory Science

Center Activities (Base Amount: \$47,086,810)

FY 2012 increase for current law user fees (MDUFA): +\$792,000; 2 FTE

FY 2012 Initiatives

Advancing Medical Countermeasures (MCM) Initiative (+\$3,621,000; 15 FTE)

Pillar 2 – Advancing Regulatory Science for MCM Development and Evaluation: (+\$3,621,000; 15 FTE)

Under Pillar 2, CDRH will provide additional scientific support to test the safety and effectiveness of MCM diagnostic and medical products and technologies; monitor safety throughout the product lifecycle; and facilitate the availability of MCM products.

These activities will support important research designed to fill in development and evaluation gaps in existing MCM resources. Examples include evaluating the safety and effectiveness of decontamination procedures for personal protective equipment and other medical devices intended for reuse; and developing animal models for use in product development, including studies to assess the feasibility of using isolated cardiac myocytes (muscle cells) as an innovative dangerous agent detection system.

Pillar 2 activities will also include working with CDC to assure that devices in the Strategic National Stockpile are safe and effective, and developing a medical device shortages database to improve CDRH's ability to anticipate, prevent, minimize and respond to a medical device shortage.

FDA Regulatory Science and Facilities Initiative: Science and Innovation Leadership (+\$500,000; 2 FTE)

This initiative will provide support for FDA-wide scientific leadership and coordination, workforce excellence, scientific collaboration, and the recruitment of next generation scientists in areas of emerging science.

Recruitment of Next Generation Scientists: FDA's Office of Chief Scientist and the Senior Strategic Advisory Leadership group will identify key areas of emerging science where FDA needs expertise. The Agency will recruit outstanding and newly independent scientists, with expertise in laboratory and population sciences, such as biostatistics, epidemiology, modeling, and risk sciences, to fill key positions to augment its existing workforce.

The requested FY2012 funds will allow CDRH to enhance expertise in the following forward-looking areas for which there is an urgent and critical need:

- *Systems of computerized devices*—to bring advanced knowledge in computer science, software engineering and networked systems to advance CDRH's ability to evaluate device systems that integrate "smart" devices which "talk to" each other directly and continually. These systems are increasingly being used by healthcare facilities to provide and manage procedures and patient care, physician decision support tools, laboratory and medical imaging management tools, and robotics, including next generation high-technology orthopedic prosthetic devices.
- *Innovative analytic methodologies*—to enhance expertise in the use of Bayesian statistics in clinical trials to incorporate innovative quantitative methods, including quantitative risk-benefit analysis and adaptive trial designs, to assess and connect different sources of information. These methodologies are critical for establishing and using a national Medical Device Registry and for conducting comparative effectiveness assessments using existing sources of healthcare-related information.

Through a more robust scientific leadership and coordination effort, FDA will be able to develop an overarching scientific strategy, and begin a multi-year process to implement a fully coordinated scientific agenda that meets the demands of the 21st century. This initiative will increase FDA's ability to use existing scientific resources more efficiently, and improve its ability to incorporate advances in biomedical research into medical product development and evaluation.

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+\$900,000; 2 FTE)

Under the nanotechnology initiative, CDRH will conduct activities that support the following FDA-wide priorities: (1) laboratory and product testing capacity, (2) scientific staff development and training and (3) collaborative and interdisciplinary

research to address product characterization and safety. Together, these priorities will improve FDA's ability to bring benefits of nanotechnology to bear while reducing its risks.

FDA Regulatory Science and Facilities Initiative: Medical Device Registry
(+\$2,333,000; 4 FTE)

Providing this funding allows the Center to:

- investigate and pilot proof-of-concept studies to understand the surveillance and observational methods needed to understand real world device safety and effectiveness using electronic healthcare data that incorporate UDIs
- investigate and conduct studies to assess optimal methods for surveillance and observational study of linked registry and longitudinal electronic healthcare data
- work within FDA Sentinel efforts to develop an infrastructure that will leverage the Agency for Healthcare Research and Quality's research and database infrastructure.

These activities will lay a strong foundation for understanding the surveillance and observational methodologies needed to optimize electronic healthcare data sources. In doing so, FDA will be in a better position to effectively detect and respond to device-related public health issues as they arise and to provide healthcare providers and patients with important, new information about the risk-benefit profile and comparative risk-benefit profile of higher risk medical devices.

With this initiative FDA will lead an effort to develop and implement the best methods for device surveillance and observational study in electronic healthcare databases that incorporate UDIs. Similar efforts will be undertaken to assess optimal methods for surveillance and observational study of linked registry and longitudinal electronic healthcare data. Additionally, the initiative will:

- significantly enhance the Sentinel Initiative effort in medical device surveillance and observational study
- provide the best methods to make optimal use of health-related electronic data that incorporates UDIs.

Field Activities (Base Amount: \$1,533,334)

Initiatives:

FDA Regulatory Science and Facilities Initiative: Nanotechnology
(+\$276,000; 1 FTE)

For the nanotechnology initiative, ORA will conduct activities that support the following FDA-wide priorities:

- (1) laboratory and product testing capacity
- (2) scientific staff development and training
- (3) collaborative and interdisciplinary research to address product characterization and safety.

Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Mammography Quality Standards Act (MQSA)

Center Activities (Base Amount: \$10,107,389)

Increase for current law user fees: \$0

Field Activities (Base Amount: \$15,838,195)

Increase for current law user fees: \$0

BA Increase for Pay Costs: +\$753,000 (Center: \$556,000; Field: \$197,000)

Contract and Administrative Savings (Total Program: -\$3,852,000)

The request for \$329,102,000 in total budget authority for the Devices and Radiological Health Program also reflects a contract and administrative savings reduction of -\$3,852,000. The Center's portion of these savings is -\$2,872,000 and the Field's portion is -\$980,000.

Center Activities

Contract and Administrative Savings (-\$2,872,000; 0 FTE)

Center for Devices and Radiological Health (CDRH) will achieve contract and administrative savings by:

- using technology to further reduce high contractor costs associated with processing and data entry
- terminating contracts that do not fully meet program needs
- using technology to improve contract management
- reducing CDRH staff travel
- replacing traditional classroom training with online training modules
- reducing services provided by outside contractors.

Field Activities

Contract and Administrative Savings (-\$980,000; -4 FTE)

The Office of Regulatory Affairs (ORA) will achieve contract and administrative savings by:

- reducing administrative support staff, both in headquarters and in the ORA field offices
- consolidating tasks and eliminating redundancies to improve productivity and efficiency gains throughout ORA
- obtaining the best value for the American public through blanket purchase agreements and agency-wide approaches to contracting.

CDRH Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
Expedited PMA Received	4	6	6
Expedited PMA Approved	4	4	4
Expedited PMA – Performance	90% ^{1/}	70%	60%
PMA Received (PDP and PMA)	48	45	45
PMA Approved (PDP and expedited)	17	35	35
Original PMA performance	90% ^{1/}	70%	60%
PMA Supplement Panel Tracks Received	16	12	12
PMA Supplement Panel Track Approved	2	10	10
Panel Track PMA Supplement Performance	90% ^{1/}	70%	60%
Humanitarian Device Exemptions Received	7	6	6
Humanitarian Device Exemptions Approved	1	4	4
Average HDE FDA Review Time (FDA days approval)	374	300	300
PMA Supplements Received	158	160	160
PMA Supplements Approved	106	155	155
510(k)s Received (Trad., Special, Abbrev., 3 rd party)	3,893	4,100	4,100
510(k)s Completed (All Decisions)	3,783	3,700	3,700
510(k) performance	98% ^{1/}	93%	80%
Investigational Device Exemptions Received	226	240	240
Investigational Device Exemptions Decisions	206	230	230
% Acted on Within 30 Days	98%	99%	99%
Investigational IDE Supplements	3,899	3,900	3,900
IDE Supplements (Approved/Total Decisions)	3,921	3,800	3,800
% Acted on Within 30 Days	99%	100%	100%
Total Standards Recognized for Application Review	898	900	940

^{1/} FY 2010 performance figures are estimates as the cohort is not yet mature enough to report complete figures.

**Combined Field Activities – ORA
Program Activity Data**

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	2,536	2,493	2,533
Bioresearch Monitoring Program Inspections	372	295	295
Pre-Market Inspections	42	68	68 ¹
Post-Market Audit Inspections	29	48	48
GMP Inspections	1,672	1,573	1,614 ¹
			0
Inspections (MQSA) FDA Domestic (non-VHA)	329	359	359
Inspections (MQSA) FDA Domestic (VHA)	37	33	33
			0
Domestic Radiological Health Inspections	96	157	157
			0
Domestic Field Exams/Tests	239	480	480
Domestic Laboratory Samples Analyzed	125	217	217
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	322	352	388
Foreign Bioresearch Monitoring Inspections	20	25	25
Foreign Pre-Market Inspections	26	33	33
Foreign Post-Market Audit Inspections	36	19	19
Foreign GMP Inspections	251	286	327 ²
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	32	26	26 ²
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	2,858	2,845	2,921
IMPORTS			
Import Field Exams/Tests	18,761	13,180	13,180
Import Laboratory Samples Analyzed	1,513	1,145	1,145
Import Physical Exam Subtotal	20,274	14,325	14,325
Import Line Decisions	8,822,633	10,942,777	13,572,408
Percent of Import Lines Physically Examined	0.23%	0.13%	0.11%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	8,168	8,496	8,496
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	72	74	74
Inspections (MQSA) by State Contract	7,060	7,356	7,356
Inspections (MQSA) by State non-Contract	1,091	1,120	1,120
GMP Inspections by State Contract	17	20	20
State Partnership GMP Inspections	72	74	74
State Contract Devices Funding	\$79,000	\$85,000	\$92,000
State Contract Mammography Funding	\$9,000,000	\$9,630,000	\$10,300,000
Total State Funding	\$9,079,000	\$9,715,000	\$10,392,000
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	11,098	11,415	11,491

¹ For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 14 premarket MCM inspections and an additional 14 GMP surveillance inspections.

² For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 14 Rad Health inspections and an additional 53 GMP surveillance inspections.