

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

	FY 2004 Actual	FY 2005 Enacted ^{1/}	FY 2006 Estimate ^{2/}	Increase or Decrease
Program Level	\$179,245,000	\$206,208,000	\$213,363,000	+\$7,155,000
<i>Total FTE</i>	<i>1,061</i>	<i>1,187</i>	<i>1,170</i>	<i>-17</i>
Budget Authority	\$156,961,000	\$180,948,000	\$183,054,000	+\$2,106,000
<i>Medical Device Review</i>	<i>\$140,646,000</i>	<i>\$163,246,000</i>	<i>\$165,042,000</i>	<i>+\$1,796,000</i>
<i>GSA Rent & Rent Related</i>	<i>\$16,315,000</i>	<i>\$17,702,000</i>	<i>\$18,012,000</i>	<i>+\$310,000</i>
<i>Total FTE</i>	<i>935</i>	<i>1,003</i>	<i>986</i>	<i>-17</i>
User Fees	\$22,284,000	\$25,260,000	\$30,309,000	+\$5,049,000
<i>MDUFMA</i>	<i>\$18,245,000</i>	<i>\$20,086,000</i>	<i>\$24,972,000</i>	<i>+\$4,886,000</i>
<i>MQSA</i>	<i>\$4,039,000</i>	<i>\$5,174,000</i>	<i>\$5,337,000</i>	<i>+\$163,000</i>
<i>Total FTE</i>	<i>126</i>	<i>184</i>	<i>184</i>	<i>-</i>

For Information Only

ORA Estimate	\$67,010,000	\$70,958,000	\$75,925,000	+\$4,967,000
<i>Budget Authority</i>	<i>\$57,939,000</i>	<i>\$58,701,000</i>	<i>\$63,354,000</i>	<i>+\$4,653,000</i>
<i>FTE</i>	<i>441</i>	<i>400</i>	<i>392</i>	<i>-8</i>
<i>User Fees</i>	<i>\$9,071,000</i>	<i>\$12,257,000</i>	<i>\$12,571,000</i>	<i>+\$314</i>
<i>FTE</i>	<i>13</i>	<i>24</i>	<i>24</i>	<i>0</i>

Includes structure changes to FDA's budget, which displays GSA and Other Rent and Rent Related Activities in the Program line, and the Office of Regulatory Affairs as its own program. ORA estimates are for information purposes only and are not included in the Center program level total.

^{1/}*Contains budget authority rescission of 0.8 percent.*

^{2/}*The FY 2006 budget authority lines without GSA or Other Rent and Rent Related Activities for CDRH and its related ORA Field activities total \$220,961,000 which meets the second trigger required under the MDUFMA legislation.*

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2002 Actual ^{1/}	\$136,385,000	\$131,466,000	\$4,919,000	997
2003 Actual	\$217,285,000	\$140,429,000	\$14,677,000	1,003
2004 Actual	\$179,245,000	\$156,961,000	\$22,284,000	1,061
2005 Enacted	\$206,208,000	\$180,948,000	\$25,260,000	1,187
2006 Estimate	\$213,363,000	\$183,054,000	\$30,309,000	1,170

Note: Does not contain GSA Rent or Other Rent and Rent Related Activities.

1/Includes FDA's FY 2002 Appropriation and the Counterterrorism Supplemental.

STATEMENT OF BUDGET REQUEST

The Center for Devices and Radiological Health is requesting \$213,363,000 in program level resources for accomplishing its mission activities including:

- Promote and protect the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products;
- Meet all statutory responsibilities for review of new medical devices;
- Assure medical product safety by monitoring the use of all medical devices, and the function and use of radiological health;
- Manage emerging hazards to prevent widespread health and safety threats and ensure safe and effective new technologies;
- Apply the Total Product Life Cycle model across the range of Devices and Radiological Health activities, by covering products from concept to obsolescence;
- Connect to the global public health community, and partner with stakeholders;
- Use science in the regulatory process to the maximum extent;
- Attract and retain a diverse and high quality workforce; and,
- Measure and set targets to maximize the program's impact on public health.

PROGRAM DESCRIPTION

CDRH regulates a wide array of medical devices, from artificial hearts, pacemakers, and drug-coated stents to deep brain stimulators and spinal implants; from dialysis machines and infusion pumps to intraocular lenses and cochlear implants; from robotic surgery devices and stair-climbing wheelchairs to *in vitro* diagnostic devices, radiologic devices and many others. To keep pace with the rapid development of new technology, and to make decisions based on the best scientific information and knowledge available, CDRH routinely consults with experts in the academic community, other government entities, clinical practice, and the military. CDRH also supports initiatives to improve the Nation's ability to respond to bioterrorism and public health challenges. Many of these counterterrorism activities include expediting review of bioterrorism diagnostics, managing product shortages, supporting safe and effective development and use of battlefield and emergency devices, ensuring safe use of people scanners in airports and other security systems, and assessing radiation products for misuse as weapons.

ORA supports CDRH by conducting preapproval inspections of both foreign and domestic establishments and other premarket-related activities such as: bioresearch monitoring of clinical research, preapproval inspections and laboratory method validations needed for premarket application decisions, and inspections of manufacturing facilities to determine if the factory is able to manufacture the product to the specifications stated in the application. The Field conducts

risk-based domestic and foreign postmarket inspections of medical device manufacturers to assess their compliance with Good Manufacturing Practice requirements, and conducts inspections of reproducers of single-use devices. ORA also monitors imported medical devices and radiological products through field examinations or sampling, as needed, to ensure the safety of such products.

In addition to overseeing regulated products on a surveillance or “for cause” basis when a problem is encountered, ORA staff also responds to emergencies and investigates incidents of product tampering and terrorist events or natural disasters that may impact FDA regulated goods. To complement the regular field force, the Office of Criminal Investigations investigates instances of criminal activity in FDA regulated industries. In FY 2006, ORA will expend an estimated \$75,925,000 in budget authority and user fees to support of the Devices and Radiological Health Program.

PERFORMANCE ANALYSIS

During the latest completed performance period, (FY 2004), CDRH met four of its performance targets, and expects to meet the remaining three when the data becomes available in June FY 2006. For more detailed explanation of these goals and results, please see their respective section contained in the Detail of Performance Analysis under the Supporting Information tab.

The Food & Drug Administration Modernization Act of 1997 gives FDA the mandate to replace universal user facility reporting with the Medical Product Surveillance Network (MedSun) that is composed of a network of user facilities that constitute a representative profile of user reports. FDA estimates that there may be as many as 300,000 injuries and deaths annually associated with device use and misuse.

FDA surpassed by 200 percent its long-term outcome goal of expanding patient surveillance by 50 percent by 2008, through increasing the number of patients covered from 17 million to 53 million this year, which will allow for more rapid identification and analysis of adverse events. MedSun is a critical component towards achieving this long-term outcome goal.

Performance Highlight:

Goal Target	Context	Results
Expand implementation of MedSun to a network of 240 facilities (FY 2004 target)	When fully implemented, MedSun will reduce device-related medical errors; serve as an advanced warning system; and create a two-way communication channel between FDA and the user-facility community.	FDA recruited, trained and have functioning 299 facilities for the network

RATIONALE FOR BUDGET REQUEST

This request, for Budget Authority and User Fees, supports various activities that contribute to the accomplishment of program outputs and performance goals, and presents FDA's justification of base resources and selected FY 2004 accomplishments by strategic goals.

PROGRAM RESOURCE CHANGES

Program Account Restructuring

GSA Rent and Other Rent Activities Structure Change

To provide increased flexibility and accountability, eliminate the need for the many reprogramming requests to the Congress, place the accountability for rental costs within the operating program, and to better reflect the total cost of each program, this budget changes the way the GSA Rent and Other Rent-Related Activities budget lines are displayed by incorporating these resources into program level requests.

Office of Regulatory Affairs Estimate and Structure Change

This budget also establishes a single budget line item for the Office of Regulatory Affairs (ORA). To help the field program provide services more effectively, especially by providing much needed flexibility to respond shifting program priorities. This additional flexibility is essential to allow FDA to respond to emerging situations without being hindered in performing its mission critical activities. These activities have been removed from each program line and the Field estimates will be provided under the Office of Regulatory Affairs to reflect the planned spending for each program area.

Budget Authority

Medical Device Review + \$1,796,000 and + 3 FTE

This \$1.796 million requested increase in appropriations for CDRH, along with the \$4.2 million requested under our Field program, will provide the resources needed to allow FDA to reach the required appropriation level for FY 2006 under the Medical Device User Fee and Modernization Act (MDUFMA). MDUFMA specifies a minimum amount of budget authority that must be provided each year in the Device and Radiological Health line of FDA's appropriation.

FDA's budget has undergone a structure change since the passage of MDUFMA and the Device and Radiological Health line of FDA's appropriation is equivalent to the Center for Devices and Radiological Health (without GSA Rent) plus the Devices and Radiological Health Estimate under the Office of Regulatory Affairs. The minimum amount is the FY 2003 base appropriation of \$205,720,000, times the adjustment factor for FY 2006^{1/}. This would yield a minimum that must be appropriated for the Devices and Radiological Products Program for FY 2006 of \$220,823,000 plus the \$138,000 needed in makeup funds from FY 2005 for a total FY 2006 request of \$220,961,000 for the Devices and Radiological Health Program.

^{1/} FDA estimates that adjustment factor for FY 2006 is 1.0734 percent, which is the April FY 2005 estimated CPI/U from the economic assumptions for the FY 2006 Budget divided by the CPI/U from April 2002 (179.8).

This increase in budget authority, coupled with the user fee funds collected for the review of medical device applications, will enable FDA to meet the aggressive Premarket performance goals committed to under the legislation. This increase will help cover the pay increases to maintain the current level of reviewers for the medical device review program.

GSA Rent + \$310,000

To help meet the rising costs of GSA rent, a total increase of \$4,100,000 is requested, of which \$310,000 is for the Center for Devices and Radiological Health. This increase will help cover inflation on FDA's current GSA leased facilities.

User Fees

Medical Device User Fee and Modernization Act (MDUFMA): + \$4,886,000 and 6 FTE

The FY 2006 request for the Devices and Radiological Health program meets the required trigger in the Devices and Radiological Health Program, enabling FDA to collect the MDUFMA user fees that supplement the appropriated portion of the medical device review program. The Agency will be able to continue its efforts to improve the quality and timeliness of the medical review process and promote the delivery of new technologies to the public. The MDUFMA User Fees it collects will allow FDA to continue to:

- Promote public health through major improvements in the review of expedited submissions for medical devices;
- Meet MDUFMA's performance goals and achieve the other prescribed improvements by MDUFMA;
- Provide information system improvements and modernization for the device tracking systems, Image system, other essential systems; and,
- Provide training and professional development for employees and contract with outside experts to ensure that FDA keeps pace with technological change and medical advancements.

Mammography Quality Standards (MQSA): + \$163,000 and -6 FTE

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. Experts estimate that one in eight American women will contract breast cancer during their lifetime. The MQSA, which was reauthorized in October 2004, addresses the public health need for safe and reliable mammography. The Act required that mammography facilities be certified by October 1994, and inspected annually to ensure compliance with national quality and safety standards. The reauthorization codified existing certification practices for mammography facilities and laid the groundwork for further study of key issues that include ways to improve physicians' ability to read mammograms and ways to recruit and retain skilled professionals to provide quality mammograms. The increase of \$163,000 will cover inflation.

JUSTIFICATION OF BASE

USING RISK-BASED MANAGEMENT PRACTICES

FDA will use science-based risk management in all Agency regulatory activities so that it can provide the most health promotion and protection at the least cost for the public. Efficient risk management efforts for FDA's medical device program are detailed below.

Medical Device Review

Premarket applications for medical devices intended for human use are required to be processed within statutorily required time frames. These processes support the Department's priorities to accelerate private sector development of medical technology. In addition, MDUFMA commits FDA to significant improvements in device review performance. 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. With the enactment of MDUFMA, FDA plans to:

- Review premarket application and focus resources on breakthrough medical device products intended for human use;
- Work with industry and other stakeholders to develop best practice documents and policy and guidance documents to make premarket applications more consistent and complete, and to reduce multi-cycle reviews;
- Maintain FDA's small business assistance program as required by the FD&C Act;
- Improve the feedback of post-approval data to premarket reviewers in order to improve the quality and timeliness of premarket reviews;

TPLC – Glucose Monitors

CDRH conducted a comprehensive postmarket literature review to determine the public health impact of new *in vitro* diagnostic (IVD) technology on home glucose monitoring. Focusing on a minimally invasive glucose biosensor that continuously tracks glucose levels without painful finger-stick testing, CDRH was able to determine promising positive trends in diabetic management based on this new device. It also identified some weaknesses in the device clinical trials. FDA is using this information to improve future premarket regulatory reviews and to better understand the strengths and weaknesses of research evaluation in the area of IVDs.

The device's initial market approval was notable for its incorporation of the Center's Total Product Life Cycle (TPLC) goal, use of inter-Office shared hires to complete the expedited PMA review, and support for the Diabetes, Obesity and Cardiovascular Disease Health Initiative.

- Foster education of the workforce on risk management, assessment and communication;
- Incorporate epidemiology expertise into post-approval investigations; and,

- Use postmarket communication to mitigate risk from medical device problems, as has been done through notifications about endotoxin in equipment and devices used in LASIK, preventable paralysis from inappropriate use of absorbable hemostasis devices, and test results on counterfeit surgical mesh.

Third Party Review Program

Third Party 510(k) Reviews are consistent with FDAMA's intent to encourage the use of outside scientific and technical expertise and provide an alternative to FDA review. In addition to being faster than reviews performed exclusively by FDA staff, this option can give manufacturers access to specialized expertise by third parties in areas such as device testing, standards, and foreign regulatory requirements. FDA plans to:

- Encourage industry's use of third party reviews. Sixty-five percent of all 510(k)s are eligible for third party review, but only six percent are submitted through this program. In 2004, the number of 510(k) submissions using the third party review program increased by 34 percent over the prior year;
- Maintain FDA's third party web site that provides information on the Accredited Persons Program;
- Maintain the Third Party Review Board to advise and assess new applicants, reassess existing Accredited Persons, and monitor FDA's periodic auditing of their work.
- Encourage ongoing training for third parties to ensure consistency and quality of their reviews; and,
- Evaluate the amount of agency resources that go into training, reviewing, and interacting with third parties.

Inspections by Accredited Persons

MDUFMA authorizes FDA to accredit third persons (Accredited Persons) to conduct inspections of eligible manufacturers of Class II and Class III medical devices. These Inspections will be conducted independent of third party inspections performed under the current US/EC Mutual Recognition Agreement. FDA has completed or planned:

- Train the Accredited Persons. Approximately 48 representatives from 14 accredited establishments attended an FDA training program in January 2004. Individual training inspections have been and are continuing to be conducted with FDA Performance Auditors after the classroom requirements were met. Accredited Persons will then be ready to conduct independent inspections of FDA regulated establishments. FDA continues to accept and review applications from establishments wishing to be certified as an Accredited Person. FDA sponsored classroom training will continue to be planned as new firms are accepted into the program.
- FDA published draft guidance for establishments to participate in the Accredited Persons program. FDA expects to have this program fully operational in FY 2005. FDA will not be able to estimate the impact of this new program on future inspection coverage until the Accredited Persons have performed independent inspections.

Human Subject Protection

One of the Department's strategic goals is to enhance the capacity and productivity of the Nation's health science research enterprise by strengthening the mechanisms for ensuring the protection of human subjects and the integrity of the research process. An effective, comprehensive Bioresearch Monitoring program is essential for the expeditious development and approval of safe and effective products and to ensure research subject safety.

The Agency continues to leverage scientific capabilities in order to respond and contribute to major breakthroughs in medical device research and technology via continued professional development/ training, and continued stakeholder collaborations. Some of the new high-risk technologies under active human subject research include: implantable cardiac defibrillators, in vitro diagnostic devices that help detect/identify biothreat agents, an artificial heart, and new models of drug-eluting stents. The human subject protection program plans to:

- Ensure follow-up to bona fide complaints of research misconduct that may compromise the safety of human research subjects or subvert regulatory review;
- Enhance the quality and integrity of investigational device research by working with non-compliant firms to develop corrective and preventative actions to improve their human subject protection or research integrity systems;
- Educate the device research community; and,
- Provide professional development opportunities for Agency staff to help them keep pace with clinical research in evolving and breakthrough device technologies.

Bovine Spongiform Encephalopathies (BSE)/Transmissible Spongiform Encephalopathies (TSE)

BSE, widely known as "Mad Cow Disease," is a deadly chronic, degenerative disorder affecting the central nervous system. TSE includes a group of related human and animal diseases for which there are no treatment or preventive vaccines and are fatal to humans and animals. FDA plans to:

- Maintain current Field Investigator's Guidance for Manufacturing Facilities. The current scientific understanding of TSEs and their potential risks are changing rapidly. Resources are needed for educational activities and document revision as our understanding changes to keep the guidance documents and field investigations scientifically accurate;
- Maintain a device tracking/animal materials data base for identifying/tracking devices containing or manufactured from animal-derived source material;
- Examine ways to prevent the transmission of TSE-related diseases during the use and reuse of medical instruments.
- Evaluate decontamination procedures for device manufacturing processes, including equipment and facilities, and for medical instruments; and hold public workshops to engage all interested parties in addressing the issue of decontamination.

International Activities

The increase in device imports and the difficulty in inspecting the majority of foreign medical device establishments have made full implementation of the U.S./European Community (EC) Mutual Recognition Agreement (MRA) a necessity. A successful MRA will help reduce the number of foreign firms FDA staff needs to inspect, while relying on FDA inspections conducted by listed European Unions (EU) Conformity Assessment Bodies (CABS). FDA plans to:

- Implement a pilot program to assess the feasibility of using an internationally harmonized format in the review of submissions for device safety and performance;
- Develop and maintain information about EU-based medical device manufacturers and provide more information about the status of those manufacturers to help expedite product approval;
- Develop a mechanism for recognizing symbols for use in In Vitro Diagnostic Labeling to allow for harmonization of package inserts;
- Continue FDA's participation as a member of the Global Harmonization Task Force.

Genetic Testing

The vast majority of genetic tests are currently not regulated by FDA. The Secretary's Advisory Committee on Genetics Testing recommended increased oversight of genetic testing. FDA participates with the CDC and other agencies to:

- Develop scientific expertise and regulatory strategies for evolving medical device areas such as genetic testing;
- Collaborate with other DHHS agencies as part of an inter-agency working group and as a participant with the CDC on genetics testing; and,
- Participate in the activities of the Secretary's Advisory Committee on Genetics, Health, and Society.

Clinical Laboratory Improvement Amendments (CLIA)

This activity is funded by a portion of the CLIA user fees collected by the Centers for Medicare and Medicaid Services. FDA collaborates with CMS to:

- Categorize commercially marketed in vitro diagnostic test systems; and,
- Determine which in vitro diagnostic test systems can be placed in the waived category under CLIA.

Information Technology

FDA will develop or maintain IT systems that support the premarket review process and postmarket activities:

- **eRadHealth:** This system will allow manufacturers to submit radiation documentation in electronic format, provide risk management prioritization of data, provide trend analyses, and allow data sharing with states and the public. It will permit more efficient use of FDA resources and industry-wide corrections of product safety problems;

- **eMAUDE:** Develop an electronic adverse event reporting system for medical device manufacturers. This will automate the review, analysis and management of the reports received each year from the manufacturers and will permit more efficient use of FDA resources while providing FDA, health care professionals and consumers and other state and Federal agencies with the information necessary to make faster and more thorough risk management decisions;
- ***eRoom:*** eRoom, to be developed for internal use, provides an easy way to review draft documents and provide comments in real time. It allows staff to find precedent setting documents for policy issues, including internal discussions leading to the decisions, along with the final correspondence that goes to industry stating the policy. eRoom allows staff to search electronically for documents from the same manufacturer, the same device type, by year, and by other topics.
- ***Image2000 Document Management System:*** This request will support development of the Image2000 Document Management System, which assists in premarket review and related document-management activities such as archiving and FOI redaction. When fully operational, Image2000 will replace the in-house system, developed in 1991, with state-of-the-art technology, which is vital to the Center's premarket review mission.

EMPOWERING CONSUMERS FOR BETTER HEALTH

Information Technology

CDRH uses innovative information technology to communicate important health messages to consumers. FDA plans to:

- Continue publishing the "FDA & You" electronic newsletter to reach the secondary schools and health education populations; and,
- Maintain the Mammography Program Reporting and Information System, which improves the quality, reliability, integrity, and accessibility of facility certification, inspection, and compliance data. The system also tracks and monitors the accreditation, certification, inspection, and compliance history of facilities. Facility certification information is available to consumers on the mammography website.

PATIENT AND CONSUMER PROTECTION

Another important function of FDA is to identify risks associated with the use of medical products and reduce the occurrence of adverse events. The enhancement of the adverse events data monitoring system and linkages with other health care systems is the first line of defense against medical errors. The following activities support the Department's initiative to improve the quality of health care services:

- Maintain the MedSun network, which is a postmarket surveillance system designed to reduce device-related medical errors by the dissemination of safety information. MedSun also serves as an advance warning system and creates a two way communication channel between FDA and its system participants. The system will be maintained by replacing those facilities that choose to rotate out of the system with new MedSun sites;

- Continue the lab-reporting project to target surveillance, initially piloted in FY 2003 and 2004. This expansion of the lab-reporting project will allow FDA to evaluate procedures for collecting data on problems with laboratory tests and the feasibility of including hospital laboratory staff;
- Maintain technical distribution capabilities to allow the content of "FDA Patient Safety News" to be readily available as a teaching tool. FDA PSN is an Agency-wide monthly television news show that brings vital information on how to improve the safety of drugs, devices, vaccines, and diagnostic products to physicians, nurses, pharmacists, risk managers and educators across the nation. Preliminary results from a recent survey of practitioners who view FDA PSN indicate that 94 percent of respondents used the program's safety recommendations "frequently" (42 percent) or "occasionally" (52 percent);
- Expand the Home Health Care Initiative that addresses medical devices used at home, which will allow for increased knowledge by health care practitioners, consumers, and patients to better understand how medical devices can be safely used outside the clinical environment, which has become a growing trend. Many of the devices were never intended to be used outside the hospital or by lay users;
- Provide human factors risk analysis in premarket and postmarket decision-making to enhance the identification of risks associated with the use of medical products and to reduce the occurrence of adverse events related to use error;
- Provide technical assistance to small medical device manufacturers and provide accessible feedback to industry, health professionals, and consumers. This assistance is provided via Device Advice—the CDRH self-service website for medical device and radiation emitting information—and Comments and Feedback;
- Partner with other Federal agencies, states and private-sector organizations to develop and communicate information that will encourage safe use of medical devices;
- Provide consumers with current and reliable information on radiation emitting electronic products and maintain the Whole Body Computer Technology Scanning website;
- Conduct applied epidemiological research using a variety of methods and databases and provide consultative services to the Agency on issues requiring epidemiological expertise, from systematic reviews of the literature to risk assessments to the design and conduct of observational studies; and,
- Provide guidance to industry on the Alternative Summary Reporting program to ease industry's reporting burden for device-based adverse events that are well known and well documented. By submitting the reports on a quarterly basis in a line-item fashion, industry is relieved of the individual reporting burden; yet the agency can continue to monitor these adverse events on an aggregate basis.

Diabetes, Obesity and Cardiovascular Disease

FDA actively participates in Administration and Department initiatives directed at improving the public health. The efforts will increase the independence and quality of life of persons with disabilities and long-term care needs. FDA plans to:

- Explore whether more effective but “least burdensome” regulatory mechanisms can be put into place for diabetes devices to assist industry in bringing to market new devices to test, monitor, and administer medications for the management and treatment of diabetes;
- Maintain FDA’s Diabetes Information website that provides detailed consumer information about the products that FDA regulates to diagnose and treat diabetes, with links to additional diabetic information. The Diabetes Information website receives approximately 4,000 visits a month;
- Monitor the use and safety of new weight loss technologies through targeted postmarket plans and partnering with NIH and other collaborators in post-approval research and information dissemination;
- Partner with the diagnostics industry, health professionals, and diabetics to assure that safe and effective diagnostics are available that are more accurate, less invasive and easier for patients to use;
- Maintain FDA’s Heart Health Online website that provides consumer information about the products FDA uses to diagnose, prevent, and treat cardiovascular disease, with links to additional cardiovascular information. This site was selected as one of the Biomaterials Network (Biomat.net) top 5 internet sites, based on general quality, scientific value, and suitability to internet browsing and,
- Partner with sponsors on new, promising, investigational weight loss devices, which support the Secretary’s goal to reduce the almost 300,000 U.S. deaths a year associated with obesity and overweight.

Science and Standards

Standards address aspects of safety and/or effectiveness relevant to medical devices. FDA will:

- Promote the use of standards for manufacturing safer and more effective medical products and to speed review and enhance the quality of regulatory decision making. In FY 2003, FDA recognized 25 new standards for a cumulative total of 618; and,
- Develop improved methods to evaluate emerging imaging technologies to allow the sorting out of the differences between old and new imaging technologies from the large variations among patients and among radiologists or mammographers. Critical features of the new CDRH-developed methodology are that it requires no assumptions of data normality data and identifies all sources of variability in present data, which allows study designers to optimally allocate the scarce resources of patients and radiologists in subsequent clinical studies.

MQSA

The MQSA program is directed to the certification of mammography facilities and to annual inspections to ensure that they remain in compliance with established quality standards. FDA plans to:

- Certify new mammography facilities and recertify one third of the approximately 9,100 existing facilities;
- Analyze and act on inspection results to ensure compliance with quality standards;
- Update and maintain data systems to monitor facility accreditation, certification and compliance status; and,
- Fund annual MQSA inspections. Approximately 9 percent of mammography facilities deemed to be governmental entities are funded through budget authority. The other 91 percent of the annual facility inspections are funded through user fees.

MQSA Consumer Outreach

When a Florida mammography facility refused to notify their patients and their referring physicians about a serious risk to human health at its facility, FDA was faced with the challenge of getting the word out to the affected parties in a timely and cost effective manner. With no ability to get access to the patient names and addresses, CDRH staffers worked with other components within FDA to issue a talk paper about the serious situation. On August 23, 2004, the talk paper was posted on the FDA website in English and Spanish. The story was then picked up by a local newspaper and radio station as well as national news media including the Associated Press.

PROTECTING THE HOMELAND -- COUNTERTERRORISM

FDA continues to monitor, evaluate, and follow up on the public health needs of new medical devices or their use in counterterrorism preparedness and response to regulate them in a manner that best serves the public health. These activities support the Department's goals to enhance the ability of the Nation's health care system to effectively respond to bioterrorism and public health challenges. FDA plans to:

- Evaluate the safety and effectiveness of diagnostic test kits that detect biothreat agents as well as other diagnostic and therapeutic devices being developed to address such threats, and evaluate the performance of diagnostic test kits that detect warfare agents being marketed to the public and the government;
- Predict and manage potential device shortages to ensure there are enough critical, commonly used devices, such as rubber gloves, to aid in rescue efforts, and develop mechanisms to use FDA's medical material shortage experts to assist in acquisition of limited critical medical countermeasures during a terrorist event;

- Develop field expertise to sample for contamination of high-risk products such as rubber gloves or surgical masks, and develop test methods for the DOD to test emergency devices for safe use on the battlefield and in civilian emergency care;
- Expand technical assistance to industry and DOD, expedite review, and expand outreach to civilian emergency medical professionals to give them more information about new devices in their field;
- Participate in the development and recognition of standards developed by other agencies such as the CDC, and DOD and outside organizations for use in reviewing and defining performance for test kits;
- Assess the in vitro diagnostic market to determine the number and type of test kits targeted to detect counter terrorism activity that are being marketed to the public and government. This will provide FDA with the capability to identify manufacturers that promote diagnostic devices, to monitor their activities and to act appropriately when unsafe practices are detected; and,
- Maintain Continuity of Operations emergency response plans and emergency response training, in conjunction with HHS and FDA, to identify the essential functions that need to be maintained to monitor and respond to a terrorist event or emergency situation.

Radiological Counterterrorism and Radiation Safety

FDA continues to monitor and assess radiation-emitting products for misuse as weapons, for safe use in deterrence and detection activities, and for the safe use and availability of new and existing radiological products. FDA plans to:

- Continue implementation of the FDA Emergency Counterterrorism Preparedness and Response Plan for radiation;
- Assist the Transportation Security Administration, Customs, and the National Institute for Occupational Safety and Health to assure worker safety during use of non-intrusive search products which emit x-rays and the use of x-ray cargo screening and electromagnetic screening products;
- Conduct field surveillance of x-ray security screening products subject to the FDA cabinet x-ray standard;
- Develop an electronic reporting system to reduce industry reporting time and FDA review time, and provide sufficient radiation data on security products and potential weapons to assure safety of workers and the public and to respond quickly in a terrorist event;
- Develop a mandatory standard for x-ray personnel security screening equipment based on the voluntary standard prepared by FDA, State and industry representatives;

- Develop a radiation safety consensus standard for cargo screening and other new non-intrusive search products that emit x-rays, neutrons or gamma rays;
- Identify safer tanning techniques. FDA's optical radiation laboratory is conducting a human study entitled "Optimization of UV Exposure Patterns" in order to gather data to support a reduction in exposure of the public from artificial tanning devices. This data will be used to modify the present FDA and ISO standards for sunlamp products;
- Coordinate with the Nuclear Regulatory Commission on laser safety of power plant security and all emergency preparedness exercises;
- Continue to evaluate the vulnerability of electronic medical implants to new security scanners, and assist in drafting a national safety standard for security screening devices. This work is being adopted by the FAA in deciding the purchases of walk through metal detectors at all of the nation's airports;
- Encourage discussion among Federal agencies with radiation control responsibilities, through the Interagency Steering Committee on Radiation Standards, to develop consistent policies on appropriate use of security products that may expose the public to ionizing radiation;
- Encourage private sector development of radiation measurement instruments to facilitate radiation testing of security screening and non-intrusive search products; and,
- Prioritize and leverage FDA's radiation protection efforts with state governments, professional societies, and other Federal agencies.

IMPROVING FDA'S BUSINESS PRACTICES

Build infrastructure, hire and train new staff, and take other steps to lay the groundwork for a strong FDA that ensures a world-class professional workforce, effective and efficient operations, and adequate resources to accomplish the Agency's mission. FDA plans to:

- Implement the goals accompanying MDUFMA that address FDA's need to build up its infrastructure to have a successful review program;
- Train new and current staff to ensure that FDA reviewers develop and maintain the skills necessary to understand and keep pace with technologies that are rapidly developing and becoming more complex;
- Provide leadership to industry in the development of innovative approaches for the evaluation of medical device safety and effectiveness;
- Prepare and disseminate information on how FDA will regulate emerging technologies, and to help support FDA's role in international harmonization on emerging technologies; and,
- Support the President's Management Agenda and competitive sourcing A-76 efforts by performing cost comparison studies for identified functions.

SELECTED FY 2004 ACCOMPLISHMENTS

USING RISK-BASED MANAGEMENT PRACTICES MUFMA IMPLEMENTATION

Medical Device User Fee and Modernization Act of 2002, P.L. 107-250

To provide more timely and cost-effective review of new medical devices, FDA has worked to implement, which allows FDA to collect user fees from companies that submit medical device applications. FDA uses these additional funds to hire more staff and develop better systems to support more effective and timely review. The law requires FDA to pursue a complex and comprehensive set of review goals. Each year brings additional goals that are more aggressive than the previous year. FDA must report on performance relative to the specified goals at the end of each year. In FY 04 CDRH met all the MDUFMA statutory deadlines and maintained or improved device review performance in areas not covered by official performance goals.

To facilitate our interactions with industry in the coming years, the agency has issued guidance documents on premarket approval applications, premarket assessment of pediatric medical devices, how FDA and industry actions on premarket notification (510(k)) submissions affect the agency's assessment, and use of validation data in 510(k) submissions for reprocessed single use devices. (See <http://www.fda.gov/cdrh> for the specific guidance documents.)

FDA also has committed to an ambitious long-term goal that is designed to reduce the average total time for marketing approval for medical devices. This goal has two targets, standard and expedited premarket applications. The target reduction for each is an average of 30 days, which is similar to priority approval for drugs and biologics. In FY 2004 FDA achieved that goal and more—a 33 day reduction in average approval time compared with the baseline of fiscal years 1999-2001.

- **MDUFMA FY 04 Documents, Notices and Reports** - In FY 04 CDRH developed twenty-three Federal Register notices and guidance documents relating to MDUFMA implementation, and published a six internal “Blue Book” memos to provide guidance to FDA staff. In addition, for FY 2004, four reports were due to Congress:
 - A one-time report to Congress on the “timeliness and effectiveness” of device reviews by centers other than CDRH.
 - Annual report to Congress on the Office created to coordinate and monitor the review of combination products - completed October 2003 for FY 2003.
 - Annual Financial Report to Congress – completed March 2004 for FY 2003.
 - Annual Performance Report to Congress – completed April 2004 for FY 2003.

A complete listing is available at <http://www.fda.gov/cdrh/mdufma/index.html>.

- **FDA Completed Review of Reprocessed Single Use Devices** - In November 2004 FDA announced that it had completed its review of supplemental validation data submitted by firms that reprocess medical devices originally intended for single use only (SUDs). MDUFMA required that reprocessors of certain types of previously cleared reprocessed SUDs must submit supplemental data to the FDA. Supplemental cleaning, sterility, and functionality validation data were needed for FDA to review in order to determine if these

reprocessed devices should continue to be legally marketed. After a careful review of the submitted data, FDA determined that while many of the devices can continue to be legally marketed, a significant number can no longer be commercially distributed. Some 1,800 models of reprocessed single use devices required validation data under MDUFMA. (<http://www.fda.gov/cdrh/Reuse/svs/index.html>)

- **Scientific Expertise** – Fifty-six new employees were hired in FY 2004, bringing the total number of MDUFMA hires to 130, while the Medical Device Fellowship Program brought sixty-four new experts to FDA. These engineers, medical officers, statisticians, scientists, project managers, consumer safety officers, program support and administrative staff increased CDRH’s scientific and technical capabilities.
- **Third Party Inspection Program** – During FY 2004, FDA:
 - Implemented the MDUFMA authority to accredit third parties to conduct inspections of eligible manufacturers of Class II and Class III medical devices. This authority will help FDA focus its limited resources on higher-risk inspections and give medical device firms that operate in global markets an opportunity to more efficiently schedule multiple inspections;
 - Issued guidance to implement the new authority and published criteria for Accredited Persons in the Federal Register; and,
 - Selected 15 third parties to participate in the program following the FDA review board’s rating of Accredited Persons applications.
- **Annual Stakeholder Meeting** - The 2nd Annual Stakeholder Meeting on the Implementation of the MDUFMA Act of 2002 took place in November 2004. Participants from the medical device industry and FDA gathered to discuss the agency's progress in implementing the various MDUFMA provisions, including the guidance FDA has issued on the new law.

SCIENCE-BASE RISK MANAGEMENT

FDA used science-based risk management in all Agency regulatory activities to provide the most cost effective health promotion and protection for the public. Premarket review accomplishments exemplify those efforts.

De Novo Process

- **Screening for Newborns** - FDA approved, through the *de novo* process, the first device available to screen newborn infants for inherited abnormalities of amino acids and for the presence of free carnitine and acylcarnitines, the NeoGram Amino Acids and Acylcarnitine Tandem Mass Spectrometry Kit. Babies born with these rare inherited abnormalities may have developmental delay, seizures, mental retardation and death, which may show up in the first weeks, months or years of life. The premarket review challenge for this device was the rare occurrence of many of the abnormalities and the lack of a predicate device to allow for its review as a 510(k) product. With literature, practice standards and public health laboratory experience support, the analytical features and selected clinical evaluation of the

device were used to establish performance. FDA then took advantage of the automatic reclassification of class III devices (the *de novo* process) to bring the product to market with a streamlined 510(k) review. The result is the availability of a powerful new diagnostic tool for newborn screening with clear labeling, proscribed quality control, and with state of the art performance that will protect the health of tens or even hundreds of thousands of newborns each year.

- **HAV Assays** - FDA worked with industry to reduce the regulatory burden for *in vitro* diagnostic hepatitis A virus assays used by clinical laboratories. On FDA's recommendation, a reclassification petition was filed with the FDA by Beckman Coulter, Inc. in October 2003. Less than one year later, in August 2004, a draft Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus was published in conjunction with a Federal Register notice announcing the proposal to reclassify HAV serological assays from class III (high risk) to class II. This is an example of FDA's ongoing effort to create a risk-based approach toward review that is consistent with the "least burdensome" but still scientifically sound regulatory process outlined in the Modernization Act of 1997. It also is an example of FDA's use of collaboration with industry to leverage resources to help get its job of protecting and promoting public health done.

Least Burdensome Path

- **CAD System for Lung CT** – The first computer-aided diagnosis (CAD) system for detecting lung nodules on CT scans, the ImageChecker® CT CAD Software System, was given FDA premarket approval in spring of 2004. This device is designed to assist radiologists by cueing suspicious regions in the hundreds of images contained in a scan, thus allowing them to reduce the number of missed nodules that might otherwise occur when they interpret a lung CT scan. FDA played a primary role in developing the statistical methodology for assessing the difference in a radiologist's performance when working unaided versus aided with the CAD device. Adopting FDA's methodology, the manufacturer showed that the device could significantly improve performance. Moreover, the methodology provided the least burdensome path to the marketplace in terms of the numbers of patient cases and radiologist readers required to rigorously assess system performance. Anticipating this and other CAD system applications for CT scans, FDA scientists have spent several years advancing the state of the art and getting consensus among peers on the statistical methods for assessing these technologies. This effort helped to speed the path to market for these technical advances.

Federal Advisory Committees

- **CDRH held 21 Federal Advisory Committee panel meetings in 2004.** – These panels of external experts reviewed and made recommendations to FDA on 20 PMAs, one 510(k), two reclassification petitions, and three general issues. Among the topics addressed at the meetings were issues associated with significant breakthrough technologies for pulmonary tumor detection, a total artificial heart, and uterine fibroid ablation.

TECHNOLOGY AND INNOVATION

Device Approvals

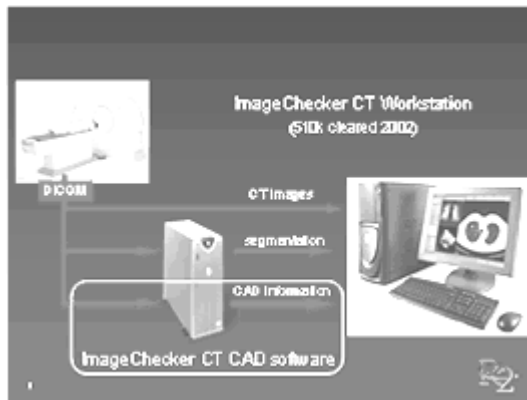
In FY 2004 CDRH approved and cleared thousands of devices used to diagnose and treat a wide variety of medical conditions, including:

- **Philips HeartStart Home OTC Defibrillator** - *the first over-the-counter AED cleared by FDA for lay users.*

The HeartStart Home Defibrillator, manufactured by Philips Medical Systems, is a small, lightweight [automatic external defibrillator \(AED\)](#) specifically designed for use without a prescription. Approved September 2004, the device shocks the heart to restore rhythm in cardiac arrest victims. The HeartStart home defibrillator is cleared for use on adults or on children who are at least eight years old or older or who weigh at least 55 pounds. Special small pads are available by prescription for pediatric use. This device was the first over-the-counter AED cleared by FDA for lay users.



- **ImageChecker® CT CAD Software System** - *the first image analysis system designed to help radiologists review computed tomography (CT) images of the chest to aid in the detection of solid nodules in the lungs.*



In July 2004, FDA approved the ImageChecker CT CAD software system, manufactured by R2 Technology, Inc. The device is a new image analysis system designed to help radiologists review computed tomography (CT) images of the chest. The software system, the first of its kind for use with CT chest exams, aids in the detection of solid nodules in the lungs. Lung nodules can be malignant. The system uses CAD software to analyze CT images that the radiologist has previously reviewed, highlighting areas of the image that appear to be solid nodules. Because the device works independently of the radiologist, it can detect suspect areas that the radiologist may have overlooked.

- **ExAblate 2000 System** - *a new medical device that uses magnetic resonance image guided focused ultrasound to target and destroy uterine fibroids, which are non-cancerous masses located in the uterus.*

The ExAblate® 2000 System, by InSightec, Ltd., is a medical device that uses MRI-guided, focused ultrasound to target and destroy non-cancerous uterine fibroids. Approved in October 2004, it is intended to treat women who have completed child bearing or do not intend to become



pregnant. ExAblate® 2000 is non-invasive surgery procedure. It spares the uterus and is an alternative to [myomectomy](#), [hysterectomy](#), watchful waiting, [hormone therapy](#), or [uterine fibroid embolization](#). The procedure generally lasts about three hours.

- **DeBakey VAD® Child** - *the first miniaturized heart pump (ventricular assist device) approved for use in children aged 5 to 16 who are awaiting a heart transplant.*

In February 2004, FDA approved the DeBakey VAD® Child by MicroMed Technology, Inc. under the humanitarian device exemption program. The DeBakey VAD® Child is intended for both home and hospital use in children who are between 5 and 16 years old, and who have end-stage left ventricular failure requiring temporary mechanical blood circulation until a heart transplant can be performed. The device may allow children with severe left ventricular failure to survive long enough to receive a donor heart.



- **AmpliChip Cytochrome P450 Genotyping Test** - *the first microarray approved by FDA and the first test for use of genomic data for personalized medicine.*



In December 2004, FDA cleared for marketing the AmpliChip Cytochrome P450 Genotyping Test made by Roche Molecular Systems, Inc. The test is cleared for use with the Affymetrix GeneChip Microarray Instrumentation System, manufactured by Affymetrix, Inc. The AmpliChip Cytochrome P450 Genotyping test is the first DNA microarray test to be cleared by the FDA that allows physicians to consider unique genetic information from patients in selecting medications and doses of medications for a wide variety of common conditions such as cardiac disease, psychiatric disease, and cancer. The test analyzes one of the genes from a family of genes called cytochrome P450 genes, which are active in the liver to break down certain drugs and other compounds. Variations in this gene can cause a patient to metabolize certain drugs more quickly or more slowly than average, or, in some cases, not at all. The specific enzyme from this family that is analyzed by this test, called cytochrome P4502D6, plays an important role in the body's ability to metabolize some commonly prescribed drugs including antidepressants, anti-psychotics, beta-blockers, and some chemotherapy drugs. The test is not intended to be a stand-alone tool to determine optimum drug dosage, but should be used along with clinical evaluation and other tools to determine the best treatment options for patients.

- **QuickELISA Anthrax-Pa Kit** - *the first rapid serum antibody test for anthrax.*



The Anthrax Quick ELISA test kit, approved June 2004, detects antibodies produced during infection with *Bacillus Anthracis* – the bacteria that causes anthrax. The test, manufactured by Immunetics Inc., provides an easy-to-use clinical laboratory tool for assessing whether patients have been infected with anthrax.

- **NeoGram Amino Acids and Acylcarnitine Tandem Mass Spectrometry Kit** - *the first pediatric device for neonatal screening for general inborn errors of amino acid metabolism.*

In August 2004, FDA cleared for marketing the NeoGram Kit, a laboratory blood test that will help doctors screen newborn infants for a variety of inherited diseases. The kit helps detect inborn errors in metabolism by measuring levels of amino acid, free carnitine and acylcarnitine. Abnormally high amounts of these substances, or abnormal patterns, may indicate different disease states including, but not limited to, phenylketonuria and maple syrup urine disease, medium chain Acyl-CoA dehydrogenase deficiency, isovaleric acidemia, homocystinuria and hereditary tyrosinemia. The symptoms of the diseases can include developmental delay, seizures, mental retardation and death. With early identification, many of the symptoms may be significantly reduced with improved long term outcome and improved quality of life.

- **CellSearch™ Epithelial Cell Kit / CellSpotter™ Analyzer** - *a new biomarker for determining survival in patients being treated for end stage breast cancer.*



The CellSearch™ Epithelial Cell Kit / CellSpotter™ Analyzer by Veridex, LLC, a Johnson and Johnson company, was cleared for marketing in January 2004 for breast cancer patients to monitor and to help determine the effectiveness of the cancer treatment. The CellSearch™ Epithelial Cell Kit helps the pathologist identify Circulating Tumor Cells (CTC) blood. The CTC are then counted by the pathologist with the aid of the CellSpotter™ Analyzer. The more CTC there are in the blood, the less effective the cancer treatment is believed to be.

- **CEDIA® Sirolimus Assay** - *the first assay for a new immunosuppressive drug in over a decade.*

Approved July 2004, the CEDIA® Sirolimus Assay, manufactured by Microgenics Corporation, is a lab test that can be used to measure concentration of the drug, [sirolimus](#), in blood. This test is used as an aid in the treatment of kidney transplant patients taking sirolimus. This is the first FDA cleared sirolimus assay using immunoassay technology that can be used in most central laboratories. Until now, sirolimus tests were performed only by specialized reference laboratories. The assay can be used for kidney transplant patients who are taking sirolimus, at any time when estimating the blood level of sirolimus might help manage treatment. The assay is used together with other lab tests and patient evaluations to help determine if a patient is receiving an appropriate amount of sirolimus. The assay should not be used alone to make treatment decisions. It should be used along with clinical evaluation and other lab tests.

- **OraQuick® Advance Rapid HIV-1/2 Antibody Test** - *the first point of care test for this antibody and the first test suitable for general field use.*



In June 2004, FDA granted a Clinical Laboratory Improvement Amendments (CLIA) waiver to the oral HIV test by OraSure Technologies (approved by CBER). The waiver extended the availability of the OraQuick Rapid HIV-1/2 Antibody Test from 38,000 laboratories permitted to perform the test

to more than 100,000 sites, including physician offices, HIV counseling centers and community health centers.

- **Ventana® Medical Systems' PATHWAY Anti-c-KIT (9.7) Primary Antibody** - *the first IHC (immunohistochemical) marker to assess in diagnosis and treatment selection in patients with a rare GI tumor.*

Approved August 2004, the PATHWAY Anti-c-KIT (9.7) Primary Antibody, manufactured by Ventana® Medical Systems, Inc, contains an antibody used in a lab test that can help identify patients with [gastrointestinal stromal tumors \(GISTs\)](#) and select patients eligible for treatment with the FDA approved cancer drug [Gleevec®/ Glivec® \(imatinib mesylate\)](#). The antibody detects a protein in the body that stimulates cancerous tissue cell growth (c-KIT tyrosine kinase). The presence of this protein indicates a diagnosis of cancer, in association with other clinical information, and indicates eligibility for GISTs cancer treatment with Gleevec®/Glivec®.

510(k) Workshop for New Manufacturers

- **FDA worked collaboratively with members of industry** to host a workshop on 510(k) submissions. Held in conjunction with the annual meeting of the Association of Medical Device Manufacturers, the workshop was designed to help companies new to the IVD industry learn how to develop and submit good 510(k) submissions. Both FDA and industry believe that helping companies understand good trial design and how to develop submissions conforming to FDA administrative and scientific requirements will produce more reliable and rapid reviews which will benefit all. The 2004 workshop was attended by more than 75 members of industry, was highly rated by attendees, and stands as a paradigm for successful outreach, transparency in work processes, and interactive learning.

Third Party Review Program

- **FDA increased the use of the Third Party Review Program** for 510(k) submissions. In FY 2004, FDA received 255 submissions, a 34 percent increase over the industry's use of the program in FY 2003, and twice that of FY 2002. This program contributed to a more rapid market entry for products using third party reviews since they receive marketing clearance approximately 30 percent faster, on average, than comparable 510(k)s reviewed entirely by FDA. In FY 2004, FDA implemented actions to improve the quality and consistency of third party reviews and to facilitate FDA's timely action on these submissions. They initiated quarterly telephone conferences with all third parties to discuss issues and answer questions; issued an updated guidance document on conducting and documenting reviews; and developed and conducted training seminars for FDA staff and third party reviewers.

Critical Path Workshop

- **Workshop Held on Drug-Diagnostics Translational Research** – The new field of pharmacogenetic research will enable pharmaceutical companies to develop drug treatments that precisely target the needs of particular patient populations. By linking drug treatments to diagnostic tests that can accurately identify appropriate receptive patients, pharmaceutical companies aim to decrease drug adverse events, increase drug response rates, and ultimately

save healthcare dollars. In July 2004, FDA initiated a national workshop on the co-development of drugs and diagnostics to give stakeholders a public venue for scientific suggestions and concerns about FDA regulatory practices in this important and growing new area. The proceedings of this conference are being used to develop guidance to ensure that this type of research translates in a rapid and cost-effective manner to new joint products that can quickly enter the medical marketplace.

RISK-BASE SCIENCE AND PROTECTING THE PUBLIC

Human Subject Protection

One of the Department's strategic goals is to enhance the capacity and productivity of the Nation's health science research enterprise by strengthening the mechanisms for ensuring the protection of human subjects and the integrity of the research process. In response, the Division of Bioresearch Monitoring's Research Misconduct program halted research associated with high risk investigational devices such as hip and knee implants for the elderly, devices for plugging holes in pediatric patients' hearts, lasers used for surgical procedures in the eye, coronary stents, ultrasound surgical devices for uterine fibroids, and diagnostic kits for infectious disease.

- **FDA's Application Integrity Policy** - FDA's Application Integrity Policy is applied to firms that have engaged in wrongful acts that raise significant questions regarding data reliability or human subject protection in research or marketing applications submitted for FDA review. FDA stops substantive scientific review of pending applications and may ask the firm to withdraw any approved applications until violations have been satisfactorily corrected and procedures and controls that will prevent further recurrence of these violations have been implemented. FDA placed three firms on its Application Integrity Policy List. As a result, one firm withdrew six suspect applications for orthopedic prostheses; FDA stopped another firm's research on a pediatric device; and FDA suspended review of a pending application for an infectious disease diagnostic device.
- **FDA's Early Intervention Program** – Initiated a program that focused on real time inspections (conducted *during* the research phase of an investigational device exemption (IDE)) for active device research involving exploitable populations such as pediatric and physically challenged subjects, as well as studies involving novel or breakthrough technologies. Normally bioresearch monitoring inspections are done after the research has been conducted and data submitted to FDA with a premarket approval application. Under this initiative, the inspection assignments are issued as the research is being conducted so that adjustments can be made during the research rather than after to help prevent improper research activities from harming patients and impeding the process for advancing medical technology.
- **Unapproved Pediatric Device Removed from the Market** - FDA stopped the research on a pediatric device to treat a congenital heart defect when inspectional findings disclosed that the sponsoring firm had failed to report two deaths that occurred with the device before FDA had approved it for use in research. FDA also found that several physicians had implanted infants and children with the device without FDA or institutional review board (IRB) approval and without informing the children's families that they had used an investigational

device. While use of the unapproved device could negate the need for open heart surgery in some cases, not all of the clinical outcomes were positive. The FDA investigation prompted the hospital's IRB to conduct their own internal investigation, resulting in dismissal of two participating doctors and a senior administrator, and termination of the research. FDA's follow up inspection of the device manufacturer revealed other physicians who had been shipped the unapproved device. Appropriate FDA regulatory and administrative response resulted in an unapproved device being removed from the market, and notification and follow-up for pediatric patients. Further research of this unapproved device will be conducted under a carefully designed, FDA-IRB approved clinical trial.

Import Monitoring and Inspections

During FY 2004, FDA continued to enhance risk-based management of the import monitoring and inspection program in order to assure the safety of medical products manufactured for use by American consumers.

- **Management of Inspection and Enforcement Actions** – FDA created and implemented a risk-based management program for inspection and enforcement actions which will improve decisions made in regulating and monitoring the medical device industry. The new program will impact how FDA prioritizes inspections and identifies and prioritizes other types of regulatory activities, such as device recalls, that present the greatest risk to public health.
- **Risk Assessment Criteria Developed** – As part of the new risk-based management program, FDA used the ISO standards' definition of risk as a foundation in developing its risk assessment criteria. This definition shows risk to be a combination of the probability of occurrence of harm and the severity of that harm. Harm is a negative effect on a person or person's health due to an unsafe or ineffective device, reduction in a device's safety/effectiveness, clinical benefit, fitness for use, improper use, or quality. FDA's new risk assessment criteria focuses its limited field resources on those medical devices and manufacturers that present the greatest risk to public health.
- **Work Planning Prioritization** – FDA developed a prioritization process proposal for work planning using Center-wide risk assessment criteria, and implemented an inclusive risk-based inspection work plan process. This process ensures that all Center program offices are afforded an opportunity to provide input into prioritizing special emphasis inspections.
- **New Division of Risk Management Operations** – The Division of Risk Management Operations was created within the Office of Compliance to focus more attention on risk management activities and support. The new division includes a Risk Management and Analysis Branch that will focus on collecting data from systems already available, but not linked, to analyze and present findings that can be used in the risk-based decision making process. In addition, the Branch will monitor program outcomes, analyze current medical device compliance programs and identify the need for more effective medical device compliance programs.

- **Reduced Inspection Delays** – Reduced premarket inspection delays, from 53 percent in FY 2003 to 15 percent in FY 2004 despite foreign inspection travel restrictions. This was achieved through improved communication and coordination with ORA management including reporting current status of inspection assignments for early intervention of problem areas, awareness of mandated timelines, and the assignment of PMA coordinators in the district offices.
- **Inspections for Reprocessed SUDs** – Inspected over 100 randomly identified U.S. hospitals to determine their compliance with the Quality System regulation for the reprocessing of single use devices. The inspections found no hospitals currently reprocessing SUDs.

Transmissible Spongiform Encephalopathy (TSE)

- **Evaluation of Prion Decontamination Procedures** - Creutzfeldt-Jakob disease (CJD,) a human form of TSE that occurs worldwide, is a rapidly progressive, invariably fatal neurodegenerative disorder believed to be caused by a prion protein. The World Health Organization has developed infection control guidelines for CJD that include the destruction of heat-resistant surgical instruments that come in contact with high-infectivity tissues. Since this safest and most unambiguous method may not be practical or cost effective, FDA scientists examined the effects of using aggressive decontamination techniques on the instruments instead. The study results, including aggressive decontamination techniques that can be used as alternatives to the destruction of heat-resistant surgical instruments that come in contact with high-infectivity tissues, were published in the peer-reviewed scientific literature. A full report on this study is available on the CDC website. (See http://www.cdc.gov/ncidod/diseases/cjd/cjd_inf_ctrl_qa.htm). FDA's data are the basis of the CDC website's cautionary warnings on TSE.

International Relations

- **Science Reviewer Residency** – FDA developed and implemented a training residency program in the Office of Device Evaluation for scientific reviewers from Japan and China. Training support for these multi-month residencies was provided by all five operating divisions to help bring these global harmonization partners into recognition and understanding of the regulatory procedures for FDA devices.
- **CAB Auditors** – Under the US/EU Mutual Recognition Agreement to facilitate transatlantic trade, trained and evaluated European Union Conformance Assessment Body (CAB) auditors through the joint inspection program, and established a team to conduct on-site evaluations of United States CABs.

Clinical Laboratory Improvement Amendments (CLIA)

- **CLIA** established quality standards for all laboratory testing to ensure accurate, reliable and timely patient test results regardless of where a test was performed. Of central importance to the CLIA program is the assignment of a complexity category to commercially marketed diagnostic tests. The tests are categorized into one of three CLIA regulatory categories based

on their complexity (i.e., potential risk to public health,) and laboratories may only purchase and use a particular test based on the laboratory's level of CLIA certification. Since FDA reviews the premarket applications for these tests, streamlining the CLIA application process necessitated a transfer of responsibility for complexity determinations from CDC to FDA. During 2004 FDA completed the delegation of authority to FDA for CLIA complexity determination and finalized a 5-year Interagency Agreement with CMS for CLIA waiver authority.

EMPOWERING CONSUMERS FOR BETTER HEALTH

FDA continued to improve communication with consumers by providing increased access to information on regulated products and health issues on its FDA websites, in newsletters, through increased outreach efforts, and through operational initiatives within CDRH. These efforts are helping consumers make smarter healthcare decisions.

OUTREACH ACTIVITIES

- **FDA Patient Safety News (PSN)** - FDA Patient Safety News (FDA PSN), a monthly video news show distributed by FDA to health care practitioners is a major agency vehicle for communicating safety messages on medical products. Now in its third year of production, incorporates stories from CDER, CDRH and CBER on medical errors, patient safety, recalls and alerts, and newly approved drugs, devices and biological products. CDRH leads the production of FDA PSN, which this year received an Award of Excellence from National Association of Government Communicators. The show is broadcast each month on several medical satellite TV networks that bring continuing education for health professionals to over 4,000 U.S. hospitals and long-term care facilities. The show also has its own web site (www.fda.gov/psn), which receives about 6,000 "hits" per month. In addition to searching stories on the site, users can report problems through MedWatch.
- **FDA & You** - "FDA & You" is published in Fall, Winter, and Spring/Summer on the CDRH Internet at <http://www.fda.gov/cdrh/fdaandyou> and is targeted towards the secondary schools population and the health educator population.
- **Cardiovascular Disease** - FDA's Heart Health Online is the Agency's newest disease-specific website. Its purpose is to provide consumer information about the products used to diagnose, prevent, and treat cardiovascular disease. <http://www.fda.gov/hearthealth/>
- **Pediatric Medical Devices** - The new Pediatric Medical Devices website provides information and guidance on pediatric devices at <http://www.fda.gov/cdrh/pediatricdevices/>.
- **Cochlear Implants** - FDA's new Cochlear Implants website, <http://www.fda.gov/cdrh/cochlear/whatare.html>, purpose is to [describe cochlear implants](#), link to [FDA-approved implants](#), tell the [benefits and risks](#) of cochlear implants, and provide news about cochlear implant [recalls and safety issues](#).

- **Home Health Care** - FDA has asked all manufacturers of infusion pumps to submit instructions for use and basic pump information for every pump marketed during or after 1984. Once collected, the pump information and instructions will become part of FDA's publicly accessible home health care device website (www.fda.gov/cdrh/cdrhhhc/.) Providing accessible information on this website will increase the likelihood that users—home health nurses, patients, and patients' families—will have the pump information and instructions needed to help ensure the safe and effective use of infusion pumps in the home.

PATIENT AND CONSUMER PROTECTION

During 2004 FDA continued to work to reduce the risks associated with FDA-regulated products in order to improve patient and consumer safety. This work has included such efforts as basic research, development of guidances, and outreach efforts to the medical community and to industry. Examples of patient safety accomplishments are described below.

Collaboration with the Center for Disease Control and Prevention (CDC)

- **Evaluation Protocol and Detection of Vancomycin-resistant S. aureus** – FDA and CDC became aware of three cases in which mutation in the important disease causing bacteria Staphylococcus aureus prevented automated test systems from detecting if the bacteria were sensitive or resistant to the standard treatment antibiotic, Vancomycin. This test failure had the potential to cause errors in treatment with serious consequences since Vancomycin-resistant S. aureus (VRSA) is difficult to treat and has the potential to spread broadly in healthcare settings, causing outbreaks of infection ranging from minor skin infections and abscesses, to life-threatening diseases such as pneumonia, meningitis and septicemia. Because of the significant clinical and public health risk involved, CDC and FDA immediately alerted both users and manufacturers to the potential failure of the devices to detect VRSA. Through a collaborative effort, the two agencies developed an evaluation protocol and worked with all manufacturers to address the detection problem. The cooperation and collaboration between CDC and FDA enabled all clinical and reference laboratories to introduce corrective actions; provided manufacturers with a system for demonstrating how they could use their devices to correct this problem; and averted major clinical and public health problems in a timely and efficient manner.

Laboratory Investigations

- **Testing Of Counterfeit Surgical Meshes** - Surgical meshes are used to cover internal body defects, and following implantation, tissue re-growth and healing reinforce the mesh repair. In fall 2003, it was discovered that some patients had been implanted with a counterfeit mesh, putting them at serious risk of infection or injury because the safety and effectiveness of the counterfeit mesh had not been established by the FDA or anyone else. To evaluate the risk, FDA compared the counterfeit mesh's chemical and mechanical properties to those of polypropylene meshes with well-established safety records. Laboratory data on cytotoxicity, porosity, weave dimensions and structure established that the counterfeit mesh did not differ significantly in any measurements from approved commercial meshes. The laboratory results were also utilized in the investigation of these products.

MedSun

- **New Programs** - FDA increased efforts to educate the MedSun sites about the importance of adverse event reporting for patient safety and about safety issues with medical devices. In FY 2004 MedSun developed a number new programs, including additional training, a workshop on electro-surgical units, a project to evaluate common problems with sutures, an engineering audio conference, a collaboration with the research organization ECRI on automatic suture devices, a study on pulmonary catheters, a study on drug eluting stents, and a pilot of the LabSun program for clinical laboratory reporting.

Public Health Issues

- **New Website on Surgical Staplers** – Each year over the past 5 years there have been 8,000 to 9,000 adverse event reports related to surgical staplers. FDA’s new website on surgical stapler adverse events is available at (www.fda.gov/cdrh/surgicalstapler/index.html) and includes information on stapler malfunctions, results from a CDRH analysis of 112 MDR death reports over seven years that were attributable to surgical stapler failures, and a link to FDA’s MedWatch Program to report problems.

Mammography and Radiological Health

- **Improved MQSA Compliance/Enforcement Strategy** - FDA developed an improved MQSA compliance/enforcement strategy that focuses on serious observations, appropriate enforcement actions, and the use of pre-warning Letter (WL) follow-up inspections. In the past, WLs were issued in some situations for less significant violations, and relatively few enforcement actions taken when a WL was issued. FDA agreed that post-inspection focus would now be on the facility’s history, the most significant current observations, meaningful enforcement, and increased pre-WL follow-up inspections. The new strategy has resulted in: quicker facility response to serious observations; more effective correction motivated by the prospect of a follow-up inspection for which the facility would be charged; and no increase in work for the District Offices to reach an acceptable facility response for violations for which the Agency is committed to take enforcement action.
- **Mammography Quality Standards Reauthorization** – In October 2004, President signed The Mammography Quality Standards Reauthorization Act of 2004, extending the standards through 2007 and codifying existing certification practices for mammography facilities and laying the groundwork for further study of key issues that include ways to improve physicians’ ability to read mammograms and ways to recruit and retain skilled professionals to provide quality mammograms.

PROTECTING THE HOMELAND -- COUNTERTERRORISM

FDA continued to evaluate and improve its counter-terrorism activities by revising emergency preparedness procedures for both medical devices and radiological health, working with other Federal, state, and local government agencies to strengthen preparation and response capabilities, managing product shortages, supporting the development and use of safe and effective x-ray screening devices, and ensuring continuity of operations.

EMERGENCY PREPAREDNESS

- **Detection of a Biothreat Pathogen with First Anthrax Quick Elisa Test: Collaboration with CDC** – In June 2004, FDA cleared the first Anthrax Quick Elisa test. Manufactured by Immunetics Inc. of Boston, it detects antibodies produced by a *Bacillus anthracis* infection in less than one hour and is an important new diagnostic tool in the ability of U.S. laboratories to address a serious potential biothreat pathogen. Before FDA approval, very few laboratories other than the CDC and the U.S. Army had the ability to test blood for antibodies to anthrax. The new test will now be available for use in state and private laboratories. This clearance is the result of a collaborative interaction between FDA, CDC and a commercial partner, showing how such cooperative work can lead to approval of diagnostic tests for biothreat agents and emerging infectious diseases.
- **Improved Process to Identify Shortages** – FDA developed a new, more responsive process of identifying potential device shortages and the responsibilities for managing the shortages during public health emergencies/terrorist events.
- **Improved Emergency Shortages Data Collection System** – FDA developed an improved Emergency Shortages Data Collection System that allows quick identification of device manufacturers and available inventories. This is intended to facilitate identifying potential shortages in medical and *in vitro* diagnostic devices that may be needed by emergency healthcare personnel in the acute phase of an emergency/disaster. This data is handled as non-releasable, confidential commercial information.
- **Emergency Preparedness SOPs** – FDA developed standard operating procedures to sustain standardization of activities relevant to successful emergency preparedness, such as SOPs for handling and storing Top Secret and Secret documents.
- **Emergency Response Coordinating Workgroup** – FDA formed the Emergency Response Coordinating Workgroup (ERCW), which includes the core emergency personnel involved in initial response to a call for action in an emergency. ERCW responsibilities cover revising and updating the Emergency and Disaster Operations Procedures, writing new SOPs to update and improve response times, trouble-shooting on issues related to emergency exercises, and developing after action reports (AAR) to clarify issues after an exercise.
- **COOP Readiness** – FDA updated the Continuation of Operations Plans (COOP) and conducted quarterly exercises to improve readiness of all COOP and communication systems in CDRH.

RADIOLOGICAL COUNTERTERRORISM AND RADIATION SAFETY

- **FDA Protects Medical Device Users from Electromagnetic Interference in Security Metal Detectors while Maintaining National Security: Collaboration with Federal Aviation Administration (FAA) and Transportation Security Administration (TSA)** – FDA's research and its collaboration with FAA and TSA produced a new test method and a

recommended practice to help protect the public health while maintaining national security against terrorism. FDA, through its research, produced unique information about the emissions from security metal detector systems (both hand-held and walk-through type), performed independent testing with several implanted medical devices such as cardiac pacemakers, and developed a new system to simulate metal detector emissions for testing medical devices.

The unique data and test methods developed by FDA were used to write the recently published ASTM F2401-04 “Standard Practice for Security Checkpoint Metal Detector Screening of Persons with Medical Devices.” FDA conducted its research in response to reports of security system-medical device problems, some involving serious injury when cardiac or neurological stimulation implants were disrupted by the security systems. This new standard will reduce the risks for millions of people using implanted and portable medical devices.

- **Research Shows No Negative Health Impacts Of Cell Phones: Collaboration with Wireless Industry** - Research, conducted under a FDA-wireless industry (Cellular Telecommunications and Internet Association) cooperative research agreement and overseen by FDA, found no link between exposure to cell phone radiofrequency (RF) emissions and genetic damage in cells. This refutes earlier industry-funded research indicating that a link exists. The results of the laboratory tests were presented in June 2004 at the annual meeting of the Bioelectromagnetics Society and by the FDA at a FCC-hosted workshop on mobile telephony and health. Researchers and other experts from around the world attended the workshop, the latest in a series held to discuss the latest studies on the health effects of RF emissions, standards, and public outreach and education.
- **Emergency Response Plan Update** – FDA updated the Emergency Counterterrorism Preparedness and Response Plan for radiation, identifying key personnel and processes for FDA to follow when responding to a national radiological emergency.
- **Nationwide Evaluation of X-ray Trends** - The Nationwide Evaluation of X-ray Trends (NEXT) program is a world-recognized collaboration of FDA with the Conference of Radiation Control Program Directors (CRCPD), the umbrella organization of state radiation control agencies, to monitor the radiation doses patients receive during diagnostic x-ray exams. Each year the NEXT program selects a particular radiological examination for study and captures radiation exposure data from a nationally representative sample of U.S. clinical facilities. In doing so, NEXT provides the radiological community with important technical indicators of diagnostic x-ray practice and addresses specific concerns from both the private and professional sectors:
 - The American Association of Physicists in Medicine is developing a report that provides reference levels for patient exposure during selected diagnostic x-ray exams. Their effort relies significantly on published NEXT data, and a formal report is expected to be published in *Radiology* in early CY05;
 - In FY 04 FDA published a comprehensive analysis of a NEXT survey of adult abdomen lumbrosacral spine examinations (*Radiology* 2004; 232:115-125); and,
 - NEXT is currently preparing for a survey of computed tomography, a procedure that administers significantly higher doses to patients than standard x-ray film procedures.

- **Amendments proposed to Federal Laser Performance Standards** – FDA developed proposed amendments to the Federal Laser Performance Standards, 21 CFR 1040.10 and 1040.100, which adopt by reference and with national exceptions, the IEC laser standards (60825-1 and 60601-2-22) as the new Federal standard. The amendments move to create a single global regulatory environment for laser product manufacturers, which will reduce the regulatory burden on industry and update the Federal standard to reflect current laser technology and bioeffects research.

IMPROVING FDA’S BUSINESS PRACTICES

During the year FDA continued to build effective and efficient operations and a highly skilled and diverse workforce needed to carry out the Agency’s goal of more effective regulation through a stronger workforce. Specific accomplishments include the following:

- **Mentoring for Excellence Program** – CDRH completed the “Mentoring for Excellence Program” pilot for new managers. The program is intended to develop management competencies which top managers have identified as crucial in CDRH’s culture. The results are being reviewed and CDRH is exploring ways to integrate this tool into the diverse leadership enhancing programs offered within the Center;
- **Continuing Science Education Program** – CDRH created the Continuing Science Education Program (CSEP), which offers joint educational programs with selected colleges and universities. CSEP has two different programs for targeted audiences: the Basic Science Education Program (BSEP) and the Science Leadership Education Program (SLEP.) These programs are designed to encourage continual learning and provide employees with an opportunity to enhance their overall scientific knowledge;
- **Competency Model** – The development of a Competency Model that will identify the essential core, science, and functional (job category) competencies for CDRH employees was initiated. The model is intended to guide employees’ professional development and ultimately enhance job performance and the accomplishment of organizational goals;
- **CDRH Communication Plan** – A Communication Plan was developed and piloted in CDRH to: provide a process to plan, prioritize, and budget for CDRH communication activities; help employees communicate across CDRH and share expertise on outreach projects; and provide consistent and coordinated messages to the public; and,
- **Paperless Assignments for BIMO** – A paperless inspection assignment process was implemented that allows over 300 Bioresearch Monitoring inspections annually to be created and issued by electronic means. This results in substantial cost savings for mail distribution and document storage as well as enhancing the efficiency of FDA's inspectional process.

**Devices and Radiological Health
Program Activity Data**

PROGRAM WORKLOAD AND OUTPUTS	FY 2004 Actuals	FY 2005 Estimate ^{1/}	FY 2006 Estimate
Expedited Original PMA MDUFMA Decision Goal (% of decisions within # of FDA days)	NA	70% in 300 days	80% in 300 days
Expedited PMA Received	14	9	9
Expedited PMA Approved	5	9	9
Expedited PMA – Performance	100% in 300 days	70% in 300 days	80% in 300 days
PMA original, panel track supplement and premarket report submissions MDUFMA Decision Goals (% of decisions within # of FDA days)	NA	NA	NA
PMA Received (PDP and PMA)	51	50	50
PMA Approved (PDP and expedited)	39	43	43
Original PMA performance	74% in 320 days	75% in 320 days	75% in 320 days
PMA Supplement Panel Tracks ^{2/} Received	8	20	20
PMA Supplement Panel Tracks ^{2/} Approved	5	15	15
Panel track PMA Supple- ment ^{2/} performance	NA	NA	NA
Humanitarian Device Exemptions Received	6	6	6
Humanitarian Device Exemptions Approved	6	5	5
Average FDA Review Time (FDA days approval)	182	110	110
180- day PMA Supplements MDUFMA Decision Goal (% of decisions within # of FDA days)	NA	80% in 180 days	80% in 180 days
PMA Supplements Received	638	650	675
PMA Supplements Approved	467	530	535

PROGRAM WORKLOAD AND OUTPUTS	FY 2004 Actual	FY 2005 Estimate ^{1/}	FY 2006 Estimate ^{3/}
180-day PMA supplement performance	74% in 180 days	80% in 180 days	80% in 180 days
510(k) MDUFMA Decision Goal (% of decisions within # of FDA days)	NA	75% in 90 days	75% in 90 days
510(k)s Received (Trad., Special, Abbrev., 3 rd party)	3634	4,325	4,325
510(k)s Completed (All Decisions)	3918	4,200	4,200
510(k) performance	89% of FY04 receipt cohort	75% in 90 days	75% in 90 days
Investigational Device Exemptions Received	226	315	315
Investigational Device Exemptions Decisions	221	315	315
% Acted on Within 30 Days	100%	100%	100%
IDE Supplements Received	4311	5,200	5,200
IDE Supplements (Approved/Total Decisions)	4348	5,200	5,200
% Acted on Within 30 Days	100%	100%	100%
Total Standards Recognized for Application Review	695	720	750

^{1/} FDA is committed to meeting the performance goals cited in the MDUFMA legislation. The user fee funds, coupled with the increased appropriated resources for medical device review received in FY 2005, will enable FDA to meet the aggressive premarket goals agreed upon by FDA and its stakeholders. The FY 2005 requested increase will strengthen the capabilities needed to meet the increased performance goals by building the medical device review infrastructure and hiring new reviewers. Outputs are not expected to increase until FY 2006 and FY 2007 when the infrastructure is in place and functioning and the new reviewers are on board and fully trained. Increased outputs in FYs 2006 and 2007 are contingent upon receipt of MDUFMA user fee revenue.

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

^{3/} Includes filing decisions, review determinations, and approval decisions.

PERFORMANCE GOALS AND TARGETS

The following table of performance goals and FY 2006 targets is presented to compliment the sequential display of this program's "outputs" by more closely linking the traditional budget presentation of base and increased activities and workload outputs contained in the Program Activity Data (PAD) charts. Activities discussed throughout this narrative support the accomplishment of outputs (PAD and performance goals) which in turn contribute to the accomplishment of long term outcome and strategic goals. Full cost information for these goals as well as other historical information has been provided in their respective sections in the Detail of Performance Analysis contained in the supporting information tab.

Performance Goals	Targets
Complete Review and Decision on 80 percent of Expedited PMAs within 300 days.* (15033)	FY 06: Complete review and decision on 80 percent of Expedited PMAs within 300 days.
Complete Review and Decision on 80 percent of 180 day PMA supplements within 180 days.* (15031) FY 2003 Review time 180 days	FY 06: Complete review and decision on 80 percent of 180 day PMA supplements within 180 days.
Complete Review and Decision on 75 percent of 510(k)s (Premarket Notifications) within 90 days.* (15032)	FY 06: Complete review and decision on 75 percent of 510(k)s within 90 days.
Maintain inspection and product testing coverage of Radiological Health industry at 10 percent of an estimated 2000 electronic products. (15027)	FY 06: Maintain inspection and product testing coverage of Radiological Health industry at 10 percent of an estimated 2000 electronic products.
Ensure at least 97 percent of an estimated 9,100 domestic mammography facilities meet inspection standards, with less than 3 percent with Level I (serious) problems. (15007)	FY 06: Ensure at least 97 percent of an estimated 9,100 domestic mammography facilities meet inspection standards, with less than 3 percent with Level I (serious) problems.
Expand implementation of MedSun to a network of 350 facilities. (15012)	FY 06: Maintain a cohort of 350. Roll-out non-performers and replace with new sites to maintain the 350.

*See footnote #1 on previous page for a rationale for the achievement of these goals.