

Center for Devices and Radiological Health

CDRH FY 2006 Highlights
October 1, 2005–September 30, 2006



U.S. Food and Drug Administration

U.S. Department of Health and Human Services

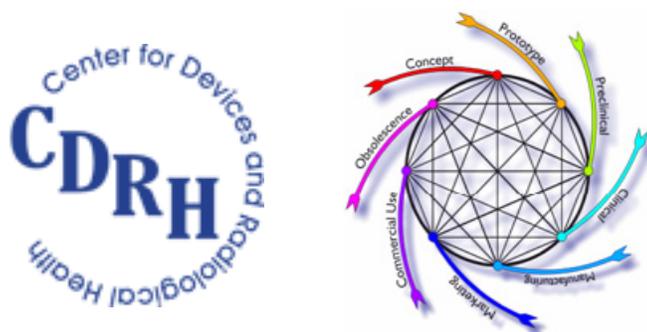
Mission/Vision

Mission

CDRH protects the health of the public by assuring the safety and effectiveness of medical devices and the safety of radiological products marketed in the United States. To further safeguard public health, CDRH monitors medical devices and radiological products while in use for continued safety and disseminates accurate, science-based information about the regulated products.

Vision

To protect the health of the public by assuring the safety of medical devices and radiological products throughout the *Total Product Life Cycle*—from product conception and development, through production and use, to obsolescence and product replacement.



Message from the Center Director

Fiscal year 2006 coincided with the 100th Anniversary of the FDA, the oldest consumer protection agency in the nation. As one of five FDA centers, the Center for Devices and Radiological Health (CDRH) plays an integral role in efforts to safeguard the public health. It is therefore fitting to align CDRH fiscal year 2006 accomplishments with four overarching Agency goals:

- To empower patients and consumers and enhance public health through better information about regulated products;
- To increase access to innovative products and technologies to improve health;
- To improve product quality, safety, and availability through better manufacturing and product oversight; and
- To transform FDA business operations, systems, and infrastructure to support FDA's mission in the 21st century.

As an introduction to the Center's Fiscal Year (FY) 2006 Annual Report, I would like to highlight select accomplishments under each of the four goals. I highlight these accomplishments on behalf of and in recognition of the many individuals—staff and stakeholders—who contributed to the successful work of CDRH during the fiscal year.

To empower patients and consumers and enhance public health through better information about regulated products

The CDRH website increasingly serves as the source of information about regulated products for consumers, clinicians, and industry. An important addition to the website this fiscal year was the *RightNow* Inquiry Management System. The system provides ready answers to consumers frequently asked questions and integrates questions posed online.

CDRH outreach staff also consolidated and organized medical device safety information on a single page of the CDRH website to afford healthcare professionals easy access to the information.

The Annual Report contains detail on numerous activities (courses, workshops, conferences, etc.) that CDRH co-sponsored with industry. These activities testify to the Center's ongoing commitment to provide information and regulatory assistance to device manufacturers.

To increase access to innovative products and technologies to improve health

I am pleased to report that CDRH continues to make steady progress in meeting MDUFMA performance goals. The Center has met or is on track to meet most goals for FYs 2003–2006. During this FY, CDRH issued 6 MDUFMA guidance documents; held 2 MDUFMA stakeholders meetings; issued 14 *Federal Register* notices and 3 reports to Congress; and granted 698 Small Business Determinations—an 8 percent increase over FY 2005.

CDRH applied research is a springboard for development of new device technologies. Among the Center's research-related strengths is the availability of scientists with cutting-edge

expertise in a range of fields. This is evident, for example, in multi-disciplinary efforts in FY 2006 to assure readiness to address future nanotechnology products and issues.

Each year one of the most rewarding aspects of developing the annual report is listing approved/cleared devices that have a direct impact on patient care. CDRH was pleased to grant a Clinical Laboratory Improvement Amendment (CLIA) waiver for a simple and accurate rapid blood lead test system. The waiver broadened access to the test to more than 115,000 point-of-care locations nationwide. Devices approved during FY 2006 included a continuous glucose monitoring system that detects blood glucose trends and tracks patterns for diabetic patients and a device that provides an alternative to open heart surgery for pediatric and young adult patients.

To improve product quality, safety, and availability through better manufacturing and product oversight

The Center continues to enhance postmarket oversight to ensure the safety and effectiveness of products. During FY 2006, CDRH received over 200,000 adverse event reports concerning medical devices, classified 651 recall actions involving 1,550 products, and took at least 55 enforcement actions. CDRH exceeded FY 2006 inspection goals by at least 20 percent for domestic, foreign, and bioresearch monitoring (BIMO) inspections. The Center also conducted annual inspections at over 8,000 mammography facilities, ensuring that 98 percent met inspection standards with less than 2 percent of the facilities having Level I (serious) problems.

To transform FDA business operations, systems, and infrastructure to support FDA's mission in the 21st century

As part of an ongoing effort to improve the postmarket tools we employ to monitor nearly 100,000 medical products, the Center produced a comprehensive report on the Postmarket Device Safety Program. The report highlighted implementation challenges and recommended action steps to strengthen the program. A senior level Postmarket Transformation Leadership Team met throughout FY 2006 to evaluate the recommendations and propose a plan for a transformed postmarket program.

During the fiscal year, CDRH enhanced Center IT systems to facilitate submissions, expedite reviews, and simplify tracking of devices throughout the product life cycle.

The availability of excellent staff is paramount to the Center's success and attention to training through the new employee orientation program, and the competency development program was another hallmark of FY 2006.

Spurred by our successes and cognizant of the challenges inherent in an ever expanding market for medical devices and radiological products, CDRH staff is committed to continuing the work outlined in this Annual Report. We hope that you will read the report with interest and that it will reinforce your trust in our ability to ensure the safety and effectiveness of the medical products you depend upon.

Daniel G. Schultz, M.D.
Director

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FDA Goal 1—Empowering Patients and Consumers and Enhancing Public Health through Better Information about Regulated Products

Through its Risk Communications Outreach Program, CDRH communicates risk/benefit information on medical devices and radiological products to Center stakeholders—consumers, healthcare professionals, and industry. During FY 2006, CDRH continued to relay information to stakeholders in a variety of ways.

Information for Consumers

Better information enables consumers to make smarter choices about the medical devices they rely upon daily. During FY 2006, CDRH staff responded to over 8,400 consumer inquiries concerning regulated products received via phone and fax, electronically, and through the mail.

CDRH Consumer Information on the Web

Important information about medical devices is available to the public via the CDRH home page on the FDA website. The page links users to news and events, health topics, device program areas, and consumer information. www.fda.gov/cdrh

❖ RightNow Inquiry Management System

To make outreach to consumers more efficient, CDRH launched the web-based *RightNow* inquiry management system. The system offers visitors a user-friendly way to find answers to frequently asked questions and the opportunity to submit new questions. Answers to questions posed online are integrated on the website. The link “*Questions?*” now appears in the CDRH banner at the top right of the Center’s home page; the link will eventually appear on every CDRH web page.

❖ Medical Device Recall Website

Medical devices that are defective and/or pose a risk to health are recalled to address the problem. CDRH alerts the public to recalled products via public health notices, press releases, and its recall website. In its recall website FDA posts consumer information about the most serious medical device recalls. These products are on the list because there is a reasonable chance that they could cause serious health problems or death. — <http://www.fda.gov/cdrh/recalls>

❖ Contact Lenses Web Page

CDRH launched the contact lenses web page in May 2006. This device-specific page provides all current contact lens related information in one place. The page contains basic information about contact lenses including the different types, valid prescriptions, a link to

approved contact lenses, risks, everyday eye care tips, and what to look out for when buying online—<http://www.fda.gov/cdrh/contactlenses/>

❖ Maturity Health Matters

CDRH published the inaugural issue of *Maturity Health Matters*. The aim of the online newsletter is to provide older adults and their caregivers with the latest information on medical products that help people live longer, more productive lives. The inaugural issue explored the link between diabetes and heart disease, highlighting the key role of medical devices in diabetes management. The newsletter will be published three times a year and feature information on FDA, regulated medical products, and health news.—

<http://www.fda.gov/cdrh/maturityhealthmatters/>

❖ FDA & You

For the third year, CDRH published *FDA & You*, an informative e-newsletter for secondary school students, parents, and educators. Published three times during the school year, *FDA & You* keeps students informed of latest news on medical products. Educators can use supplementary lesson plans for news-related classroom activities. *Soft Contact Lens: Risk of Serious Eye Infection* is an example of a newsletter article posted online during the fiscal year.—<http://www.fda.gov/cdrh/fdaandyou/index.html>

❖ FDA Centennial at CDRH

To commemorate the 100th anniversary of FDA and the major milestones celebrated by CDRH in 2006, the Center launched the FDA Centennial at CDRH website.—<http://www.fda.gov/cdrh/centennial>. The site includes an overview of CDRH, a chronological recap of Center milestones, and insights on challenges faced by past and present Center leadership. In conjunction with the website, CDRH developed a Centennial brochure and a commemorative calendar.

Information for Healthcare Professionals

Public health is improved when the clinical community is well-informed about the safe use of medical devices. During FY 2006, CDRH continued educational outreach to healthcare professionals in a variety of ways.

Epidemiology and Surveillance

CDRH staff were principal authors as well as editors of Epidemiology and Surveillance. The textbook describes how epidemiology and surveillance are conducted on marketed medical devices and why this is necessary in order to ensure that devices remain safe and effective during the course of their use. Because there are currently no published books, university courses, or professional societies that focus on the topic, Epidemiology and Surveillance will fill an important void in the American public's knowledge of this subject.

Medical Device Safety

The Center's resource for health care professionals is the Medical Device Safety page on the CDRH website. In FY 2006, staff consolidated and organized all medical device safety information (safety tips and articles, public health notifications, the adverse events database, etc.) and related links to appear on the page. To enhance effective distribution of

safety information, CDRH updates the page regularly to feature high priority risk messages. <http://www.fda.gov/cdrh/medicaldevicesafety>

Safety Tips for Laboratorians

During the postmarket lifecycle of in vitro diagnostic devices (IVDs), CDRH collects information on a variety of experiences relating to the proper use of the devices. This experience-based information also includes precautions that laboratorians, prescribing physicians, or the lay user must exercise in order to perform tests and use results appropriately. To communicate this valuable postmarket experience, CDRH posts *Safety Tips For Laboratorians* on its website at <http://www.fda.gov/cdrh/oivd/labsafetytips.html>. The short articles on conducting laboratory tests properly include guidance on test limitations and interfering factors that cause false or inaccurate test results.

FDA Patient Safety News

CDRH leads the Agency production of FDA Patient Safety News (FDA PSN), an award winning televised series carried on satellite broadcast networks aimed at hospitals and other medical facilities across the country. Now in its fifth year of production, FDA PSN is a major Agency vehicle for communicating FDA safety messages on drugs, medical devices, and biologics to physicians, nurses, pharmacists, risk managers, and educators across the nation. <http://www.fda.gov/psn>

Public Health Notifications

CDRH communicates critical health information the health care community through public health notifications. The notifications alert consumers and healthcare providers to actual or potential risks associated with use of a medical device and provide recommendations to avoid or reduce risks. In addition to being posted on the CDRH website, public health notifications are disseminated through MedWatch (the FDA safety information and adverse event reporting program), professional associations, two listservs, and press releases. CDRH encourages readers to [subscribe to email updates](#) to receive email announcements when a new or revised notification is issued. —<http://www.fda.gov/cdrh/safety.html>

Information for Industry

Outreach to educate industry stakeholders is a Center priority. During FY 2006, CDRH staff responded to over 63,000 industry requests concerning regulated products received via phone and fax, electronically, and through the mail; collaborated with trade organizations to co-sponsor educational activities on a range of topics; and solicited industry expertise concerning new initiatives. Center outreach to industry is international; during FY 2006, staff met with 22 foreign officials representing 5 foreign governments to improve the safety of medical devices around the world. Below are some examples of CDRH outreach to industry during FY 2006.

Frequently Asked Questions for Manufacturers of Electronic Products that Emit Radiation

CDRH launched the *Frequently Asked Questions for Manufacturers of Electronic Products that Emit Radiation* web page in July 2006. The web page provides basic explanations to common questions related to manufacturer reporting and recordkeeping responsibilities, report acknowledgement letters and accession numbers, product certification to performance standards, and importation of electronic products.

<http://www.fda.gov/cdrh/radhealth/rademitfaq.html>

Unique Device Identifiers

FDA published a notice requesting comments to help the Center understand how the use of unique device identifiers (UDI) similar to identifiers mandated for drugs might enhance patient safety. CDRH subsequently held a public meeting which focused on factors influencing the development of a UDI system (e.g., costs, benefits, design and implementation challenges, data repository, automatic identification technologies). The Center is currently analyzing the comments to determine FDA's role and approach to a UDI system.

Courses, Workshops, and Presentations

❖ PMA and 510(k) Device Submission Workshops

In March 2006, several CDRH staff members participated in the annual PMA and 510(k) Device Submission Workshops sponsored by the Advanced Medical Technology Association (Advamed) Medical Technology Learning Institute (MTLI). The objective of these annual workshops is to educate regulatory professionals on how to prepare a successful PMA or 510(k) application, and how to comply with FDA regulatory requirements. During the workshops, CDRH staff also share practical review experience with the participants.

❖ IVD Roundtable 510(k) Workshop

In April 2006, CDRH and the Association of Medical Diagnostics Manufacturers (AMDM) co-sponsored the In Vitro Diagnostic Devices (IVD) Roundtable 510(k) Workshop. The objective of the workshop was to foster communication among the professional, manufacturing, and regulatory communities. During the interactive workshop, participants had the opportunity to learn from CDRH experts who review 510(k) submissions. Experienced industry regulatory affairs personnel also provided guidance and helpful tips on 510(k) submissions.

❖ PMA and 501(k) Web Casts

In May 2006, CDRH regulatory experts were invited to participate in the Regulatory Association Professional Society (RAPS) web cast. The objective of this web cast was to educate the regulated industry on the fundamentals of 510(k) and PMA applications. CDRH staff also discussed tips on how to prepare for an FDA panel meeting. The training was broadcast over the Internet and attended by many regulatory professionals throughout the world.

- ❖ **Medical Design and Manufacturing (MD&M) East 2006 Conference**
In June 2006, CDRH staff participated in the annual MD&M East 2006 Conference. CDRH staff hosted a booth at the conference and sponsored a one-day seminar dealing with pre- and postmarket activities. The MD&M East 2006 Conference attracted more than 25,000 design engineers, production managers, quality control specialists, manufacturing executives, and other product development professionals from across the industrial landscape.

- ❖ **Good Manufacturing Practices/Quality System Requirements and Industry Practices**
This Association for the Advancement of Medical Instrumentation (AAMI) course offered in September 2006 was co-presented by CDRH and industry instructors to educate members of regulated industry on the fundamentals of the Quality System Regulation. CDRH staff presented multiple training modules and provided guidance on FDA expectations related to implementing medical device Current Good Manufacturing Practice Requirements/Quality System Regulation.

- ❖ **Risk Communication on Medical Devices: Sharing Perspectives**
In September 2006, FDA and the Advanced Medical Technology Association (AdvaMed) presented a workshop entitled *Risk Communication on Medical Devices: Sharing Perspectives*. Senior FDA and industry representatives explained to participants how the government and the medical device industry communicate expected and unexpected risks to practitioners, patients, and the public. Attendees also learned from physicians, risk managers, and the media how this information is received and transmitted to hospital staff, patients, and the public.

- ❖ **Connecting the Dots on FDA's Postmarket Safety Activities**
This was the first in a series of planned public workshops on postmarket safety of medical devices. The goal of the workshops, held in collaboration with the Advanced Medical Technology Association (AdvaMed) Medical Technology Learning Institute (MTLI), is to improve regulatory processes and oversight of marketed medical devices by gaining a better mutual understanding of current barriers to postmarket device monitoring and follow-up. Workshop topics included FDA analysis of postmarket trends; industry's perspective on postmarket issues and regulations; new perspectives on product recalls, removals, and corrections; future trends in postmarket regulation; and industry/FDA collaboration.

FDA Goal 2—Increasing Access to Innovative Products and Technologies to Improve Health

A critical aspect of protecting and promoting public health is facilitating access to innovative medical devices. To achieve this objective, CDRH is developing better ways to predict earlier in the review process which new products are likely to be safe and effective. CDRH is also promoting scientific innovation in product development and focusing device research using cutting-edge science.

Approved/Cleared Devices

FDA does not test new medical devices to determine whether they are safe and effective before they are sold in the United States. Instead, FDA gives guidance to manufacturers on what tests they should conduct. CDRH evaluates the scientific test data manufacturers submit for review prior to making a decision whether the devices are allowed to be marketed.

Manufacturers wishing to sell a new type of medical device—or market an approved device for new uses that represent a high risk to public health—must submit a premarket approval (PMA) application to CDRH. A PMA must include valid scientific evidence showing that the product does what it claims to do (is effective) and that the benefits of using the product outweigh the risks (is safe). Examples of PMA devices include: mechanical heart valves, implantable pacemakers, intra-ocular lenses, and cochlear implants.

Most new medical devices are similar to products already on the market and do not represent a high risk to public health. Manufacturers wishing to sell these products must submit a premarket notification [also called 510(k)]. This process is for lower-risk devices that require less rigorous testing and evaluation. A 510(k) must include information demonstrating that the new device is very similar (substantially equivalent) to another device already on the market. Some applications for devices with well-established records of safety and use receive no review. Examples of 510(k) devices include: non-invasive blood pressure monitors, ventilators, and daily wear soft contact lenses.

Medical devices successfully evaluated through the PMA process are *approved*; devices successfully evaluated through the 510(k) process are *cleared*.

During FY 2006, CDRH approved and cleared a significant number of medical devices which exemplify advanced device technologies that have a valuable impact on patient care. A comprehensive list of approved medical devices is available at <http://www.fda.gov/cdrh/consumer/mda/index.html>.

LeadCare® II Blood Lead Test System

<http://www.fda.gov/cdrh/pdf5/k052549.pdf>



The LeadCare II Blood Lead Test System is used to screen children and adults for harmful levels of lead using a finger stick or venous whole blood sample. It is performed while the patient is present in as little as three minutes. The rapid result means a second sample for confirmatory testing can be obtained quickly, reducing the need for a follow-up visit. Because the test is simple, accurate, and reasonably free of harm, CDRH broadened access to the test system by granting a Clinical Laboratory Improvement Amendment (CLIA) waiver. The waiver permits widespread distribution of the test system to nontraditional laboratory sites that have CLIA certification.

STAN® S31 Fetal Heart Monitor

<http://www.fda.gov/cdrh/mda/docs/p020001.html>

The STAN® S31 Fetal Heart Monitor is a new type of fetal monitor that uses the fetal electrocardiogram (ECG) obtained through a [fetal scalp electrode](#) during labor to help the doctor or midwife decide whether to allow the mother to continue to labor or to intervene and deliver the baby. The new monitor is used when there is concern that the fetus might be at increased risk for [metabolic acidosis](#).

X STOP® Interspinous Process Decompression System

<http://www.fda.gov/cdrh/mda/docs/p040001.html>

The X STOP® Interspinous Process Decompression System (X STOP) is used to relieve symptoms of lumbar spinal stenosis, a narrowing of the passages for the spinal cord and nerves. The titanium implant that fits between the spinous process of the lower (lumbar) spine may relieve some or all of the symptoms of lumbar spinal stenosis and may improve a patient's ability to function.

Avian Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set

<http://www.fda.gov/cdrh/pdf6/k060159.pdf>

The Avian Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set provides preliminary results on suspected H5 influenza samples within four hours once testing begins. This is in contrast to previous testing technology which required at least two to three days for results. If the presence of the H5 strain is identified, then further testing is conducted to identify the specific H5 subtype (e.g., H5N1).

UniCel[®] Dx_C 600i Synchron[®] Access[®] Chemistry-Immunoassay System

<http://www.fda.gov/cdrh/pdf6/k060256.pdf>



The UniCel[®] Dx_C 600i Synchron was cleared as the only system of its kind with closed-tube sampling (CTS) and closed-tube aliquotting (CTA) capabilities. By eliminating the de-capping and re-capping steps in the laboratory process, these features help increase lab efficiency and enhance operator safety. The system offers a throughput up to 990 chemistry tests per hour and up to 100 immunoassay tests per hour.

LUMA[™] Cervical Imaging System

<http://www.fda.gov/cdrh/mda/docs/p040028.html>

The LUMA[™] Cervical Imaging System is an optical detection system that helps the doctor identify areas on the cervix that are likely to contain precancerous cells. The doctor uses this device immediately after colposcopy (a high magnification evaluation of the cervix for women who have recently had an abnormal Pap smear) to decide where to take additional tissue samples (biopsies). The LUMA[™] Cervical Imaging System will help improve the chances that the doctor does not miss an area that may contain precancerous cells.

DexCom[™] STS[™] Continuous Glucose Monitoring System

<http://www.fda.gov/cdrh/pdf5/p050012a.pdf>



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

MonoPrep Pap Test

<http://www.fda.gov/cdrh/mda/docs/p040052.html>



The MonoPrep Pap Test (MPPT) system is a device used to collect and prepare cell samples from a female patient's cervix for [Pap stain-based screening](#) for [cervical cancer](#), its precursor lesions, and other cytologic categories and conditions. Clinical trial results demonstrate that the MPPT system is safe and effective for preparing gynecological slides to screen for cervical abnormalities.

PhiCal™ Fecal Calprotectin Immunoassay

<http://www.fda.gov/cdrh/pdf5/k050007.pdf>

The PhiCal™ Fecal Calprotectin Immunoassay is a quantitative ELISA assay for measuring concentrations of human fecal calprotectin, a neutrophilic protein that is a marker of mucosal inflammation. The PhiCal™ test can be used as an in vitro diagnostic to aid in the diagnosis of inflammatory bowel diseases (IBD), Crohn's disease, and ulcerative colitis, and to differentiate IBD from irritable bowel syndrome (IBS) when used in conjunction with other diagnostic testing and the total clinical picture.

Birmingham Hip Resurfacing (BHR) System

<http://www.fda.gov/cdrh/mda/docs/p040033.html>

The Birmingham Hip Resurfacing (BHR) System is a metal on metal resurfacing artificial hip replacement system, surgically implanted to replace a hip joint. The BHR System relieves hip pain and improves hip function by replacing the parts of the hip that have been severely damaged by degenerative joint diseases (e.g., osteoarthritis, rheumatoid arthritis, traumatic arthritis, dysplasia, avascular necrosis). The BHR System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip replacement due to an increased possibility of requiring future hip joint revision.

Xpert GeneXpert™ Dx Test For Group B Streptococcus

<http://www.fda.gov/cdrh/pdf6/k060540.pdf>

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

Adept® Adhesion Reduction Solution (4% Icodextrin)

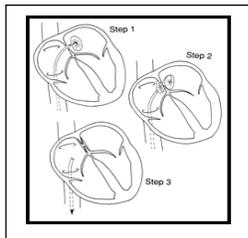
<http://www.fda.gov/cdrh/mda/docs/p050011.html>

Adept® Adhesion Reduction Solution (4% Icodextrin) is a pale yellow fluid that contains icodextrin. The fluid is used during or after [laparoscopic gynecological surgery](#) to separate and protect tissues, and decrease the number of new [adhesions](#) after surgery. Adhesions are a common complication of gynecological surgery, and can cause pelvic pain, bowel obstruction, or infertility.

APTIMA Combo 2® Assay on the TIGRIS® System

<http://www.fda.gov/cdrh/pdf6/k060652.pdf>

The APTIMA Combo 2® Assay is cleared to detect Chlamydia infections and gonorrhea from a wide variety of sample types. These sample types include liquid-based ThinPrep Pap Tests and vaginal swabs, endocervical and urethral swab specimens, and female and male urine specimens.



Gore HELEX™ Septal Occluder

<http://www.fda.gov/cdrh/mda/docs/p050006.html>

This new technology is an alternative to open heart surgery for pediatric and young adult patients. The device uses cardiac catheterization to position an occluder over a hole in the heart, allowing tissue to grow over the device, closing the defect, and making the device part of the wall of the heart.

Regulations, Standards, and Guidance

CDRH is responsible for setting and enforcing FDA regulations and performance standards for medical devices and radiation-emitting electronic products. To describe FDA's interpretation of policy on regulatory issues, CDRH staff prepare guidance documents for regulated industry and the general public. Regulations, standards, and guidance documents are intended to assist manufacturers improve the quality of premarket submissions, expedite the FDA review process, and speed consumer access to life-saving medical devices.

During FY 2006, CDRH cleared 20 regulations, reviewed and coordinated the Agency's actions with regard to 16 Citizens' Petitions, and cleared 46 guidance documents—which is a 59 percent increase from FY 2005.

CDRH Standards Program

The Standards Management Staff (SMS) develops and manages the standards used for regulatory assessments and facilitates the participation of CDRH and other FDA staff in developing national and international standards. In addition, the SMS manages CDRH's process for the recognition of voluntary consensus standards for medical devices and radiation-emitting electronic products. As part of this responsibility, the staff annually publishes lists of recognized standards, consistently increasing the number of available

standards. During FY 2006 CDRH withdrew 10 standards considered “no longer appropriate”; withdrew 80 additional standards and recognized new editions of each; incorporated 66 changes to existing recognized standards; and recognized 43 new voluntary consensus standards. The new standards address newly developing technologies to improve the quality of future submissions.

Guidance Documents

CDRH worked with industry and other stakeholders to develop best practices, policies, and guidance documents to make premarket applications more consistent, complete, and less subject to multi-cycle reviews. Below are examples of guidance documents issued during the FY 2006.

- ❖ *Draft Guidance for the Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program* was developed and issued in collaboration with FDA’s Office of Regulatory Affairs.
- ❖ *Draft Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials* provides a flexible alternative framework to classical clinical trial design for sponsors of innovative new devices.
- ❖ *Draft Guidance for Pharmacogenetic Tests and Genetic Tests for Heritable Markers* was issued to facilitate progress in the field of pharmacogenomics and genetics by helping to shorten development and review timelines, facilitate rapid transfer of new technology from the research bench to the clinical diagnostic laboratory, and encourage informed use of pharmacogenomic and genetic diagnostic devices.
- ❖ *Draft Guidance Class II Special Controls: Bone Sonometers* supports the reclassification of bone sonometers into class II (special controls) devices. Class II devices are exempt, subject to certain limitations, from the premarket notification requirements. Bone sonometers transmit ultrasound energy into the human body to measure the acoustic properties of bone that indicate overall bone health and fracture risk.
- ❖ *Final Guidance for Keratome and Replacement Keratome Blades Premarket Notification [510(k)] Submissions* will assist industry in preparing premarket notification submissions for keratomes and replacement keratome blades. The intended use of the device is to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant. Keratomes, originally used during cornea transplant surgery, are now widely used during the laser refractive surgical procedure known as laser-assisted in situ keratomileusis (LASIK).

Quality Review Program for Premarket Submissions

The purpose of CDRH's Quality Review Program for Premarket Submissions is to evaluate the quality and consistency of the Center's scientific review process. During the fiscal year, CDRH expanded the program to five review areas: biocompatibility, sterilization and packaging, statistical analysis, software, and clinical reviews. The expanded program allows CDRH to improve the quality of its reviews in key scientific areas, ensuring that reviewers consistently ask the right questions at the right times to minimize review time.

Advisory Committees

CDRH held 10 Federal Advisory Committee panel meetings in fiscal year 2006. These panels of external experts reviewed and made recommendations to FDA on six premarket approval (PMA) applications, three reclassifications, one classification, and three general issues. Among the topics addressed at the panel meetings were issues associated with significant breakthrough technologies for facial fillers, breast cancer detection, implanted telescope for macular degeneration, and cervical disc system for the treatment of degenerative disc disease.

Premarket Critical Path

Examples follow of CDRH's Critical Path initiative to address innovative medical therapies and support product development that is more predictable, efficient, and less costly:

- ❖ Established a collaboration with the Juvenile Diabetes Research Foundation to promote the development of an artificial pancreas;
- ❖ Established collaborative interactions with other government entities and external stakeholders to advance the development of new biomarkers for diseases; and
- ❖ Developed guidance to foster the development of new technologies in the area of genetics, pharmacogenomics, and drug/device co-development.

MDUFMA

In 2002, the Federal Food, Drug, and Cosmetic Act was amended to provide FDA important new responsibilities, resources, and challenges. The *Medical Device User Fee and Modernization Act of 2002* is commonly referred to as MDUFMA.

One particularly significant provision of MDUFMA permits FDA to collect user fees for certain premarket reviews received on or after October 1, 2002. The additional funds obtained from user fees will enable FDA to improve the medical device review process in order to meet MDUFMA performance goals.

To meet these progressively challenging performance goals, CDRH consulted with its stakeholders, developed guidance documents, and implemented new review processes and process improvements. Key MDUFMA-related accomplishments for FY 2006 follow.

Progress in Meeting MDUFMA Performance Goals

CDRH met, or is on track to meet, most of the MDUFMA performance goals for fiscal years 2003 through 2006 receipt cohorts, and maintained review performance in areas not covered by official performance goals. <http://www.fda.gov/cdrh/mdufma/index.html>

MDUFMA Third Party Inspection Program

CDRH continued implementation of the MDUFMA authority to accredit third parties to conduct inspections of eligible manufacturers of Class II and Class III medical devices, which will help FDA focus its limited resources on higher-risk inspections and give medical device firms operating in global markets an opportunity to more efficiently schedule multiple inspections.

FDA issued guidance to implement the new authority and published criteria for Accredited Persons (AP) in the *Federal Register*. The FDA review board received, reviewed, and rated AP applications which resulted in 16 third parties being selected to participate in the program.

Industry use of the Third Party Inspection Program for 510(k) submissions in FY 2006 increased 18 percent over use of the program in FY 2005. CDRH received 287 510(k) submissions reviewed by Accredited Persons and made final decisions on 268, up from 250 in FY 2005. This review option may be faster than reviews performed exclusively by FDA staff and gives manufacturers access to specialized expertise by third parties. <http://www.fda.gov/cdrh/ap-inspection/>

MDUFMA Guidance Document Development

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

MDUFMA Stakeholders Meetings

In November 2005, CDRH held the third Annual Stakeholders Meeting on the Implementation of MDUFMA. In addition to addressing the Agency's progress in implementing the various MDUFMA provisions, meeting participants discussed the current qualitative performance goals, participation of eligible manufacturers in the inspection program, and the current requirements for reprocessing single use devices. The meeting gave stakeholders an opportunity to provide information and share their views on the implementation of MDUFMA. <http://www.fda.gov/cdrh/meetings/111705.html>

A MDUFMA Public Stakeholders meeting was also held in May 2006 to consult with stakeholders and to determine whether the following two goals are appropriate for implementation in FY 2007:

- 50 percent of PMA applications will have an FDA decision in 180 days;
- 80 percent of premarket notifications [510(k)s] will have an FDA decision in 90 days.

<http://www.fda.gov/cdrh/meetings/052206.html>

MDUFMA Public Notices and Reports

CDRH issued 14 *Federal Register* notices and three reports to Congress: FY 2005 MDUFMA Performance Report, FY 2005 MDUFMA Financial Report, and FY 2005 Office of Combination Products Report.

MDUFMA Small Business Determinations (SBDs)

CDRH received, evaluated, and responded to 717 Small Business Determinations (SBDs) under the meaning of MDUFMA, and granted 698, an increase of 8 percent over FY 2005. (Establishments judged to be a small business are eligible to receive a reduced or waived user fee for premarket reviews.) CDRH completed all SBDs within 7 days of the allowable 60-day timeframe.

<http://www.fda.gov/cdrh/mdufma/guidance/2006.pdf>

Applied Research

Research findings improve the predictability, efficiency, and effectiveness of premarket reviews and the development of new device technologies. Following are CDRH applied research-related accomplishments during FY 2006.

Nanotechnology in Medical Devices

CDRH took major steps to assure its readiness to address future nanotechnology products and issues. Steps included building a knowledge base and developing experimental expertise and collaborative research with other key participants in the field, and discussing regulatory processes and standards coordination issues. A major Center strength is the availability of scientists from many disciplines—some with significant prior experience with nanotechnology. Other activities in progress include coordination of standards activities, identification of regulatory issues/gaps, and training of staff.

The focus of CDRH research projects is primarily to address mechanistic understanding of nanoparticles behavior from physical, chemical, and biological aspects. The other major focus is on advancing the knowledge regarding the characterization of nanoparticles. The knowledge and data developed in these projects would help address potential questions related to:

- ❖ Available methods/technologies for characterization of nanoparticles and their limitations;
- ❖ Physico-chemical stability/interaction of nanoparticles;
- ❖ Physical, chemical, and biological interaction of nanoparticles;
- ❖ Toxicity and behavior of nanoparticles in in-vitro and in-vivo environment; and
- ❖ Test methods to assess biocompatibility of nanoparticles' exposure to blood elements.

Device Safety in Magnetic Resonance Imaging (MRI) Environments

CDRH developed a new standard practice for marking medical devices and other items safe in the magnetic resonance environment. The revised system replaced the old system and its confusing MRI compatible terminology, which may have resulted in patient injuries. CDRH measured and modeled implants in MRI radio frequency fields to develop data on induced heating. These data will aid in the formulation of guidance and standards for MRI compatibility of implants.

Relationship Between Bone Cement Dose and Mechanical Strength after Vertebroplasty

CDRH conducted research to determine whether bone mineral density (BMD) can be used to predict mechanical strength and stiffness of the vertebral body after cement injection. Vertebroplasty has been reported to have high success rates in providing pain relief, but the procedure is not without serious risks. Adverse events associated with cement leakage have been reported, including persistent pain, paralysis, loss of sensation, and death. Laboratory results suggest that there may be significant differences between osteoporotic and non-osteoporotic patients in terms of the relative improvement in strength and stiffness that larger cement volumes can offer. In general, laboratory study suggests that clinicians may be able to select an appropriate cement volume and to make predictions about the expected improvement in mechanical stability after vertebroplasty for a specific patient based on his or her bone mineral density.

Exposure to Electromagnetic Fields and the Effect on Implanted Devices

CDRH measured and modeled exposure to electromagnetic fields and the effects on implanted devices from hand-held and walk-through security systems, cellular telephones, hand-held computers, and MRI systems. This research included models of the head for evaluation of cellular phone exposure and models of pregnant women representing nine fetal gestational ages to evaluate heating during MRI. This effort resulted in the standardization of specific absorption rate (SAR) across multiple systems. Results of this work include:

- ❖ Nine journal articles and 14 proceedings and other presentations during the past year;
- ❖ Support from the Federal Aviation Administration (FAA)/Transportation Security Administration (TSA) for the security system studies; and
- ❖ Establishment of a Cooperative Research and Development Agreement (CRADA) to further the virtual family modeling.

Modeling of the heating effects of MRI upon implanted pacemakers, implantable cardioverter-defibrillators (ICDs), neural stimulators, and cardiac stents helped define the parameters for acceptable application of MRI for individuals with these implanted medical devices and has a potentially large impact on public health as industry uses the information to improve device safety.

Test Methods for Intraocular Lenses (IOL)

CDRH developed a significantly more accurate and applicable confocal laser method for testing intraocular lenses (IOL) diopter power. Precise measurement is critical for evaluating the effectiveness and safety of IOLs, which are implanted during cataract surgery. The test method has been used to evaluate samples of new IOL designs and on IOLs on regulatory hold because of questions about the labeled power. This work resulted in a pending patent, 4 journal articles, and more than 10 proceedings publications and presentations during the past year.

CDRH also developed accelerated testing procedures to identify IOL materials that are prone to the formation of “glistenings” (fluid filled ellipsoidal voids within the lens). Both of these testing procedures ensure the effectiveness and safety of a device for the treatment of cataracts that is critical to an aging population.

Combined Approach to Evaluate Circulatory Assist Devices

CDRH developed a combined approach of review and laboratory expertise to evaluate proposed ‘subtle’ design changes to critical components of life-sustaining mechanical circulatory assist devices. Design of the blood path in these devices is critical for avoiding damage to blood components, stroke, and embolism. CDRH’s new combined approach for review significantly reduces the review burden while reducing the uncertainty of evaluations.

Effects of Optical Energy

CDRH evaluated the effects of optical energy on cellular and intracellular structures and components. This resulted in improved understanding of the effects of light on energy production in cells. CDRH developed a new confocal fiber-optic nano-biosensing system that enables measurements at resolutions better than the theoretical half wavelength limit, resulting in work below the 200 nanometer range. This work, supported in part by an interagency agreement with the Air Force Office of Scientific Research, resulted in 4 journal articles, numerous proceedings and presentations during the past year, and a proposal to the Army’s Telemedicine and Advanced Technologies Research Center to evaluate optical methods of stimulation that may enhance the field of neuro-prostheses.

Device-Tissue Interfaces

CDRH also worked towards developing a better understanding of the device-tissue interface for optical spectroscopy leading to improvements in the efficiency of spectroscopic methods for minimally invasive disease detection. This area has the potential to improve the detection of mucosal cancers and the monitoring of changes following therapeutic applications. This work resulted in journal articles and several presentations.

Better Animal Models and Biomarkers to Improve Public Health

CDRH conducted research to stimulate the development of new evaluation tools—biomarkers and clinically-relevant preclinical models—for assessing the safety and efficacy of new medical products. An animal model of subclinical renal insufficiency that was able to detect known nephrotoxicants at doses that were non-toxic in “healthy” control animals was developed and partially validated. The regulatory impact is significant in that adverse effects detected using the disease model would have been missed using healthy animal models typically used to test medical devices. CDRH also evaluated a new kidney toxicity biomarker, a kidney injury molecule that can be measured in kidney tissue and urine and appears to be more sensitive for renal injury detection than traditional clinical markers. The public health impact is significant in that the new biomarker may be useful to identify patients with subtle renal disease at an earlier stage and prevent pathogenesis of renal failure as well as reduce uncertainties in the preclinical assessment of FDA-regulated products.

Infection Control: Reuse of Single-use Devices and Cleaning Validation

CDRH developed cleaning and disinfection-sterilization methods to ensure that no microbial contamination remains on a reusable device. Improper cleaning can cause misdiagnosis due to tissue contamination and toxicity from residual detergents and sterilization agents. CDRH has determined that total organic carbon is an effective marker of residual soil from patients exposed to the devices and residual chemicals used in reprocessing on cleaned devices versus measuring total protein only as an endpoint of cleaning. The research will improve safety of patients exposed to single-use and reusable medical devices. Protein residual data from CDRH research have provided an endpoint for device reprocessors to meet requirements of supplemental validation submissions for single-use devices and aided CDRH review and inspection functions.

Drug Coated Stents: Drug Eluting Stents Associated Thrombosis

The drug eluting stents have been shown to exhibit late-stent thrombosis which may be mediated by an increased expression of tissue factor (TF) and decreased levels of thrombomodulin in endothelial cells that line the arteries. CDRH research on the treatment of endothelial cells with either rapamycin or paclitaxel resulted in a slight increase in coagulation activity. However, addition of vascular endothelial growth factor (VEGF) significantly augmented the coagulation cascade. Coagulation correlated with increased expression of TF in endothelial cells. Thrombomodulin expression was unaffected by either rapamycin or paclitaxel in the presence of VEGF. Data suggest that platelets and rapamycin/taxol may elevate TF expression. However, platelets themselves are not affected by either drug. These results suggest that anti-proliferative drugs exhibit prothrombotic effects which could be potentiated by VEGF. These findings imply that high levels of VEGF in atherosclerotic plaques could potentially contribute to thrombotic effects observed following drug eluting stent implants. Experimental and computational studies of model coatings have led to an understanding of the role of processing conditions on the rate of drug release. For example, increases in processing temperature leads to a decrease in the size of included drug particles and an increase in the rate of drug release. These

observations have been used in evaluating proposed changes to manufacturing procedures in currently approved drug eluting stents.

Computational Fluid Dynamics of Left Ventricular Assist Device

CDRH laboratory scientists worked with an industry sponsor to assess the effect of a proposed design change to a left ventricular assist device (LVAD). The sponsor proposed making a change to the blood flow path within the pump that could have adversely affected hemolysis and thrombogenesis in the pump such that patient safety and/or device efficacy could have been compromised. It would have been extremely difficult, if not impossible, to validate the design changes using animal or human data. After discussions and a meeting with CDRH staff, the sponsor agreed to provide experimental (flow visualization, hemolysis) and analytical (computational fluid dynamics [CFD]) testing to support the design changes. CDRH experts recommended appropriate CFD models to the sponsors and analyzed the results.

Computer-Assisted Diagnostic Systems

CDRH developed new models and methods for assessing computer-assisted diagnostic (CAD) systems in the review of digital mammography systems, breast cancer screening, lung cancer screening, and computed tomography (CT) colonoscopy. The new assessment tools can be used with the most common clinical study design paradigms. The new assessment tools have been developed to improve the evaluation of reader variability and algorithm complexity for imaging and CAD devices by extending these assessment tools to the most common clinical study design paradigms. CDRH research has also led to a better understanding of the impact of CAD used concurrently instead of as a second reader, and to the development of assessment tools for measuring CAD stand-alone performance. Having these tools and methods available has greatly assisted developers of these innovative imaging and CAD devices.

Tools for the Simulation of Imaging Physics

CDRH scientists have developed and made available to the scientific community, an advanced simulation package for studying radiation imaging systems. The code, developed in collaboration with scientists at the Universitat Politecnica de Catalunya in Spain, allows for the simulation of medical imaging systems involving x-rays, gamma-rays, electrons, and optical radiation, such as digital mammography, breast tomosynthesis, breast, and other flat-panel based CT. The tool will enhance the Center's understanding of the physics behind novel imaging technologies that are currently being considered by industry and possibly submitted to FDA for review in the near future.

Performance Testing of Pulse Oximeters

CDRH scientists and engineers have developed test methods for a range of non-invasive monitoring devices. CDRH laboratory studies on pulse oximeter performance, for example, enabled substantial improvements in the ISO/IEC standard and the CDRH Guidance Document. This testing facilitated the development of a single test protocol for SpO₂ accuracy studies, which simplified the premarket evaluation process by unifying the basis for establishing substantial equivalence. The work has established the groundwork to

enable the extensions of claims being made for perfusion measurements and established acceptable performance criteria.

Test Methods for High Intensity Focused Ultrasound

The lack of standardized methods to assess the acoustic and thermal characteristics of high intensity focused ultrasound (HIFU) has challenged the regulatory review of these devices, especially in the pre-clinical phase, and has been burdensome to the industry. In the past, CDRH scientists and engineers have developed measurement instrumentation and computational modeling techniques for characterizing other types of medical ultrasound devices such as diagnostic imaging and therapeutic ultrasound. This work has resulted in the creation of numerous regulatory guidance and standards documents. This expertise is being used to accelerate the review of submissions for HIFU devices. For example, in a device for the ablation of uterine fibroids, CDRH-developed computational modeling was used to predict the performance of the device under conditions that would have been difficult to investigate experimentally, thus shortening the review time.

Effect of RFID on Drug Potency

CDRH initiated, at the request of FDA, important new research to determine whether exposure to electromagnetic fields from radiofrequency identification (RFID) systems has any effect on the potency of pharmaceuticals. Of primary interest are exposures that are several times more severe than the anticipated worst-case field strengths and durations.

Reorientation of the CDRH Radiation Metrology Program

As part of the CDRH reorganization of the radiation health program, the CDRH X-ray Calibration Laboratory underwent significant changes. The laboratory continues to be accredited by the National Voluntary Accreditation Program (NVLAP). During the fiscal year, the laboratory provided 840 radiation calibrations of general diagnostic instruments, 202 radiation calibrations of mammographic instruments, 484 electrical calibrations of radiation monitors, 147 calibrations of non-invasive kVp meters, and 36 calibrations of light meters. In addition, the laboratory provided instrumentation and logistics support to FDA and Agreement-State inspectors for compliance testing of general radiography installations, mammography machines, and voluntary surveys under the Nationwide Evaluation of X-ray Trends (NEXT) program.

Medical Device Fellowship Program

The Medical Device Fellowship Program (MDFP) provides select individuals the opportunity to get unique, hands-on experience helping to evaluate the safety and effectiveness of cutting-edge medical devices. MDFP fellows include student interns starting their careers in science and engineering and senior scientists and physicians with vast experience in academia and clinical practice. By increasing the range and depth of collaboration between CDRH and the outside scientific community, the MDFP helps ensure that CDRH decisions are based on the best scientific information and knowledge available. In 2007, MDFP fellows contributed expertise in ophthalmology, interventional cardiology, cardiac surgery, neurology, gastroenterology, biostatistics, and biomedical engineering.

The Center's technology transfer program, managed through the MDFP, makes possible collaboration with people and programs outside FDA, augmenting CDRH expertise and resources. Government and academic partnerships (e.g., cooperative research agreements, grants, memorandums of understanding for academic partnerships, interagency agreements, material transfer agreements) result in scientific information being used to develop standards, guidance, and regulatory decisions.

FDA Goal 3—Improving Product Quality, Safety, and Availability through Better Manufacturing and Product Oversight

To ensure the safety and effectiveness of medical devices and radiation-emitting products, CDRH sets and enforces good manufacturing practice requirements; monitors compliance and surveillance programs for products on the market; and collects, analyzes, and acts on reports of adverse effects of products. The Center's goal is to improve the prioritization, coordination, consistency, quality, and timeliness of inspections, reporting, and enforcement actions to ensure the continued safety and effectiveness of products on the market.

Postmarket Surveillance

These accomplishments exemplify CDRH's efforts during FY 2006 to advance patient safety by improving problem detection capabilities in marketed device products.

Post-approval Studies Program

CDRH continued to make great strides in its Post-approval Studies (PAS) Program. The Center issued a draft guidance—*Procedures for Handling Post-approval Studies Imposed by PMA Order*—to enhance the efficiency and effectiveness of studies conducted by manufacturers as a condition of device approval. The guidance presents suggested format and content for reports on these studies, mentions presentations to Advisory Panels (to enhance study transparency), and notes possible enforcement actions when there is failure to comply. In addition, CDRH conducted regular meetings with the Implementation Workgroup (providing CDRH management oversight) to assure the smooth transition of the program and develop best practices. The epidemiology staff thoroughly reviewed all submissions for new PMAs and led the identification of post-approval questions, the design of new PAS, and review of ongoing PAS.

Postmarket Surveillance

CDRH continues to monitor postmarket product performance through the Center's nationwide reporting system and by conducting applied epidemiologic research. For the last quarter of FY 2006, safety analysts identified over 100 new and ongoing medical device safety issues. They also responded to over 100 consult requests related to information in the reports database. Epidemiologists, in addition to the central role in PAS, participated in new and ongoing applied research projects, such as the accuracy of troponin assays (for myocardial infarction) and the safety and effectiveness of vertebroplasty.

Section 522 Studies

FDA may order a manufacturer to conduct postmarket surveillance of a medical device under section 522 of the Food, Drug, and Cosmetic Act. In FY 2006, CDRH staff collaborated with industry sponsors to design science-based Section 522 studies that answer important postmarket questions. The Center issued a consolidated guidance document for postmarket surveillance, ordered postmarket surveillance for two devices (overnight orthokeratology lenses and a coronary vascular anastomosis device), continued postmarket surveillance of three critical products, began development of an enforcement plan for postmarket surveillance, and issued the first Warning Letter citing postmarket surveillance violations under Section 522.

MedSun

The Medical Product Surveillance Network (MedSun) plays an important role in post-market surveillance efforts by connecting CDRH to device users. Hospitals, nursing homes, and other healthcare facilities use this interactive Internet-based reporting program to report medical device problems. This information helps CDRH, device manufacturers, and medical facilities proactively address device safety concerns.

During the fiscal year, CDRH exceeded by 15 percent its 2006 goal of obtaining a 71 percent participation rate from the 350 participating user facilities. MedSun expanded to include interactive networks that address particular health issues, including LabNet (laboratory devices), KidNet (pediatric devices), TissueNet (human cells and tissues), and HeartNet (electrophysiology devices, such as pacemakers), and used surveys of network facilities to determine the effectiveness of recalls and the training needed to reduce adverse events.

Medical Device Reports

Medical device reporting is how FDA receives information on significant medical device adverse events from manufacturers, importers, and user facilities so that problems can be detected and corrected quickly. CDRH received 224,197 medical device reports during the fiscal year.

Report Type	Mandatory Reports (FDA Form 3500A)	Alternative Summary Reporting	Voluntary Reports (FDA Form 3500)	Totals
Death	2,683	0	147	2,830
Injury	38,349	75,409	2,328	116,086
Malfunction	65,863	29,225	1,397	96,485
Other	7,396	7	1,393	8,796
Totals	114,291	104,641	5,265	224,197

Compliance and Enforcement

CDRH risk management actions aimed at preventing harm to the public from regulated products include public health notifications, warning letters, and recalls. The following actions were taken during FY 2006.

Enforcement Actions

CDRH protects the American public by ensuring that manufacturers of medical devices comply with Current Good Manufacturing Practice (CGMP) requirements and the Quality System Regulation, taking enforcement actions if warranted. During the FY 2006, CDRH developed and implemented the *Real Time Regulatory Review Process* to help reduce timeframes so that enforcement actions are processed in a timely manner.

CDRH improved product quality and the safety of numerous medical devices by taking at least 55 enforcement actions during FY 2006 including a corporate warning letter, 4 seizures, and 1 injunction.

Warning Letters

Warning letters are intended to alert a device manufacturer that their product is in violation of the laws that FDA enforces. In the letter, the manufacturer is advised to take appropriate and prompt corrective action to avoid administrative or regulatory action. In FY 2006, 154 of the 538 warning letters issued were related to medical devices and radiological health (29%).

Recalls

Recalls are issued to remove or correct a medical device that violates FDA law. Though FDA can order a recall, manufacturers initiate most recalls voluntarily in collaboration with FDA. During FY 2006, CDRH initiated 651 recall actions involving 1,550 products. This represents approximately a 10 percent increase in recall actions from FY 2005 (571 actions involving 1598 products) and includes 143 in vitro diagnostic device recall actions.

Class	Description
Class I	Likely that use of the product will cause serious health problems or death
Class II	Unlikely that use will cause serious health problems, or problems resulting from use will be temporary and reversible
Class III	Unlikely that use will cause health problems

Recall Actions

	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006
Class I	29	7	15	7	23	25	21
Class II	344	395	467	460	473	423	500
Class III	122	153	146	141	142	123	130
Totals	495	555	628	608	638	571	651

Expert Witnesses

The use of experts who provide testimony and certification to the compliance status of firms is very important in cases in which the Agency takes regulatory actions. In FY 2006, three cases required the services of expert witnesses. Their testimonies were critical to the success of these cases processed by the CDRH Office of Compliance.

Inspection

Inspection Goals

CDRH and the Office of Regulatory Affairs (ORA) exceeded the FY 2006 inspection goals by at least 20 percent for domestic, foreign, and bioresearch monitoring (BIMO) inspections in FY 2006:

- ❖ 122% (1,299 of 1066) for registered domestic Class II and Class III medical device manufacturers;
- ❖ 123% (207 of 168) for foreign Class II and Class III medical device manufacturers; and
- ❖ 120% (336 of 278) for BIMO inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations.

Bioresearch Monitoring (BIMO) Audits and Enforcement Activities

In addition to compliance with Good Manufacturing Practices (GMP) requirements, industry must comply with bioresearch monitoring (BIMO) requirements. BIMO requirements include good laboratory practices (GLP) and regulations related to human subject protection and data integrity.

CDRH collaborates with the Office of Regulatory Affairs (ORA) to conduct data audits to determine if devices should be approved. FY 2006 BIMO audit-related accomplishments include the following:

- ❖ Issued 24 BIMO Warning Letters and 13 BIMO Untitled Letters to bring non-compliant firms and researchers into compliance with the regulations;
- ❖ Entered into a consent agreement to restrict a device clinical investigator from participating in device research;
- ❖ Entered into an agreement to restrict an Institutional Review Board's ability to approve any new FDA-related research;
- ❖ Entered into formal agreements with 3 medical device companies to stop the substantive review of their research/marketing submissions until they develop and implement corrective and preventive action plans to ensure the integrity of data submitted to support their premarket submissions;
- ❖ Identified and analyzed all inspections from the past 6 years with serious violations and issued 44 follow-up inspections to confirm whether corrective and preventive actions were implemented as promised;
- ❖ Removed four firms from FDA's Application Integrity Policy list as a result of their comprehensive development and implementation of corrective and preventative actions to assure human subject protection and data reliability in submissions;
- ❖ Conducted inspections and subsequent analysis that resulted in 2 firms withdrawing their pending 510(k)s submissions due to unreliable substantial equivalence data/information, and 1 pediatric device sponsor withdrawing its Investigational Device Exemption (IDE) for lack of proper oversight and subject safety issues;
- ❖ Conducted 105 data audit inspections, addressed data integrity concerns, and issued compliance actions related to 54 active PMAs or PMA supplements; and
- ❖ Received and evaluated 157 allegations of research misconduct that could compromise the safety of human research subjects or undermine the quality of research data. Evaluation of the allegations resulted in the issuance of 82 inspections or investigations.

Approximately 85% of FDA inspections of clinical research with medical devices reveal only minor problems with research conduct. To help improve the remaining device research that may be problematic, the Division of Bioresearch Monitoring has increased outreach activities with regulated industries including study sponsors, clinical investigators, study site staff, and Institutional Review Boards plus small businesses through pre-IDE meetings and the Office of Orphan Product Development. In addition, staff have published several articles in professional journals to improve awareness of proper clinical research practices. These outreach activities have resulted in improvements in non-compliance over the past few years.

Risk-Based Inspection Work-Plan

CDRH continued to refine a risk-based management program for inspection and enforcement actions to improve the regulation and monitoring of the medical device industry. In order to utilize resources efficiently, the cross-Center risk-based inspection work plan prioritization process was used to identify public health concerns and issued special emphasis inspection assignments in three areas:

- ❖ IV Administration Test Kits
- ❖ Internal Cardioverter Defibrillators (ICD)
- ❖ Automatic External Defibrillators (AED)

Infusion Pump Project

This project initiated during the fiscal year will transform the way CDRH does business by making available the most up-to-date analysis of market share information on the infusion pump industry. This project should improve CDRH capability to make informed decisions that impact public health and medical necessity. This project also looked at the industry as a whole in order to determine areas that need to be addressed. As a result, numerous firms came into compliance while others were subject to regulatory action. An initiative to better educate the community is planned.

Evaluation of Inspection Violations

CDRH conducted a simple analysis of the Turbo EIR (establishment inspection report) database and identified the top five reasons violations were issued during a medical device inspection. The information will enable CDRH to develop strategies to work with industry to address inadequacies and bring firms into compliance.

Mammography Quality Standards Act (MQSA)

Congress enacted the Mammography Quality Standards Act (MQSA) to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. FDA was charged with developing and implementing MQSA regulations. Examples follow of CDRH accomplishments in advancing mammography quality standards during FY 2006.

MQSA Program Inspections

CDRH conducted annual inspections at over 8,800 mammography facilities and ensured that 98 percent of those facilities met inspection standards with less than 2 percent having Level I (serious) problems. CDRH has completed over 104,000 facility inspections nationwide since the MQSA program inception.

MQSA Enforcement Actions

An Additional Mammography Review (AMR) is performed in cases where FDA or the Certifying State has reason to believe that mammography quality has been compromised and may present a serious risk to human health. CDRH has performed 80 AMRs since the MQSA program began.

Although not a regulatory action, an AMR occasionally results in a regulatory action, such as a Patient and Physician Notification (PPN). A PPN explains the problem found to patients and referring physicians and outlines actions to take to reduce related health risks.

If an accreditation body revokes a facility's accreditation, FDA may conduct an investigation to determine the reasons for the revocation and may determine that the facility's certificate shall *no longer be in effect*. A facility whose certificate is *no longer in effect* because it has lost its accreditation may not legally practice mammography.

<http://www.fda.gov/cdrh/mammography/index.html>

During the FY 2006, CDRH completed several regulatory actions against mammography facilities including one Patient and Physician Notification (PPN) and one instance where FDA declared a facility's MQSA certificate *no longer in effect*.

Collaborations

Through increased collaboration with external partners, CDRH is enhancing its ability to identify, analyze, and act on postmarket information, and improve enforcement strategies and outcomes.

Software Forensics Laboratory

In consultation with other federal agencies involved with software integrity issues (e.g., Department of Defense, FBI, National Institute of Standards and Technology, NASA), the CDRH Software Forensic Laboratory leveraged the latest academic research to implement a state-of-the-art software forensic capability during 2006. This capability may be used in any phase of the product life cycle, but is particularly valuable in understanding the root causes of adverse events due to software failures. In 2006, this new capability was used to the great benefit of the Center in several high-profile compliance cases. Ultimately, such tools will increasingly be used by medical device manufacturers in their own product development phase, thereby reducing the frequency of software defects and the incidence of adverse events and product recalls.

Defibrillator Working Group

CDRH established the Defibrillator Working Group to coordinate pre- and post-market FDA activities for implantable and external defibrillators. The working group addressed specific processes related to the regulation of defibrillators and collaborated with the Heart Rhythm Society and AdvaMed to assure a full perspective on the issues. The working group piloted a model for effective communication across the entire device life cycle.

Agency for Healthcare Research and Quality

CDRH continued several collaborations with the Agency for Healthcare Research and Quality (AHRQ) which administers several datasets of interest, including the Healthcare Utilization Project Nationwide Inpatient Sample (NIS) of hospital discharge claims and the State Inpatient Databases (SID) of hospital discharge claims. Although similar studies have

been done with smaller patient groups, this is the first to use a national dataset to make national estimates of the short-term outcomes of hip prosthesis surgery.

Interagency Registry for Mechanically-assisted Circulatory Supports (Intermacs)

This effort aims to capture detailed clinical data on all patients receiving ventricular-assist devices for destination therapy. The effort is funded by NIH, requires facilities to meet Centers for Medicare and Medicaid Services (CMS) standards to receive reimbursement, and accommodates FDA needs for active surveillance and post-approval studies of these devices. <http://www.intermacs.org/>

e-Bay and the Federal Trade Commission (FTC)

CDRH continued grass root and collaborative efforts with e-Bay and the Federal Trade Commission (FTC) to ensure that unapproved products were removed and not offered for sale on the e-Bay website.

Global Harmonization

The market place for medical devices is global—40 percent of approved device firms have manufacturing facilities abroad while 6,000 overseas establishments export devices to the United States. CDRH plays an important role supporting global harmonization activities including assisting foreign manufacturers to comply with U.S. medical device regulations. As part of the effort to minimize burden to industry, CDRH participates in the development of international as well as national product standards.

Health Canada

In September 2006, CDRH and Health Canada announced a pilot multi-purpose audit program (PMAP). The purpose of the pilot, slated to begin in 2007, is to evaluate the effectiveness of performing a single third party inspection/audit of medical device manufacturers' quality systems that would meet the needs and regulatory requirements of both countries.

<http://www.fda.gov/cdrh/ap-inspection/pmap-letter.html>.

International Organization for Standardization (ISO)

The International Organization for Standardization (ISO) is the world's largest developer of standards. ISO standards are designed for implementation worldwide and include requirements for medical devices.

During FY 2006, CDRH participated in the ISO Technical Committee 94, Workgroup 4 (WG4), meeting in Chicago, Illinois to discuss and revise the draft standard for *Clinical Investigation of Medical Devices for Human Subjects*. The Workgroup voted to advance the standard for further review within the ISO. CDRH collated the comments of FDA representatives and other U.S. participants for the WG4 Editing Committee in an 11-page document to ensure that the comments were included in the final work product.

Global Medical Device Nomenclature

The Global Medical Device Nomenclature (GMDN) is an international standard for naming, defining, and coding medical device groups to ease identification of products worldwide and reduce confusion when investigating device-related problems. CDRH has contributed considerably to administration and technical maintenance of the standard such as promoting improved nomenclature practices for better data management and efficient communication of data with international regulatory partners.

Global Harmonization Task Force (GHTF)

The Global Harmonization Task Force (GHTF) is an international member organization dedicated to fostering convergence of medical device regulatory practices worldwide while ensuring the quality, safety, and effectiveness of medical devices. GHTF members also work to promote technological innovation and facilitate international trade. In FY 2006, CDRH actively participated in the work of 5 GHTF Study Groups:

- ❖ Study Group 1 – Regulatory and Premarket Requirements
- ❖ Study Group 2 – Postmarket Vigilance
- ❖ Study Group 3 – Quality Systems
- ❖ Study Group 4 – Regulatory Auditing of Quality Systems
- ❖ Study Group 5 – Clinical Evidence

FDA Goal 4—Transforming FDA Business Operations, Systems, and Infrastructure to Support FDA's Mission in the 21st Century

CDRH is integrally involved in FDA-wide efforts to create a stronger, more unified Agency. The increasingly complex regulatory mission of the FDA requires improved business practices to create efficiencies, standardize processes, enhance infrastructure, and improve planning. CDRH FY 2006 efforts to augment FDA's mission in the 21st Century included IT enhancements, development of an operational plan, expanded training for staff, and attention to homeland security.

CDRH Management

Efficient and effective management is necessary to support CDRH programs.

Medical Device Postmarket Transformation Initiative

Assuring the postmarket safety and effectiveness of medical devices which may remain in use for 10–20 years is a daunting task. In January 2006, as the result of an internal review of CDRH postmarket tools and processes, the Center issued a comprehensive report on the Medical Device Safety Program. In response to the report, the Center convened a Postmarket Transformation Leadership Team (PTLT) composed of CDRH senior staff and external medical experts to consider recommendations to make the Center's postmarket program more comprehensive and timely. The recommendations focused on four areas designated for improvement:

- ❖ Create a culture of collaboration to improve joint efforts within and without the Center to identify and solve postmarket problems;
- ❖ Develop world class data sources and systems to more rapidly recognize, analyze, and track device usage problems;
- ❖ Enhance risk/benefit communication efforts to quickly and clearly share postmarket information with practitioners, patients, and consumers; and
- ❖ Increase collaboration to improve enforcement strategies and outcomes.

The PTLT met several times from January to September 2006, recommending actions under each area and suggesting next steps to achieve postmarket transformation.

CDRH Operational Plan

The Center concluded FY 2006 with development of a CDRH operational plan. The purpose of the plan is to provide the Center with a roadmap aligning CDRH's strategic goals with those of the FDA. CDRH is the first among FDA centers to develop a

comprehensive, strategic operational plan linking mission to objectives, actions, and performance measures.

Communications Improvement Initiative

During the fiscal year, CDRH conducted an evaluation of internal communications processes. Interviews and focus groups with management and staff were used to identify processes working well and areas needing improvement. CDRH is evaluating recommendations to determine a workable plan for improving Center-wide communications, and to support CDRH and FDA external communications goals.

IT Enhancements

IT systems allow for better tracking and monitoring of medical devices throughout the total product life cycle. CDRH continued working in FY 2006 to ensure that IT projects are consistent with the Center's strategic goals and priorities. Efforts to map out 60 business processes and determine cross-cutting functions and IT support needs contributed significantly to development of the first CDRH IT Strategic Plan.

IT enhancements initiated during FY 2006 included systems development for submissions, review, and tracking.

Electronic Submissions

❖ FURLS

In support of the Expanded Electronic Government Initiative of the President's Management Agenda (PMA) and information collection requirements of the Bioterrorism Act, CDRH completed the design phase and began implementation of the FDA Unified Registration and Listing System (FURLS). FURLS will allow for electronic submissions from industry and result in significant savings for CDRH in contract costs.

❖ CeSub eSubmitter

After a very successful pilot program for the in vitro diagnostic device industry [Turbo 510(k)] and for the electronic product industry (eRadHealth), CDRH improved submission software to produce a new e-tool called CeSub eSubmitter. CeSub eSubmitter is free software that allows sponsors to complete and submit submissions electronically. Since the roll out of the CeSub software applications, CDRH has received well over 100 IVD 510(k) submissions, almost entirely from new companies, as well as over 100 electronic product submissions.

To increase electronic product industry use of the CeSub software, CDRH is enclosing a CeSub flyer with acknowledgement letters sent in response to reports received from industry. Manufacturers are also referred to the CDRH website for information on how to comply with requirements and encouraged to download the software.

<http://www.fda.gov/cdrh/cesub/>

During FY 2006, CDRH also increased the number of electronic submission templates for the Radiological Health Program.

Industry can now submit applications electronically for a larger number and variety of products. Electronic submissions improve the review process and result in reduced costs and time for both industry and the FDA.

❖ **Rad Health Processor (RH Pro)**

CDRH began development of an electronic document processing system, RH Pro, to replace the legacy data system used since the beginning of the radiological health program. RH Pro facilitates storage and management of both scanned paper and electronically submitted reports and correspondence on electronic products and manufacturers.

❖ **eCopies Program**

CDRH initiated the eCopies program to encourage sponsors of premarket medical device submissions to include a copy of their submission in the prescribed electronic form along with the required paper copies. During the fiscal year, 2,374 premarket submissions (2,376,036 pages) were scanned off site and received through the FDA Gateway.

Electronic Review

❖ **Documentum**

As part of FDA commitment to improve procedures and move toward an e-government environment, CDRH is shifting from paper to electronic review. CDRH participated in the development of Center-wide procedures for use of the software Documentum for the review of Premarket Approval Applications and provided training to reviewers and consulting reviewers to ensure uniform implementation. Further, procedures were developed to allow electronic archival and review of electronic product Radiation Safety Reports. CDRH also participated in a Business Process Improvement initiative to map out the current review process and propose options to improve the review process by integrating electronic review tools.

Electronic Tracking

❖ **Export Certificates**

CDRH began planning an electronic program for processing and issuing export certificates. On average, CDRH produces 2,280 certificates per month.

❖ **Center Tracking System (CTS)**

FDA Office of the Commissioner and FDA Office of Combination Products began use of the CDRH Tracking System (CTS) for managing/tracking combination products requests for designation (RFD). CDRH also deployed enhancements to CTS to support business processes and rules across the total product life cycle of medical devices. In addition, the

Center completed enhancements to the device nomenclature management system (DNMS) and completed development of the electronic consultations tracking (eConsult) module of CTS.

The tracking capabilities provided by CTS, electronic document archival provided by Documentum, and the electronic submission and control capabilities provided by CeSub and RH Pro will provide a paperless document control and review process for electronic product submissions.

❖ Compliance Operations and Program Support System

CDRH implemented the first phase of the Compliance Operations Program Support (COPS) workflow management system and integrated it into the Center Tracking System (CTS). The new COPS-CTS component will track regulatory actions and their outcomes and will improve workflow management and tracking capabilities.

❖ Premarket Modernization Program (PMP)

CDRH initiated the Premarket Modernization Program (PMP) to update and optimize access to CDRH's data through the creation of a total product life cycle (TPLC) data warehouse. Initially the warehouse will be loaded with premarket data, but it is designed to eventually include postmarket and compliance data.

❖ Electronic Medical Device Reporting

CDRH initiated development of a program to modernize the data entry process for adverse events and for accepting and processing electronic adverse event reports (eMDR) using the Health Level Seven Individual Case Safety Report (HL7 ICSR) message format. This will allow for more rapid transfer of adverse event reports to the clinical analyst for review and possible action. When the system is fully produced, implemented, and used by the manufacturing firms, it will reduce data entry costs by over 50 percent.

❖ Postmarket Studies Tracking

CDRH worked with a contractor to develop the Conditions of Approval tracking database for all post approval studies January 1, 2005, and forward. The database automatically keeps track of due dates; the status of studies will be placed on a web posting for the public.

Training CDRH Staff

Recruiting and training of scientists and health professionals in technologies is crucial for CDRH to accomplish its public health mission and to create and maintain an excellent workforce. Training and continuing education for CDRH staff is also important to enhance job performance and maximize career potential.

Staff College

Seven hundred thirty-six (736) CDRH employees attended 2,333 Staff College courses—an average of 3 courses per employee. The Staff College presented 126 different courses: 17 percent in law and policy, 36 percent in science, 29 percent in professional development, and 18 percent in leadership.

New Employee Orientation Program

Gateway to Success is CDRH's orientation program for new employees. Administered by the Office of Communication, Education, and Radiation Programs (OCER) Staff College, *Gateway to Success* consists of several program components.

- ❖ The New Employee Toolkit is a hard copy resource given to new employees on their first day in CDRH. The toolkit contains an overview of *Gateway to Success*, background information on CDRH, a map of CDRH facilities, a new employee checklist, and contact information.
- ❖ The Peer Guide Program pairs new employees with more seasoned employees who are equipped to answer questions and share information about their experiences at CDRH. Peer guides are provided with the brochure *CDRH Peer Guides: Tips for Communicating with Your Assigned Peer*.
- ❖ Discovery Portal is an online portal accessed through the Staff College's Learning Management System. The website has links to both FDA and CDRH administrative, personnel, and organizational information; a repository of forms; facility maps; and a checklist for new employees.
- ❖ *Gateway to Success* resources for supervisors include *Supervisor Checklist for Welcoming New Employees* and *Supervisor Talking Points for Meeting with New Employees*.
- ❖ *Gateway to Success* classroom training includes interactive exercises and dialogue designed to help new employees reflect on their first few months as a CDRH employee and understand their role relative to CDRH's mission. The training also provides guidance on career development at CDRH.

Competency Development Program

During FY 2006, CDRH implemented a voluntary *Competency Development Program* for staff. The program is based on nine core business and science competencies:

- ❖ Communication
- ❖ Computer skills and knowledge
- ❖ Critical thinking
- ❖ Ethics and integrity
- ❖ Medical and radiation products and devices
- ❖ Organizational knowledge
- ❖ Scientific, medical, and radiation terminology
- ❖ Teamwork
- ❖ Time management

The Competency Development Program will help CDRH managers assess staff needs and pinpoint training and development opportunities to equip staff to achieve the mission and goals of CDRH.

CDRH Leadership Programs

During FY 2006, CDRH continued to develop the skills of existing leaders and foster the growth of the next generation of Center leaders. CDRH leadership programs offer senior staff executive coaching opportunities and annual 360 degree feedback. Motivated, highly skilled non-managerial staff are competitively selected to participate in the Center's Leadership Readiness Program.

Educational Broadcasts

The Division of Communications Media (DCM) within CDRH's Office of Communication, Education, and Radiation (OCER) Programs produces satellite broadcasts and video productions for diverse clientele in the federal government and the private sector. During FY 2006, DCM provided 8 hours of mission-related programming every day to CDRH employees via the CDRH fiber-optic network, including 37 educational and training programs received live via satellite and delivered simultaneously. They also produced 18 teleconferences for FDA and other government agencies on a wide variety of topics.

<http://www.fda.gov/cdrh/ocer/dcm/>

Homeland Security

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

Radiological Counterterrorism and Radiation Safety

During FY 2006, CDRH consulted with fellow FDA Centers, and state and federal partners to address radiation safety of security screening and defense products.

- ❖ CDRH participated in measurement instrument testing with the Transportation Security Administration (TSA) and helped revise radiation safety training that TSA is preparing for its security staff working with security screening products.
- ❖ CDRH participated in the Interagency Steering Committee on Radiation Standards (ISCORS) to develop a federal guidance entitled *Guidance for Security Screening of Humans Utilizing Ionizing Radiation*.
- ❖ CDRH worked with the Federal Aviation Administration (FAA), the Department of Homeland Security (DHS), the Department of Defense (DoD), and industry representatives to evaluate the safety of air-based and ground-based laser anti-missile defense systems to protect commercial air traffic.

Emergency Preparedness

❖ Hurricane Response Assistance

CDRH deployed five staff members to assist with FDA's efforts in response to Hurricanes Katrina, Rita, and Wilma. In addition, CDRH emergency team members actively participated in operations to supply regulatory and other helpful medical device and safety information for use post hurricane to FDA's Emergency Operations Center (EOC) and ultimately to emergency personnel, public health professionals, and consumers.

❖ Rapid Response Team to Combat Pandemic (Avian) Flu

In response to the emerging threat of pandemic (avian) influenza, FDA announced the formation of a Rapid Response Team. In the event there is an avian flu outbreak in the United States, the team, including representatives from CDRH, will assist in locating and monitoring stockpiles of medical devices that will be in high demand but may be in short supply. In addition, the Rapid Response Team will work collectively with other healthcare centers and FDA's Office of Counterterrorism Policy and Planning (OCTTP) to resolve regulatory policy issues that may occur prior to and during an influenza pandemic.