CDRH 2010 STRATEGIC PRIORITIES - FY 2010 ACCOMPLISHMENTS

In January we released to the public and began implementing our 2010 strategic plan. The plan, CDRH FY 2010 Strategic Priorities, identified four priority areas of activity that presented significant opportunities to improve our effectiveness in fulfilling our mission. In an effort to set both clear and aggressive timelines, the strategic plan included time-bound goals associated with each strategy we were planning to implement, and time-bound actions associated with the goals listed under each strategy.

We committed to achieve many of the goals in fiscal year (FY) 2010. For those goals that would take longer to accomplish, we identified the supporting actions we would take in FY 2010 to stay on track. In total, we committed to 123 actions, with 107 of those actions due in FY 2010. Recognizing that by setting aggressive timeliness many of the deadlines we set for ourselves were really stretch goals, we set as our performance target accomplishing at least 85 percent of the actions with due dates in the fiscal year. (See CDRH's FDA-TRACK Management Dashboard.)

We are pleased to report that we met our FY 2010 performance target having successfully completed 86 percent, 92 of the 107 actions due in FY 2010. As of November 30, 2010 we have successfully completed 91percent, 99 0f 109 actions due by the end of November. The following examples highlight some of our accomplishments:

- We completed and released for public comment two preliminary reports recommending concrete steps we could take to strengthen the 510(k) program and increase the predictability of our use of science in regulatory decision making by fostering medical device innovation, enhancing regulatory predictability, and improving patient safety.

- We launched the CDRH Transparency Website; a website which will eventually serve as a one-stop-shop for publicly released information about our decisions, as part of our efforts to increase transparency in our decision making.

- We implemented the CDRH Leadership Program and are finalizing the development of core competencies and recommended coursework for premarket reviewers and medical officers, as part of our effort to enhance CDRH's ability to meet the Center's mission critical needs and to maintain high-quality employees.

- We established and held a public meeting of the Council on Medical Device Innovation, comprised of representatives from FDA and other federal agencies, as part of our efforts to proactively facilitate medical device innovation to address unmet public health needs. We also worked, and continue to work, with industry and others to facilitate improvements in the design of devices that have been associated with safety problems across multiple manufacturers: (i) in February, we announced an Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging; and (ii) in April, we announced the Infusion Pump Improvement Initiative.

Before we issue our strategic plan for 2011, we want to highlight the significant amount of work accomplished by our dedicated staff in support of the FY 2010 Strategies Priorities. The tables below provide an account of the status of those goals and actions whose due dates have elapsed as of November 30, 2010. Following a scorecard approach, we used a checkmark to indicate actions and goals we accomplished; we labeled with "Started" actions that are ongoing; and used italics to indicate actions not covered by this progress report.

PRIORITY 1. FULLY IMPLEMENT A TOTAL PRODUCT LIFE CYCLE APPROACH

Strategy 1.1. Enhance and Integrate Premarket, Postmarket, and Compliance Information and Functions

1.1.1. Strengthen Premarket Review

Goal 1.1.1.1.	**By September 30, 2010, CDRH will begin to implement the recommendations of the 510(k) Working Group.**	
	❖ By February 28, 2010, collect input from external constituencies through a public docket and a public meeting.	✓
	❖ By March 31, 2010, hold an all-hands meeting to collect additional input from CDRH employees.	✓
	❖ By March 31, 2010, develop and implement changes to the 510(k) Quarterly Quality Review Program that will allow CDRH to assess the impact of changes to the 510(k) program.	✓
	❖ By May 31, 2010, submit to the Center Director the recommendations of the 510(k) Working Group.	✓
	❖ By July 31, 2010, develop an implementation plan.	Started
	❖ By September 30, 2010, begin to implement the recommendations of the 510(k) Working Group.	✓
Goal 1.1.1.2.	*By June 30, 2011, CDRH will complete our evaluation of recommendations from the IOM report.*	
Goal 1.1.1.3.	**By December 31, 2010, CDRH will take steps to improve the quality of clinical data submitted in support of premarket approval applications (PMAs).**	
	❖ *In 2010, issue draft guidance on study design for clinical trials submitted as part of a PMA.*	
	❖ By August 31, 2010, complete phase I of CDRH's assessment of the quality of clinical studies submitted in support of PMAs.	✓
	❖ By November 30, 2010, begin to take steps to improve the quality of clinical data submitted in support of PMAs.	Started
Goal 1.1.1.4.	**By September 30, 2010, CDRH will fully adopt iReview to support the structured review of 510(k) submissions.**	
	❖ By February 28, 2010, release the iReview pilot application.	✓
	❖ By May 30, 2010, complete user acceptance testing for iReview.	✓
	❖ By June 30, 2010, design and launch iReview staff training course.	Started
	❖ By September 30, 2010, fully implement iReview for 510(k) submissions.	Started
Goal 1.1.1.5.	**In 2010, CDRH will take steps to address class III device types currently allowed to enter the market through the 510(k) process.**	✓

1.1.2. Align Our Scientific Resources throughout the Center

Goal 1.1.2.1.	**By September 30, 2010, CDRH will establish policies and procedures to determine how to optimally use CDRH's scientific resources to support the Center's programmatic functions.**	
	❖ By March 31, 2010, hire a permanent Deputy Center Director for Science.	✓
	❖ By March 31, 2010, develop policies and procedures for utilizing Scientific Computing resources across the Center and collaboratively with other Centers.	✓
	❖ By June 30, 2010, establish a CDRH-wide Science Prioritization Program.	✓
	❖ By September 30, 2010, formalize procedures that enable CDRH to redirect research efforts to address emergent public health issues.	✓

1.1.3. Optimize Meaningful Data Collection and Analysis

Goal 1.1.3.1.	**By January 31, 2012, CDRH will put in place systems and procedures to more efficiently and effectively capture, analyze, and share high-quality information about adverse events.**	
	❖ By March 31, 2010, realign product code assignments to medical device report (MDR) analysts.	✓
	❖ By April 30, 2010, implement the new Event Problem Code system.	✓
	❖ *By January 31, 2012, implement improvements to CDRH's adverse event reporting data systems.*	
Goal 1.1.3.2.	**By January 31, 2011, CDRH will implement strategies to increase real-time adverse event reporting and establish pathways for interactive information exchange with healthcare providers through MedSun.**	
	❖ By February 28, 2010, work with OMB to develop and implement a strategy that allows CDRH to conduct rapid-response surveys with MedSun sites.	✓
	❖ By September 30, 2010, expand and enhance selected MedSun "Nets."	✓
	❖ By September 30, 2010, complete and evaluate the effectiveness of the MedSun Regional Representative Pilot.	✓
	❖ *By January 31, 2011, identify and incorporate into MedSun large healthcare providers.*	
Goal 1.1.3.3.	**By January 31, 2011, CDRH will develop collaborative relationships to promote the establishment of and gain access to registries that provide important information for medical device surveillance.**	
	❖ By June 30, 2010, identify the top five medical device types for which registry-based surveillance is feasible, will provide the most public health value, and has not yet been established, and develop collaborative relationships to participate in the establishment and use of registries for these medical device types.	✓
	❖ *By January 31, 2011, evaluate progress achieved through existing collaborations and identify next steps.*	
Goal 1.1.3.4.	**By September 30, 2013, CDRH will implement a Unique Device Identification (UDI) system.**	
	❖ By September 30, 2010, complete Phase 4 of the UDI database pilot (test UDI requirements).	✓

1.1.4. Institute Knowledge and Process Management

Goal 1.1.4.1.	**By December 31, 2011, CDRH will have in place systems, analytical methods, and processes for compiling, distributing, and storing information, including data related to regulated products and institutional knowledge, to support the Center's programmatic functions.**	
	❖ By June 30, 2010, evaluate existing internal information-sharing programs, including Collaborative Review, OSB WEBs, and CDRH Networks, and identify best practices and lessons learned.	✓
	❖ By June 30, 2010, hire a senior-level medical officer to coordinate pediatric activities.	✓
	❖ By September 30, 2010, identify the day-to-day information needs of Center employees.	**Started**
	❖ *By December 31, 2010, assess the data systems and analytical tools we use to compile information and identify gaps.*	
	❖ *By June 30, 2011, begin to develop systems, analytical methods, and processes to meet identified needs.*	
	❖ *By December 31, 2011, implement selected systems, analytical methods, and processes to meet identified needs.*	

1.1.4. Institute Knowledge and Process Management (continued)

Goal 1.1.4.2. By December 31, 2010, CDRH will fully implement a business process for signal escalation.	
❖ By February 28, 2010, define criteria for what constitutes a signal in each of the Offices. By	✓
❖ February 28, 2010, define roles, responsibilities, and workflow for sharing signals, as well as criteria for escalating, de-escalating and taking action on different signal types.	✓
❖ By May 31, 2010, design and pilot a signal escalation business process.	✓
❖ By September 30, 2010, begin to evaluate the established signal escalation business process.	✓
❖ *By December 31, 2010, finalize and implement the signal escalation business process across the Center.*	
Goal 1.1.4.3. By September 30, 2010, CDRH will develop a strategy for and begin to incorporate use of the @Work toolset into day-to-day Center functions.	
❖ By March 31, 2010, identify high-value uses of the @Work toolset.	✓
❖ By September 30, 2010, develop and launch staff training on high-value uses of @Work toolset.	✓
Goal 1.1.4.4. By September 30, 2010, CDRH will pilot and evaluate Appian's business process management suite.	
❖ By May 31, 2010, design an IT-supported business process using Appian and, pending resources, implement the process.	✓
❖ By September 30, 2010, evaluate the Appian pilot.	✓

1.1.5. Reorganize to Effectuate Integration

Goal 1.1.5.1. By July 31, 2010, CDRH will assess possible organizational structures to effectuate integration of Center functions.	✓
Goal 1.1.5.2. By December 31, 2010, CDRH will begin implementation, if a decision is made to reorganize across offices.	

1.1.6. Address Challenges Associated with Globalization

Goal 1.1.6.1. By July 31, 2010, CDRH will enhance our internal capacity to coordinate international activities.	
❖ By May 31, 2010, hire a permanent Associate Director for International Affairs to coordinate CDRH international activities.	Started
❖ By July 31, 2010, put in place processes to better coordinate ongoing international activities across the Center.	✓
Goal 1.1.6.2. By June 30, 2011, CDRH will have in place mechanisms to exchange medical device information with trusted foreign regulatory authorities.	
❖ By February 28, 2010, establish a Center action team to develop processes and tools for the exchange of medical device information with foreign regulatory authorities through an international network.	✓
❖ By September 30, 2010, complete implementation of the ongoing ISO 13485 Audit Report initiatives.	✓
❖ By November 30, 2010, finalize Center plan for the exchange of medical device information with foreign regulatory authorities.	Started
❖ *By June 30, 2011, implement Center plan.*	

1.1.6. Address Challenges Associated with Globalization (continued)

Goal 1.1.6.3.	**By January 31, 2012, make use of Good Manufacturing Practices inspections conducted by other countries (see Goal 1.1.6.2.).**	
	❖ By January 31, 2010, finalize the evaluation of the Health Canada (HC) pMAP pilot and communicate results to participants and constituents.	✓
	❖ By February 28, 2010, determine the feasibility of developing a single audit program in collaboration with HC and Australia's Therapeutic Goods Association (TGA).	✓
	❖ By May 31, 2010, depending on the findings and conclusions of the feasibility assessment, develop an implementation plan for a single audit program with HC alone, or with both HC and TGA.	✓
Goal 1.1.6.4.	**By January 31, 2011, CDRH will have in place a public database of results from device inspections conducted by FDA and accredited third parties.**	
	❖ By April 30, 2010, publish online information from FDA inspections.	✓
	❖ *By January 31, 2011, begin to post accredited third-party inspection information.*	
Goal 1.1.6.5.	**By July 31, 2011, CDRH will create a collaborative consultation and premarket review pilot program with other countries.**	
	❖ By March 31, 2010, develop a Proof of Concept (POC) plan for the Collaborative Consultation and Review of Premarket Applications pilot program for novel/innovative cardiovascular technologies with Japan.	✓
	❖ *By January 31, 2011, utilize shared review information from Harmonization by Doing (HBD) in the review of two non-cardiovascular device types.*	
	❖ *By July 31, 2011, develop a Summary Technical Document (STED) POC prospective study with Japan (and Canada) for at least four device types.*	

1.1.7. Seamlessly Incorporate New and Evolving Science into Regulatory Decision-Making

Goal 1.1.7.1.	**By September 30, 2010, CDRH will begin to implement the recommendations of the Task Force on the Utilization of Science in Regulatory Decision-Making.**	
	❖ By February 28, 2010, collect input from external constituencies through a public docket and a public meeting.	✓
	❖ By March 31, 2010, hold an all-hands meeting to collect additional input from CDRH employees.	✓
	❖ By May 31, 2010, submit to the Center Director the recommendations of the Task Force on the Utilization of Science in Regulatory Decision-Making.	✓
	❖ By July 31, 2010, develop an implementation plan.	Started
	❖ By September 30, 2010, begin to implement the Task Force recommendations.	✓

Strategy 1.2. Improve Guidance and Regulation Development

Goal 1.2.1.	**By September 30, 2010, CDRH will have in place a centralized team of regulatory and policy specialists dedicated to the strategic development of policies and practices that support the Center's mission and programmatic functions.**	
	❖ By March 31, 2010, hire a Deputy Center Director for Policy.	✓
	❖ By May 31, 2010, hire a Director of the Regulations Staff.	✓
	❖ By June 30, 2010, hire three policy analysts.	✓
	❖ By September 30, 2010, clarify the role of the Regulations Staff.	✓
	❖ By September 30, 2010, centralize coordination of the development, writing, and processing of guidance documents and regulations within the Office of the Center Director.	✓
Goal 1.2.2.	**By January 31, 2011, CDRH will institute standard roles, responsibilities, practices, and procedures for guidance and regulation development.**	
	❖ By February 28, 2010, define roles, responsibilities, and workflow for developing guidance and regulation.	✓
	❖ By July 31, 2010, revise the Good Guidance Practices Manual and existing standard operating procedures for guidance and regulation development, and post updated versions of these documents and other related information on CDRH's intranet page.	✓
	❖ By July 31, 2010, design a guidance and regulation development business process and accompanying tracking tools.	✓
	❖ By September 30, 2010, develop and begin training on guidance document and regulation development for appropriate Office staff.	✓

Strategy 1.3. Develop a Cross-Center Compliance Strategy

Goal 1.3.1.	**By May 31, 2010, CDRH will finalize and begin implementation of the Center's Compliance Strategic Plan.**	
	❖ By February 28, 2010, finalize the compliance Critical Elements document and the Compliance Strategic Plan.	✓
	❖ By May 31, 2010, develop and launch implementation plans for strategic goals selected for 2010.	✓
Goal 1.3.2.	**By November 30, 2010, CDRH will assess progress on implementation of the Compliance Strategic Plan and identify next steps.**	
	❖ By August 31, 2010, assess interim progress on implementation.	✓
	❖ By November 30, 2010, assess progress on implementation and identify next steps.	✓

PRIORITY 2. ENHANCE COMMUNICATION AND TRANSPARENCY

Strategy 2.1. Develop and Implement a Strategic Approach to Public Communication

Goal 2.1.1.	**By September 30, 2010, CDRH will implement a strategic communication program to optimize the public health benefit of the information we distribute to our external constituencies.**	
	❖ By March 31, 2010, finalize and train staff on the CDRH Risk Communication Process.	✓
	❖ By June 30, 2010, hire an Associate Director for External Relations.	✓
	❖ By September 30, 2010, develop and implement a Center strategic communication program.	✓
Goal 2.1.2.	**By February 28, 2010, CDRH will develop and begin to implement mechanisms for routinely engaging external constituencies in two-way communication.**	
	❖ By January 31, 2010, identify mechanisms that will enable meaningful two-way communication.	✓
	❖ By February 28, 2010, begin to implement selected mechanisms.	✓

Strategy 2.2. Improve Internal Communications

Goal 2.2.1.	**By March 31, 2010, CDRH will develop and implement mechanisms for engaging Center leadership, other managers, and employees in two-way communication about issues important to employees.**	
	❖ By February 28, 2010, identify mechanisms that will enable meaningful two-way internal communication.	✓
	❖ By March 31, 2010, begin to implement selected mechanisms.	✓
Goal 2.2.2.	**By September 30, 2010, CDRH will develop and implement tools and processes for routinely sharing, discussing, refining and vetting new ideas among employees about ways to improve the Center (ideation).**	
	❖ By June 30, 2010, identify tools, processes, and goals for an internal ideation pilot.	✓
	❖ By September 30, 2010, launch the ideation pilot.	✓

Strategy 2.3. Increase Transparency in Decision-Making

Goal 2.3.1.	**By June 30, 2010, implement and begin to assess web-based strategies to increase transparency, consistent with Agency efforts.**	
	❖ By January 31, 2010, identify and prioritize information that CDRH will make public through our Transparency Website.	✓
	❖ By February 28, 2010, develop and launch CDRH's Transparency Website.	✓
	❖ By May 31, 2010, begin to obtain feedback from our constituents about our transparency initiative.	✓
	❖ By June 30, 2010, launch CDRH's improved Medical Device Safety Website.	✓

PRIORITY 3. STRENGTHEN OUR WORKFORCE AND WORKPLACE

Strategy 3.1. Recruit, Develop and Retain High Quality Employees

Goal 3.1.1.	**By September 30, 2010, CDRH will implement a Center succession program.**	
	❖ By March 31, 2010, determine the methods and tools that the Center will use to identify succession targets and assess bench strength.	✓
	❖ By July 31, 2010, begin to identify succession targets and assess bench strength across the Center.	Started
	❖ By September 30, 2010, develop a program to keep bench strength aligned with identified succession targets and to regularly evaluate effectiveness.	Started
Goal 3.1.2.	**By June 30, 2010, CDRH will implement a strategy for recruitment and Center-wide policies for the use of recruitment and retention tools, consistent with Agency policy.**	
	❖ By March 31, 2010, develop Center policies for the use of recruitment and retention tools.	✓
	❖ By May 31, 2010, develop resources for managers, explaining the tools available and their appropriate use.	✓
	❖ By June 30, 2010, develop recruitment materials for Center-wide use.	Started
Goal 3.1.3.	**By December 31, 2010, CDRH will begin to develop and put in place core competencies, recommended coursework, and other formal programs for role-specific employee training in support of an "Employee Life Cycle" approach.**	
	❖ By June 30, 2010, implement the CDRH Leadership Readiness Program.	✓
	❖ By June 30, 2010, identify the jobs within CDRH, in addition to premarket reviewers and medical officers, for which core competencies and recommended coursework need to be developed.	✓
	❖ *By December 31, 2010, develop core competencies and recommended coursework for premarket reviewers and medical officers.*	

Strategy 3.2. Leverage External Expertise

Goal 3.2.1.	**By June 30, 2010, CDRH will enhance our mechanisms for establishing collaborative projects with external partners.**	
	❖ By February 2010, create an External Expertise & Partnerships (EEP) Partnership and Leveraging Resource Manual to educate Center employees about the establishment of formal information-sharing relationships with external experts.	✓
	❖ By June 30, 2010, establish a prioritization program for collaborative external projects as part of the CDRH-wide Science Prioritization Program (see Goal 1.1.2.1.).	✓
Goal 3.2.2.	**By June 30, 2010, identify options for creating a network of external experts.**	✓

Strategy 3.3. Establish Pathways for Resolving Differences of Opinion

Goal 3.3.1.	**By February 28, 2010, CDRH will implement and train staff on a Center-wide Standard Operating Procedure (SOP) for Resolution of Internal Differences of Opinion in Regulatory Decision-Making.**	
	❖ By November 30, 2009, announce SOP.	✓
	❖ By December 31, 2009, develop training and support materials for staff.	✓
	❖ By February 28, 2010, train staff on the SOP.	✓
Goal 3.3.2.	**In 2010, CDRH will clear a draft revised guidance on resolving differences of opinion between CDRH and external parties.**	Started

Strategy 3.4. Improve Internal Administrative Processes

Goal 3.4.1.	**By August 31, 2010, identify and begin to implement improvements in the provision of administrative services within CDRH.**	
	❖ By March 31, 2009, identify options for improvement in the delivery of administrative services related to budget execution and reconciliation, hiring and recruitment, and contract development.	
	❖ By August 31, 2010, begin to implement improvements in the identified areas.	

Strategy 3.5. Make CDRH White Oak Facilities More Workplace Friendly

Goal 3.5.1.	**By September 30, 2010, CDRH will improve the physical functionality of common-use spaces in and around Center buildings.**	
	❖ By January 31, 2010, identify the top ten physical improvements to common-use areas of CDRH facilities that are feasible and will maximize employee productivity, accessibility, and quality of work life.	
	❖ By May 31, 2010, working with the General Services Administration, begin implementing improvements.	
Goal 3.5.2.	**By March 31, 2010, CDRH will improve our systems and processes for reserving and making use of available conference rooms.**	
	❖ By January 31, 2010, assess current systems and processes for reserving and making use of CDRH and Central Shared Unit (CSU) conference rooms and identify areas for improvement.	
	❖ By March 31, 2010, implement improvements to the processes for reserving and making use of CDRH and CSU conference rooms.	
Goal 3.5.3.	**By May 31, 2010, CDRH will address our shortage of offices to accommodate current staff needs and anticipated growth.**	
	❖ By January 31, 2010, work with FDA to obtain use of Ground Floor offices in Building 66.	
	❖ By March 31, 2010, assess the appropriateness and feasibility of addressing current office shortage through a coordinated office-sharing and Flexi-Place program.	
	❖ By April 30, 2010, pending the results of the appropriateness and feasibility assessment, develop and a pilot for an office-sharing and Flexi-Place program.	
	❖ By April 30, 2010, if no agreement on the use of Building 66 Ground Floor has been reached, arrange for the use of additional office space at other FDA-leased facilities.	

PRIORITY 4. PROACTIVELY FACILITATE MEDICAL DEVICE INNOVATION AND ADDRESS UNMET PUBLIC HEALTH NEEDS

Strategy 4.1. Foster the Development of Medical Devices to Respond to Unmet Public Health Needs

Goal 4.1.1.	**By June 30, 2010, CDRH will identify the top five most important unmet public health needs.**	
	❖ By March 31, 2010, establish a Council on Unmet Public Health Needs (Council) composed of participants from federal agencies.	✓
	❖ By June 30, 2010, the Council will hold one or more public workshops to identify the most important unmet public health needs and the barriers to the development of medical devices that can cure, significantly improve, or prevent these illnesses or injuries.	✓
Goal 4.1.2.	**By September 30, 2010, CDRH will establish an internal capacity to facilitate the development of medical devices to address unmet public health needs.**	
	❖ By July 31, 2010, hire a medical device innovation coordinator.	✓
	❖ By September 30, 2010, identify key agency staff who will devote at least part of their time to medical device innovation and establish roles and responsibilities.	✓
Goal 4.1.3.	**By September 30, 2010, CDRH will identify the necessary steps to facilitate development of medical devices to respond to at least two of the top five most important unmet public health needs.**	
	❖ By September 30, 2010, based on information obtained from the public workshop(s) and through other means, the Council will identify the steps the federal government can realistically take to remove or minimize barriers to the development of devices respond to two or more of the top five most important unmet public health needs.	✓
Goal 4.1.4.	**By September 30, 2010, CDRH will establish at least one mechanism to solicit innovative solutions to unmet public health needs from external constituencies.**	
	❖ By July 31, 2010, identify feasible, high return-on-investment options.	✓
	❖ By September 30, 2010, implement one to two of the identified options across all devices or for specific types of devices.	✓
Goal 4.1.5.	**By September 30, 2010, CDRH will identify and publicly announce steps we will take to facilitate improvements in the design of device types that have been associated with safety problems across multiple manufacturers.**	
	❖ By June 30, 2010, identify two or more device types that have been associated with safety problems across multiple manufacturers.	✓
	❖ By September 30, 2010, identify and publicly announce steps CDRH will take to address problems with the identified device types through improvements in device design.	✓

Strategy 4.2. Develop a Personalized Medicine Program

Goal 4.2.1.	**By December 31, 2010, CDRH will have in place the infrastructure and procedures for managing personalized medicine submissions across Centers.**	
	❖ By December 31, 2009, develop methods for identifying and tracking therapeutic/in vitro diagnostic (IVD) personalized medicine submissions within CDRH.	✓
	❖ By June 30, 2010, develop draft formal mechanisms to address Personalized Medicine issues between CDRH, CBER, CDER, and OCP.	✓
	❖ *By December 31, 2010, develop methods for identifying and tracking therapeutic/non-IVD diagnostics personalized medicine submissions within CDRH.*	