Center for Devices and Radiological Health

CDRH FY 2010 Strategic Priorities

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EXECUTIVE SUMMARY

In keeping with our mission, the Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health by assuring the safety, effectiveness, and quality of medical devices, assuring the safety of radiation-emitting products, fostering innovation, and providing the public with accurate, science-based information about the products we oversee, throughout the total product life cycle.

We have identified four priority areas of activity for the coming year, each of which presents significant opportunities to improve our effectiveness in fulfilling our mission. These priorities are not intended to capture all the valuable work CDRH employees undertake every day. However, a concerted effort in these specific areas will support and enhance all we do.

Priority 1. Fully Implement a Total Product Life Cycle Approach

Our public health responsibilities span the entire life cycle of medical devices, from early product development to long-term experience with the marketed device, from manufacturing to market use. At any stage of a device's life cycle we must make well-supported regulatory decisions, taking into consideration all of the relevant information available to us.

To fully implement a total product life cycle approach, we will: (1) enhance and integrate premarket, postmarket, and compliance information and functions, in order to enable each part of our organization to meet current and anticipated challenges, and work together with a unity of effort toward our mission. To do so, we will: improve the quality and consistency of our science-based decision making by strengthening premarket review and aligning our use of scientific resources across the Center; make better use of information by enhancing our systems and processes for collecting, analyzing, and sharing information to support day-to-day Center needs; consider ways to better integrate our work across Offices by re-examining our organizational structure; and prepare to meet the demands of the future by addressing challenges associated with globalization and establishing mechanisms to incorporate new scientific information into our decision making. We will also: (2) improve guidance and regulation development, in order to convey current expectations and requirements to our external constituencies in a clear and timely manner; and (3) develop a cross-Center compliance strategy, in order to more effectively identify and address compliance issues across the total product life cycle.

Priority 2. Enhance Communication and Transparency

Improving communication and increasing transparency – with our external constituencies and among our employees – will maximize the public health benefit of our actions, increase the trust and confidence of our external constituencies, and better enable collaboration within CDRH.

To enhance communication and transparency, we will: (1) develop and implement a strategic approach to public communication, in order to provide our external constituencies with meaningful and timely information, and with opportunities to engage in a dialogue with us; (2) improve internal communications, in order to facilitate discussion, foster the sharing of ideas, and enhance our work; and (3) increase transparency in our decision making, in order to help the public understand the work we do and the reasons behind our decisions.

Priority 3. Strengthen Our Workforce and Workplace

A skilled staff and a productive work environment will improve our ability to address the many challenges presented by the range of products we oversee, and increase our effectiveness in protecting and promoting the public health.

To strengthen our workforce and workplace, we will: (1) recruit, develop, and retain high-quality employees, capable of meeting our mission-critical needs; (2) leverage external expertise, in order to expand the breadth and depth of our expertise; (3) establish pathways for resolving differences of opinion, in order to support a culture of collaboration within CDRH and assure fair consideration of issues raised by our external constituencies; (4) improve internal administrative processes, in order to increase our efficiency; and (5) make CDRH's White Oak facilities more workplace-friendly, in order to support productivity, accessibility, and quality of work life.

Priority 4. Proactively Facilitate Innovation and Address Unmet Public Health Needs

Our regulatory authority and our unique understanding of the products we oversee put us in a position to identify and respond to critical public health needs that could be met by innovative medical device development or improvement.

To proactively facilitate innovation and address unmet public health needs, we will: (1) foster the development of medical devices to respond to unmet public health needs, by collaborating with our federal government partners and our external constituencies to reduce identified barriers; and (2) develop a personalized medicine program, in order to strengthen our ability to support regulatory oversight of diagnostic devices and therapeutics whose safety and efficacy are intimately related.

This document identifies broad strategies that CDRH will implement in alignment with these four priorities. It includes time-bound goals associated with each strategy, and specific actions we will take to meet those goals. We will be able to accomplish many of the identified goals in fiscal year (FY) 2010. For those goals that will take more time to accomplish, we have identified supporting actions that we will take in FY 2010.

The statements under each priority and strategy describe the ideal end-state that CDRH aspires to reach by undertaking these activities. Working together to pursue these areas of opportunity, we will strengthen CDRH and increase our ability to protect and promote the public health.

Priority 1. Fully Implement a Total Product Life Cycle Approach

CDRH will make well-supported regulatory decisions that take into consideration all of the relevant information available to the Center, at any stage of a product's life cycle to assure the safety, efficacy, and quality of medical devices, and the safety and quality of non-device radiation-emitting products.

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

CDRH will have in place strong, mutually reinforcing organizational components supported by integrated knowledge management systems, that work with a unity of effort toward our mission, and that are equipped to anticipate and address changes in the scientific and global-market landscape.

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.
- 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, clear within CDRH 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.

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.
- By September 30, 2010, fully implement iReview for 510(k) submissions.

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.
- 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.

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.
- 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.
- By June 30, 2011, implement Center plan.

Goal 1.1.6.3. By January 31, 2012, CDRH will 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.
- By September 30, 2010, begin to implement the Task Force recommendations.

Strategy 1.2. Improve Guidance and Regulation Development

CDRH will have in place processes and well-established institutional roles for formalizing and publishing the practices, recommendations, and requirements of CDRH policies and programs in clearly written guidance documents, regulations, and other appropriate forms of communication.

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

CDRH will have in place a fully integrated compliance program capable of identifying important compliance problems and addressing them through prompt, strategic, clear, and visible actions. CDRH will apply metrics to assess the impact of compliance actions on public health.

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 implementation plans for 2010 strategic goals selected for prompt implementation.

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

To improve public health and foster trust among our employees and with our constituencies, CDRH will provide meaningful and timely information about the products we regulate and the decisions we make, through strategic outreach and systems that support transparency and two-way communication.

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

CDRH will implement processes for timely development and distribution of medical device and radiation-emitting electronic product information that is useful to our external constituencies using methods that meet their needs, while giving them opportunities to engage in a dialogue with the Center about the issues important to them.

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.
  - Integrate Risk Communication Processes into the Center strategic communication program.
  - Integrate components of the Agency-wide Risk Communication Strategic Plan into the 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

CDRH will have mechanisms in place to assure that our employees have timely information about what the Center is working on and the ability to dialogue, share ideas and make suggestions to enhance CDRH's ability to successfully achieve our mission.

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

To enhance our credibility, CDRH will provide up-to-date information to our constituencies about our regulatory decisions and the rationale for those decisions.

Goal 2.3.1. By June 30, 2010, CDRH will 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 March 31, 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

CDRH will be a thriving organization with the knowledge, skills, and technical bandwidth we need to fulfill our mission; a collaborative employee culture; an efficient administration; and a workplace environment that supports productivity.

Strategy 3.1. Recruit, Develop, and Retain High-Quality Employees

CDRH will have the expertise needed to accomplish our mission and to meet the anticipated demands of the future.

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.
- By September 30, 2010, develop a program to keep bench strength aligned with identified succession targets and to regularly evaluate effectiveness.

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.
  - Catalog all available recruitment and retention tools.
  - Establish criteria for the use of these 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.

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

CDRH will have in place formal and informal mechanisms that allow us to capitalize on the knowledge and experience of external experts, in order to expand our breadth and depth of 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, CDRH will identify options for creating a network of external experts.

Strategy 3.3. Establish Pathways for Resolving Differences of Opinion

CDRH will support a culture of collaboration among employees at all organizational levels by adhering to clear procedures for resolution of internal differences of opinion that encourage discussion and promote fair, transparent, and scientifically robust decision making. CDRH will adhere to clear procedures for resolution of differences of opinion with external constituencies so that issues are addressed in a fair, transparent, consistent, and well-documented manner.

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 the 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.

Strategy 3.4. Improve Internal Administrative Processes

CDRH will provide administrative services in an efficient, effective manner with consistently high levels of service to employees across CDRH. Through the collective efforts of the members of the administrative team, CDRH will contribute to the overall administrative management of the Agency.

Goal 3.4.1. By August 31, 2010, CDRH will identify and begin to implement improvements in the provision of administrative services within CDRH.

- By March 31, 2010, 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's White Oak Facilities More Workplace-Friendly

The White Oak campus, Buildings 66, 64, 62, and 130, and CDRH workplace policies will provide CDRH employees with a work environment that promotes productivity, accessibility, and quality of work life.

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 Innovation and Address Unmet Public Health Needs

CDRH will identify public health challenges and opportunities and collaborate with our partners in federal government and external constituencies to foster innovative solutions.

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

CDRH will work with our federal government partners and external constituencies to identify important unmet public health needs defined as illnesses and injuries that (1) are serious or have moderate adverse impact on health but affect many individuals; (2) could be cured, significantly improved, or prevented by the development or redesign of a device; and (3) the device(s) is not being developed or redesigned due to barriers that the federal government can directly or indirectly remove or minimize. CDRH will also work with our federal government partners and external constituencies to take steps to reduce these barriers.

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

CDRH will work collaboratively with other FDA Centers to assure the appropriate regulatory oversight of therapeutics and diagnostics when their safety and efficacy are intimately tied to one another.

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.

Appendix

CDRH FY 2010 Strategic Priorities at a Glance

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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.
	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).
	Goal 1.1.1.4. By September 30, 2010, CDRH will fully adopt iReview to support the structured review of 510(k) submissions.
	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.
	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.
	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.
	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.
	Goal 1.1.3.4. By September 30, 2013, CDRH will implement a Unique Device Identification (UDI) system.
	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.
	Goal 1.1.4.2. By December 31, 2010, CDRH will fully implement a business process for signal escalation.
	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.
	Goal 1.1.4.4. By September 30, 2010, CDRH will pilot and evaluate Appian's business process management suite.
	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.
	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.
	Goal 1.1.6.3. By January 31, 2012, CDRH will make use of Good Manufacturing Practices inspections conducted by other countries (see Goal 1.1.6.2.).
	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.
	Goal 1.1.6.5. By July 31, 2011, CDRH will create a collaborative consultation and premarket review pilot program with other countries.

CDRH FY 2010 Strategic Priorities at a Glance

Priority 1. Fully Implement a Total Product Life Cycle Approach *(continued)*		
Strategy 1.1. Enhance and Integrate Premarket, Postmarket, and Compliance Information and Functions *(continued)*	**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.
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.
	Goal 1.2.2.	By January 31, 2011, CDRH will institute standard roles, responsibilities, practices, and procedures for guidance and regulation development.
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.
	Goal 1.3.2.	By November 30, 2010, CDRH will assess progress on implementation of the Compliance Strategic Plan 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.
	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.
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.
	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).
Strategy 2.3. Increase Transparency in Decision Making	Goal 2.3.1.	By June 30, 2010, CDRH will implement and begin to assess web-based strategies to increase transparency, consistent with Agency efforts.

CDRH FY 2010 Strategic Priorities at a Glance

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.
	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.
	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.
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.
	Goal 3.2.2.	By June 30, 2010, CDRH will 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.
	Goal 3.3.2.	In 2010, CDRH will clear a draft revised guidance on resolving differences of opinion between CDRH and external parties.
Strategy 3.4. Improve Internal Administrative Processes	Goal 3.4.1.	By August 31, 2010, CDRH will identify and begin to implement improvements in the provision of administrative services within the Center.
Strategy 3.5. Make CDRH's 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.
	Goal 3.5.2.	By March 31, 2010, CDRH will improve our systems and processes for reserving and making use of available 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.

Priority 4. Proactively Facilitate 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.
	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.
	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.
	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.
	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.
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.