PLAN OF ACTION FOR IMPLEMENTATION OF 510(K) AND SCIENCE RECOMMENDATIONS

In August 2010, the Food and Drug Administration's Center for Devices and Radiological Health (CDRH or the Center) released for public comment the preliminary reports from the 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making. These committees were established in September 2009 to address critical challenges facing the Center and our external constituencies. In recent years, concerns have been raised both within and outside of FDA about the current 510(k) program. The 510(k) Working Group was charged with evaluating the 510(k) program and exploring actions CDRH could take to enhance our 510(k) decision making. The Task Force was charged with making recommendations on how the Center can quickly incorporate new science — including evolving information, novel technologies, and new scientific methods — into its decision making in as predictable a manner as is practical. In addition, the Institute of Medicine (IOM) is conducting an independent evaluation of the 510(k) program

We have solicited and received a range of perspectives in developing these reports and on the recommendations contained in these reports at two public meetings and three town hall meetings, through three open public dockets and many meetings with stakeholders over the past several months.

This document outlines which recommendations we intend to implement in 2011, as well as the projected timeline for completion or reaching a major milestone. We will give the IOM an opportunity to provide feedback on seven recommendations about which significant concerns were raised in comments submitted to the public docket.

For some of the 25 Action Items listed in this chart, there will be additional opportunities for the public to provide input, where appropriate. Recommendations that are regulatory actions — such as draft guidances and proposed regulations — will have their own individual comment periods to give interested stakeholders an opportunity to comment on the draft proposals before they are finalized. In addition, a Public Meeting will be held to gather additional public feedback on two recommendations prior to their implementation. Lastly, CDRH may issue device-specific guidance on (1) when and what type of manufacturing data to submit; (2) when a pre-clearance inspection would be conducted; (3) when and what types of modifications should be periodically reported in lieu of submitting a 510(k); or (4) when and what type of safety and effectiveness information for the device to be reviewed that is known to the manufacturer should be submitted as a brief description. However, because CDRH would only issue guidance on any of these four issues on a case-by-case basis, and, therefore, there is no set timeframe for taking an action, we have not included such guidances in the chart below.

We will post updates on the status of planned actions on CDRH's website. We look forward to working with all of our constituents as we implement the selected recommendations of the Task Force and Working Group. We believe that these improvements will foster medical device innovation and enhance patient safety.

PLAN OF ACTION—IMPLEMENTATION

DESCRIPTION	ACTION	PURPOSE	MILESTONE	DATE OF COMPLETION
GUIDANCE	**510(k) Modifications Guidance**	To clarify which changes do or do not warrant submission of a new 510(k) and which modifications are eligible for a Special 510(k).	Draft Guidance	June 15, 2011
	Clinical Trial Guidance	To improve the quality and performance of clinical trials.	Draft Guidance	July 31, 2011
	Evaluation of Automatic Class III Designation (De Novo) Guidance	To streamline the de novo classification process.	Draft Guidance	September 30, 2011
	Standards Guidance	To clarify the appropriate use of consensus standards.	Draft Guidance	October 31, 2011
	Appeals Guidance	To clarify the process for appealing CDRH decisions, including decisions to rescind a 510(k).	Draft Guidance	October 31, 2011
	510(k) Paradigm Guidance	To provide greater clarity regarding: 1) when clinical data should be submitted in support of a 510(k); 2) the submission of photographs or schematics for internal FDA use only; 3) the appropriate use of multiple predicates; 4) the criteria for identifying "different questions of safety and effectiveness" and technological changes that generally raise such questions; 5) resolving discrepancies between the 510(k) flowchart and the Food, Drug, and Cosmetic Act; 6) the characteristics that should be included in the concept of “intended use”; and 7) the development of 510(k) summaries to assure they are accurate and include all required information.	Draft Guidance	September 30, 2011
	Pre-Submission Interactions Guidance	To supplement available guidance on pre-IDE meetings and enhance the quality of pre-submission interactions between industry and Center staff.	Draft Guidance	November 30, 2011
	Product Code Guidance	To more consistently develop and assign unique product codes.	Draft Guidance	December 31, 2011

			MILESTONE	DATE OF COMPLETION
INTERNAL and ADMINISTRATIVE MATTERS	**Establish a Center Science Council**	To: 1) oversee the development of a business process and SOP for determining and implementing an appropriate response to new scientific information; 2) promote the development of improved metrics to continuously assess the quality, consistency and effectiveness of the 510(k) program; 3) periodically audit 510(k) review decisions to assess adequacy, accuracy and consistency; and 4) establish an internal team of clinical trial experts to provide support and advice on clinical trial design for Center staff and prospective IDE applicants.	Post Council Charter to FDA Website	March 31, 2011
			Post initial results of 510(k) audit to FDA Website	June 15, 2011
	Assess Center Staffing Needs	To formalize the Center's internal process for identifying staffing needs, and to enhance recruitment, retention, training, and professional development of review staff. To create a mechanism to assemble an experienced ad hoc team to temporarily assist with unexpected surges in workload.	Develop process for identifying, recruiting, retaining, and training needed staff	July 15, 2011
	Enhance Training	To train new Center staff on core competencies. To train Center staff and industry on**:** 1) the determination of "intended use"; 2) the determination of whether a 510(k) raises "different questions of safety and effectiveness"; 3) the review of 510(k)s that use "multiple predicates"; 4) the development and assignment of product codes; 5) the interpretation of the "least burdensome" principles; and 6) the appropriate use of consensus standards.	Develop and implement training on core competencies	August 31, 2011
	Leverage External Experts	To develop a network of external experts to appropriately and efficiently leverage external scientific expertise. Also, to assess best-practices and develop SOPs for staff engagement with external experts.	Post SOP to FDA Website	September 15, 2011
	Continue Integration and Knowledge Management	To improve knowledge management across the Center.	Complete evaluation of methods used to integrate device information into a dynamic format so that it can be more readily	September 30, 2011

			MILESTONE	DATE OF COMPLETION
			used by staff to make regulatory decisions	
PROGRAMMATIC and REGULATORY	**Implement an "Assurance Case" Pilot Program**	To explore the use of an “assurance case” framework for 510(k) submissions.	Start pilot program	March 31, 2011
	Provide Additional Information About Regulated Products	To make device photographs available in a public database without disclosing proprietary information.	Public Meeting *	April 7 - 8, 2011 *
	Improve Collection and Analysis of Postmarket Information	To develop better data sources, methods and tools for collecting and analyzing meaningful postmarket information, and to enhance the Center’s capabilities to support evidence synthesis and quantitative decision making.	Determine system requirements and select the platform for a new adverse event database	June 30, 2011
	Establish "Notice to Industry Letters" as a Standard Practice	To clarify and more quickly inform stakeholders when CDRH has changed its regulatory expectations on the basis of new scientific information.	Post SOP to FDA Website	June 15, 2011
	Improve the IDE Process	To better characterize the root causes of existing challenges and trends in IDE decision making.	Complete program assessment	June 30, 2011
		Assess, characterize and mitigate challenges in reviewing IDE’s.		
	Implement a Unique Device Identification (UDI) System	To permit the rapid and accurate identification of devices, to facilitate and improve adverse event reporting and identification of device-specific problems.	Issue proposed regulation	June 30, 2011

			MILESTONE	DATE OF COMPLETION
PROGRAMMATIC and REGULATORY (cont.)	**Multiple Predicate Analysis**	To conduct additional analyses to determine the basis for the apparent association between citing more than five predicates and a greater mean rate of adverse event reports.	Complete analysis and make results public	October 31, 2011
	Clarify and Improve Third-Party Review	To develop a process for regularly evaluating the list of device types eligible for third-party review and to enhance third-party reviewer training.	Post SOP to FDA Website	September 30, 2011
	Streamline Guidance and Regulation Development Process	To provide greater clarity, predictability, and efficiency in the guidance and regulation development process.	Post SOPs to FDA Website	July 31, 2011
	Draft 510(k) Transfer of Ownership Regulation	To better document 510(k) transfers of ownership.	Issue proposed regulation	December 31, 2011
	Improve Medical Device Labeling	To develop an on-line labeling repository.	Public Meeting *	April 7 - 8, 2011 *
		To clarify the statutory listing requirements for the submission of labeling.	Issue proposed regulation	December 31, 2011

DESCRIPTION	ACTION	PURPOSE	MILESTONE	DATE OF COMPLETION
ISSUES TO BE REFFERRED TO THE IOM	**Rescission Authority**	To consider defining the scope and grounds for the exercise of the Center's authority to fully or partially rescind a 510(k) clearance.	IOM REPORT	SUMMER 2011
	Postmarket Surveillance Authorities	To seek greater authorities to require postmarket surveillance studies as a condition of clearance for certain devices.		
	Establish a Class IIb	To develop guidance defining "class IIb" devices for which clinical information, manufacturing information or, potentially, additional evaluation in the postmarket setting would typically be necessary to support a substantial equivalence determination.		
	Predicate Clarification	To clarify when a device should no longer be available for use as a predicate.		
	Clarify and Consolidate Regulatory Terms	To consolidate the concepts of "indication for use" and "intended use" into a single term, "intended use".		
	Device Review	To consider the possibility of requiring each 510(k) submitter to keep at least one unit of the device under review available for CDRH to access upon request.		
	Off-Label Use	To explore the possibility of pursuing a statutory amendment that would provide the agency with the express authority to consider an off-label use when determining the "intended use" of a device.		

* The April 7-8, 2011 meeting will discuss both actions.