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Client Alert

FDA & Life Sciences Practice Group

April 20, 2011

FDA Issues Draft Charter for CDRH Center Science Council

FDA CDRH Center Science Council will Serve as an Internal Advisory and Decision-Making Body on Various Issues, Including Clinical Data Requirements and Trials

The Food and Drug Administration (FDA) issued a draft charter of the Center for Devices and Radiological Health (CDRH) Center Science Council (CSC) and fact sheet on March 31 that describes its responsibilities and organization.[i] The formation of the CSC was recommended in FDA's August 2010 510(k) Working Group and Utilization of Science in Regulatory Decision Making Task Force Reports. Its purpose is to help CDRH better identify and incorporate evolving science and technology into regulatory decision-making and enhance both communication and utilization of scientific knowledge throughout the Center. The Chairperson of the CSC is the CDRH Deputy Center Director for Science, Dr. William Maisel.

Responsibilities of the CSC. The draft charter defines five core responsibilities:

- *Identification and Incorporation of New Science into Regulatory Decision-Making.* The CSC is charged with aiding in the establishment of standard procedures and business processes for determining, among other things, how CDRH reacts to new information, when external experts, stakeholders or other parties are needed to address new information, and when new information requires a change in regulatory policy.

- *Oversight of Issues Related to Clinical Data and Clinical Trials.* The CSC is responsible for developing standard procedures for assuring consistency in decisions related to clinical trials. In carrying out this responsibility, the CSC may, among other things, establish criteria for first-in-man clinical trials; put in place a device feasibility program that would facilitate iterative device design modifications based on pre-clinical and early human data; and determine when post-market clinical requirements, including clinical trial designs, should be changed based on new scientific information.

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- *Management and Oversight of the Innovation Pathway.* The CSC is responsible for oversight of FDA's newly proposed Innovation Pathway, which is intended to facilitate the marketing of critical cutting-edge devices. The Council will oversee implementation of the Innovation Pathway by establishing criteria for products to apply for and be selected for review through the Innovation Pathway and overseeing the review process for those devices.

- *Quality Assurance of CDRH's Scientific Programmatic Functions*. The CSC will develop metrics for measuring performance and conducting periodic audits of CDRH's science program for effectiveness, appropriateness of decisions, and consistency.

- *Oversight and Prioritization of Issues of Public Health Importance.* The CSC is responsible for prioritizing, managing and addressing important public health issues that impact multiple Center disciplines and offices.

These responsibilities will be implemented by the establishment of three initial subcommittees including the Clinical Data and Clinical Trial Subcommittee, Quality Assurance Subcommittee, and Innovation Pathway Subcommittee. The first meeting of the CSC is scheduled for April 2011.

Potential Implications for Manufacturers and Unanswered questions. Based on the responsibilities of the CSC outlined in the draft charter, device manufacturers may be most impacted by the Council's role in (1) determining when new information should lead to new premarket requirements (*e.g.*, clinical data) for a device or class of devices, (2) advising staff on premarket clinical trial designs and when clinical data may be needed to support a 510(k) submission, and (3) establishment of criteria for devices eligible for review through the Innovation Pathway. In addition, the charter does not clarify whether manufacturers may request input from the CSC during disagreements regarding matters within the Council's purview, such as disputes concerning the design or interpretation of a clinical study that is intended to support a marketing application or a post-market requirement. It also does not specify when or how FDA reviewers are to initiate a consultation with the CSC or whether the Council will serve as a mechanism of dispute resolution regarding clinical data requirements, eligibility for acceptance of review under the Innovation Pathway, or other decisions within the CSC's purview.

It will be important to monitor the activities of the CSC to better understand the practical implications of its establishment and influence on day-to-day review activities within CDRH. King & Spalding welcomes queries regarding the Center Science Council and its impact on medical device manufacturers.

[i] Accessible at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm