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FDA Law Update

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FDA Announces Its Plan For Changes to the 510(k) "Approval" Pathway

By Peter S. Reichertz and Allie Frumin

January 19, FDA announced its plan to modify the 510(k) "approval" pathway, the most common review path for medical devices. Specifically, FDA released a report containing twenty-five actions it intends to take in 2011 to "improve" the review process. Importantly, however, no changes have yet been made to the process; FDA has just announced its plan of action of how it intends to address potential changes to the process.

A medical device manufacturer who wishes to market a device classified in Class II or, in limited cases, Class I or III, that it believes is substantially equivalent in both safety and effectiveness to a device already on the market (a "predicate device") must make what is known as a 510(k) notification. Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") requires medical device manufacturers to notify FDA of their intent to market a medical device at least 90 days in advance of doing so. A 510(k) premarket notification allows FDA to determine whether the particular device is substantially equivalent in safety and effectiveness to a predicate device already being legally marketed. Many changes to medical devices previously cleared for marketing must also be submitted for review prior to implementation.

In September 2009, two committees were established by FDA's Center for Devices and Radiological Health ("CDRH" or the "Center") to address challenges facing the medical device review process. Concerns had been raised that the 510(k) program had become less predictable, less consistent, and less transparent, resulting in stifled innovation and the shifting of companies and jobs to overseas locations. Some were concerned that the current 510(k) process was neither providing adequate assurances of safety and effectiveness, nor providing sufficient information for healthcare providers and patients to make well-informed treatment or diagnostic decisions. Within CDRH, employees were dissatisfied with the 510(k) program's adaptation to the increasing complexity of devices, and expressed frustration that a reviewer's ability to make well-informed decisions was undermined by the poor quality of 510(k) notifications.

The two committees created by CDRH ultimately produced a list of recommendations which were then submitted for public comment. Based on the feedback CDRH received, FDA has issued a schedule as to how and when it plans to implement these changes. Along with the changes the FDA plans to implement, it announced a date by which it expects each will be addressed. Below is each action listed chronologically by its planned date of action. [Note: There are twenty-six dates listed below because one action, the establishment of the Center Science Council, has a two-part timeline for completion.]

March 31: Implement an "Assurance Case" pilot program to explore the use of an "assurance case" framework for 510(k) notifications.

March 31: Establish a Center Science Council and post the Council's charter to FDA's website. The Council's responsibilities will be 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.

April 7-8: A public meeting will be held on these dates to discuss making device photographs available in a public database without disclosing proprietary information.

April 7-8: A public meeting will be held on these dates to discuss the development of an on-line medical device labeling repository.

June 15: Draft guidance on 510(k) modifications to clarify which changes to previously cleared devices do or do not warrant submission of a new 510(k) and which modifications are eligible for a Special 510(k).

June 15: Post a Standard Operating Procedure ("SOP") to FDA's website in order to clarify and more quickly inform stakeholders when CDRH has changed its regulatory expectations on the basis of new scientific information.

June 15: Post the initial results of the Center Science Council's 510(k) audit to FDA's website.

June 30: Determine system requirements and select the platform for a new adverse event database in order 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.

June 30: Complete an assessment of the IDE process in order to better characterize the root causes of existing challenges and trends in IDE decision-making.

June 30: Issue a proposed regulation on implementing a Unique Device Identification (UDI) System with the goal of permitting the rapid and accurate identification of devices and facilitating and improving adverse event reporting and identification of device-specific problems.

July 15: Develop a process for identifying and responding to Center staffing needs by:

1. formalizing the Center's internal process for identifying staffing needs and enhancing recruitment, retention, training, and professional development of review staff; and

2. creating a mechanism to assemble an experienced ad hoc team to temporarily assist with unexpected surges in workload.

July 31: Draft guidance on strategies for improving the quality and performance of clinical trials.

July 31: Post SOPs to FDA's website to provide greater clarity, predictability, and efficiency in the guidance and regulation development process.

August 31: Enhance training of Center staff by training new Center staff on core competencies; and training 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.

September 15: Post SOP to FDA's website to develop a network of external experts to appropriately and efficiently leverage external scientific expertise, assess best-practices and develop SOPs for staff engagement with external experts.

September 30: Draft guidance on the evaluation of automatic Class III designation (de novo) to clarify the appropriate use of consensus standards.

September 30: Draft 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 FDCA;
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.

September 30: Complete an evaluation of the methods used to integrate device information into a dynamic format so that it can be more readily used by staff to make regulatory decisions.

September 30: Post SOP to FDA's website to develop a process for regularly evaluating the list of device types eligible for third-party review and to enhance third-party review training.

October 31: Draft guidance to clarify the appropriate use of consensus standards.

October 31: Draft guidance to clarify the process for appealing CDRH decisions, including decisions to rescind a 510(k).

October 31: Complete and make the results public of additional multiple predicate analysis to determine the basis for the apparent association between citing more than five predicates and a greater mean rate of adverse event reports.

November 30: Draft guidance to supplement the available guidance on pre-IDE meetings and enhance the quality of pre-submission interactions between industry and Center staff.

December 31: Draft guidance to more consistently develop and assign unique product codes.

December 31: Issue a proposed 510(k) transfer of ownership regulation to better document the 510(k) transfer of

ownership process.

December 31: Issue a proposed regulation on medical device labeling to clarify the statutory listing requirements for the submission of labeling.

In addition to the above actions to be taken in 2011, CDRH has submitted seven more areas of possible changes to the 510(k) process to the Institute of Medicine (IOM) for evaluation. IOM is to provide its feedback to CDRH during Summer 2011. These particular recommendations were selected because, while they did garner general public support, significant concerns were raised about each one in comments submitted to the FDA docket. The additional areas of potential changes for feedback from IOM are as follows:

- To consider defining the scope and grounds for the exercise of the Center's authority to fully or partially rescind a 510(k) clearance.
- To seek greater authorities to require postmarket surveillance studies as a condition of clearance for certain devices.
- 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.
- To clarify when a device should no longer be available for use as a predicate.
- To consolidate the concepts of "indication for use" and "intended use" into a single term, "intended use".
- 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.
- 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.

Again, CDRH has no plan to implement any of the above recommendations until it receives feedback from IOM and adjusts the recommendations accordingly.

It remains to be seen just how significantly these changes will modify the current system, which most in the device industry support. We will discuss further developments and proposals, when announced, on this blog.

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