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**FDA Preserves 510(k) Pathway; Announces Initial Modifications in Reform Program**

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The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) today announced its plan of action for implementation of its 510(k) and science recommendations. The plan of action represents a scaling back of the extensive recommendations the agency issued in August 2010, but is confirmation of FDA's continued commitment to the 510(k) pathway. Some potentially significant actions remain, including, for example, implementation of a pilot program to explore the use of an assurance case framework for 510(k) submissions. The implementation plan includes 25 specific actions and time lines for 2011, with seven additional actions pending review and consideration by the Institute of Medicine (IOM), whose report is expected to be issued in the summer of 2011.

**Initial Actions in CDRH's 510(k) Reform Program**

In the press conference held to announce its plan of action, CDRH unveiled the initial actions in the 510(k) reform program. The Director of CDRH, Dr. Jeffrey Shuren, emphasized the agency's concern with facilitating innovation to promote the public health, which it intends to achieve by increasing predictability and reducing uncertainty in the premarket review of Class II medical devices. The information released by FDA revealed that the following seven issues, many of which are among the most controversial items, have been referred to the IOM for additional analysis:

- Pursuit of a statutory amendment for FDA to consider off-label use when determining the "intended use" of a device
- Establishment of a Class IIb that would require additional clinical information, manufacturing information, or postmarketing evaluation for a determination of substantial equivalence
- Definition of the scope and grounds for FDA to fully or partially rescind a 510(k) clearance
- Clarification of when a device should no longer be available for use as a predicate
- Requirement that at least one unit of the device under review be retained for CDRH to access upon request
- Greater authorities to require postmarket surveillance studies as a condition of clearance
- Consolidation of "indication for use" and "intended use" to "intended use"

At the teleconference with members of the press, Dr. Shuren explained that the IOM was conducting an independent review of these seven issues, but could request information or consultation with FDA or any other source. He also noted that he expects the IOM report to be issued in the summer of 2011.

Of the 25 specific items for implementation in 2011, the initiation by March 31 of a pilot program for use of an "assurance case" framework for 510(k) submissions has the potential to have the most immediate impact on the medical device industry. FDA defines an "assurance case" as

> a formal method for demonstrating the validity of a claim by providing a convincing argument together with supporting evidence. It is a way to structure arguments to help ensure that top-level claims are credible and supported. In an assurance case, many arguments, with their supporting evidence, may be grouped under one top level claim. For a complex case, there may be a complex web of arguments and sub-claims.

In other words, an assurance case requires the manufacturer to substantiate each claim, and not simply compare to claims made by the predicate device. FDA first imposed assurance case requirements on infusion pump manufacturers in 2010. Infusion pump manufacturers have found this to be a burdensome requirement that significantly extends the time line for preparation and submission of a 510(k).

Another significant item slated for implementation by October 31, 2011 is completion of the 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. Presumably, this is a prerequisite for further action by CDRH to limit the number of predicates referenced in a 510(k) submission.

In response to concerns about transparency, CDRH intends to post the standard operating procedure (SOP) establishing "Notice to Industry Letters" as a standard practice by June 15, 2011. FDA intends to use these letters to more quickly inform stakeholders when the CDRH has changed its regulatory expectations on the basis of new scientific information. This appears to be a faster and less formal communication than a *Federal Register* notice or a guidance document drafted by FDA. However, these notices do not appear to be subject to public comment prior to implementation.

Eight action items will be addressed by draft guidance documents. Draft guidances will be issued on the requirement for clinical data, reforms to the de novo classification process, and 510(k) modifications requiring submission of a new 510(k). The clarification of when clinical data should be submitted in support of a 510(k) will be part of the "510(k) Paradigm Guidance" issued in response to the industry's concern with predictability and transparency in the 510(k) review process. The draft guidance documents are scheduled to be completed between June 15 and December 31, 2011.

Finally, six action items address internal staffing requirements and training, as well as the development of SOPs for staff engagement with external experts.

The complete list of action items and the implementation timelines are available on CDRH's website (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240418.htm). Posted on the site are a summary and overview of public comments submitted on the 510(k) program and next steps for the 510(k) reform process, as well as a letter from Dr. Shuren to the American public stating that the steps being announced will "remove roadblocks to innovation while protecting patient safety" and "increase the global market position of U.S. medical devices."

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact its authors, **Phoebe Mounts** (202.739.5898; pmounts@morganlewis.com) and **M. Elizabeth Bierman** (202.739.5206; mebierman@morganlewis.com).

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