FDA RELEASES CDRH ACTION PLAN FOR 510(K) AND SCIENCE INITIATIVES

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On January 19, 2011, the U.S. Food and Drug Administration (FDA) released a plan for 2011 involving 25 action steps to improve the most common regulatory-approval path for medical devices, the 510(k) process.

In September 2009, the Center for Devices and Radiological Health (CDRH) set up two internal working groups to address concerns relating to the premarket notification process, and in August 2010, the FDA released 55 recommendations from the two working groups. The comment period on the 55 recommendations ended on October 4, 2010, and FDA has since reviewed the comments and prepared the action plan released this past week.

Summary of the Action Plan

The FDA reviewed all 76 comments on the working group recommendations and found that 28 of the 55 recommendations received support from comments submitted, 12 of the 55 recommendations received qualified support, and 15 of the 55 recommendations were not supported—in fact, these "comments…expressed significant concern."

The FDA has determined to focus on those recommendations that received significant support, including streamlining the de novo process, issuing guidance to provide greater clarity about the 510(k) program, improving training for the CDRH staff and industry, making greater use of external experts, and making critical business process improvements in CDRH, such as establishing a Center Science Council.

Specifically, a new guidance clarifying eligibility for the Special 510(k) process and identifying when the FDA expects new 510(k) submissions for modifications to a marketed device is expected by June 15, 2011. The FDA has provided no information on this guidance, but industry insiders anticipate that the guidance will be a significant change to the existing guidance, perhaps even eliminating the familiar flowchart mechanisms in the guidance. A new clinical trials guidance is expected by July 31, 2011, and it will be the first general clinical trials guidance applicable to medical devices. It is anticipated that this guidance will begin to address some of the FDA's concerns with 510(k) submissions that do not contain clinical data and perhaps even begin the process of identifying which devices require

clinical data (short of implementing the full Class IIb restructuring recommendation). On an administrative front, the FDA will release a guidance on product codes and a guidance on the use of standards by the end of 2011—both a welcome relief to regulatory teams confused by recent changes to the FDA's database and the instructions on the standards conformity forms.

Arguably the most anticipated guidance documents might well be the de novo guidance and the appeals guidance, expected by September 30, 2011, and October 31, 2011, respectively. Many industry groups have been calling for a more predictable application of the available de novo process and a clearer pathway for appealing adverse regulatory determinations. These guidance documents should begin a dialogue that may open to device companies a very useful administrative option for innovative device technologies.

Perhaps more interesting are the recommendations that the FDA will not implement. Specifically, the FDA has confirmed that it does not intend to implement the recommendation to eliminate the use of split predicates. Seven of the 55 recommendations were vehemently opposed in the comments, and in fact were the subject of multiple letters from Congress to the FDA in the past two months. In the January 19 announcement, the FDA has confirmed that the following recommendations will NOT be implemented until further input has been received from the Institute of Medicine in a report expected in summer 2011:

- CDRH should consolidate the terms "indication for use" and "intended use" into a single term, "intended use,"
- CDRH should expand its statutory authority to consider off-label use when determining the intended use of a device,
- CDRH should issue guidance on when a device should no longer be available for use as a predicate,
- CDRH should issue a regulation on its rescission authority,
- CDRH should require manufacturers to keep one unit of a device available,
- CDRH should issue guidance to create a Class IIb, and
- CDRH should seek greater authorities to require postmarket surveillance studies as a condition of clearance for certain devices.

Significance

The ability to utilize split predicates in 510(k) submissions is a useful tool, particularly for emerging technologies that do not raise new issues of safety and effectiveness. And the careful distinction between "intended use" and "indications for use" is also a specific legal tool utilized by many device companies to ensure compliant labeling, to ensure appropriate communications with consumers, and to prevent off-label marketing or use. Given the potential legal challenges to many of the seven recommendations the FDA has proposed, postponement of implementation seems a reasonable action by the FDA. Device companies should continue to monitor these proposed changes and regularly check for updated guidance on the FDA's website. The guidance documents anticipated will be drafts and not immediately legally enforceable, but they will demonstrate what the agency is thinking and, as may device companies know, how the FDA will handle specific aspects of submissions. Hopefully the FDA will continue to be transparent about the changes made to the 510(k) process so manufacturers and investors can again be able to predict the process and rely on the established mechanisms to bring

innovative products to the U.S. market.