Morgan Lewis

March 2014 Medical Device Update

In February 2014, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) implemented major policy initiatives and issued several significant guidance documents, procedures, and reports, making it one of CDRH's busiest months from the medical device industry's perspective. These developments include the issuance of a final rule on electronic medical device reporting; a report to Congress on 510(k) device modifications; guidance documents on pre-submission meetings, premarket approval (PMA) annual reports, and investigational device exemptions (IDEs); and the FDA's report on its 2014 strategic priorities. We have provided a brief summary of each of these recent developments below.

Final Rule and Guidance: Electronic Medical Device Reporting

On February 14, the FDA issued a final rule requiring that device manufacturers and importers submit mandatory medical device reports (MDRs) in an electronic format.[1] The final rule is effective August 14, 2015. The FDA also issued a question and answer guidance document, "Questions and Answers about eMDR — Electronic Medical Device Reporting."[2]

The final rule and guidance are part of CDRH's overall plan to improve its postmarket surveillance program and will enable CDRH to more effectively collect and analyze adverse event information. Manufacturers and importers will have two options for electronic submission of MDRs: (1) eSubmitter, which allows submission of a single report at a time and (2) HL7, which allows submission of batches of reports. A manufacturer or importer may request an exemption for the electronic reporting requirement by submitting a written request to the FDA. The request must explain why the request is justified and include a statement of how long the exemption will be needed.

Report to Congress: Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices

The Food and Drug Administration Safety and Innovation Act (FDASIA) required the FDA to submit to Congress, by January 9, 2014, a report on when a 510(k) premarket notification should be submitted for a modification to a legally marketed 510(k) device. This was in response to the FDA's issuance of a highly controversial draft guidance on 510(k) modifications, which it was required to withdraw by FDASIA. The report to Congress[3] was posted on the FDA's website on February 25.

The FDA's report indicates that CDRH has determined not to make substantial revisions to the existing 1997 guidance on device modifications, as it did in the withdrawn guidance. Specifically, the report indicates that the FDA will (1) make targeted revisions to the 1997 guidance to clarify key terms and explain how quality system processes may be used in deciding whether to submit a 510(k); (2) include updated flowcharts and additional appendices to the 1997 guidance; (3) as appropriate, develop device-specific guidance documents that include recommendations on modifications requiring a new 510(k); and (4) develop a separate guidance on 510(k) submissions for changes to software. The FDA stated that it will first issue an updated guidance as a draft for further comments before issuing a final guidance.

Guidance: FDA Guidance on the Pre-Submission Program

The FDA issued a final guidance titled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" on February 18.[4]

Because the final guidance is broader in scope and includes significant differences from the draft guidance that

1. Medical Device Reporting: Electronic Submission Requirements, 79 Fed. Reg. 8832 (Feb. 14, 2014) (to be codified at 21 C.F.R. pt. 803), *available at* http://www.gpo.gov/fdsys/pkg/FR-2014-02-14/pdf/2014-03279.pdf.

2. View the question and answer document at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM179471.pdf.

3. View the report at http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/UCM387121.pdf.

4. View the pre-submission guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf.

was issued in July 2012, we will prepare a separate analysis of the final guidance for inclusion in a future Morgan Lewis Medical Device Update.

Guidance: Annual Reports for Approved PMA Applications

On February 7, the FDA issued a new guidance, "Annual Reports for Approved Premarket Approval Applications," which addressed the format and content of PMA annual reports.[5] This guidance also describes the steps the FDA staff generally takes in reviewing annual reports and the actions they may recommend after reviewing the reports.

Procedure: FDA Standard Operating Procedures for Review of IDE Application–Specific Issues

On February 5, CDRH issued new standard operating procedures[6] for the review of IDE issues. These procedures are intended to address when there are unresolved issues that stall progress on an IDE. CDRH has developed a protocol for escalating these issues to a "Clinical Trial Director" when they cannot be resolved at the staff level. The new procedures are effective March 1, 2014.

Report: CDRH 2014–2015 Strategic Priorities

CDRH also issued a report on its strategic priorities[7] for 2014 and 2015 on February 5. Unlike the previous year's report, CDRH has described a short list of priorities. These include (1) strengthening the clinical trials enterprise, (2) striking the right balance between premarket and postmarket data collection, and (3) providing excellent customer service. Regarding the last priority, CDRH also issued a document titled "Standards of Excellence,"[8] which is intended to set forth its policy on customer service.

We will continue to monitor the FDA's progress with respect to the guidance documents that it has announced are on its priority list for issuance in fiscal year 2014. These include guidance on de novo classification of devices and on companion in vitro diagnostic devices. Others are listed in CDRH's FY 2014 Proposed Guidance Development list.[9]

Contacts

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5. View the PMA guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089398.pdf,

6. View the standard operating procedures at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/UCM384605.pdf.

7. View the report at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/ucm384132.htm.

8. View the Standards of Excellence at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/UCM384638.pdf.

9. View the list at http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/mdufaiii/ucm321367.htm.

