4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1021]

Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2013 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Web site location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH) is intending to publish in Fiscal Year (FY) 2013. In addition, FDA has established a docket where stakeholders may provide comments and/or propose draft language for those topics, suggest new or different guidance documents, and comment on the priority of topics for guidance.

DATES: Submit either electronic or written comments at any time.

ADDRESSES: Submit electronic comments on the proposed guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Philip Desjardins,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 5452,

Silver Spring, MD 20993-0002,

301-796-5678.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the Medical Device User Fee Amendments of 2012 (MDUFA III), Title II, Food and Drug Administration Safety and Innovation Act (Public Law 112-114), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of prioritized medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the "A-list") and a list of device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year (the "B-list"). In addition to posting lists of prioritized device guidance documents, FDA has committed to updating its Web site in a timely manner to reflect the Agency's review of previously published guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency. Fulfillment of this commitment will be reflected through the issuance of updated guidance on existing topics, removal of guidances that that no longer reflect FDA's current thinking on a particular topic, and annual updates to A-list and B-list announced in this notice.

This notice announces the Web site location of the two lists of guidance documents which CDRH is intending to publish during FY 2013. We note that the Agency is not required

to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. The Agency is not precluded from issuing guidance documents that are not on either list.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. CDRH's experience in guidance development has shown that there are many reasons that CDRH staff may not complete the entire agenda of guidance documents it undertakes. Staff are frequently diverted from guidance development to other priority activities. In addition, at any time new issues may arise to be addressed in guidance that could not have been anticipated at the time the annual list is generated. These issues may involve newly identified public health issues as well as special control documents that are necessary for the classification of de novo devices.

FDA anticipates that feedback from stakeholders, including draft language for guidance documents, will allow CDRH to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the lists. FDA has established a docket where comments on the FY 2013 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted (see ADDRESSES). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual Agency-wide notice issued under its good guidance practices (21 CFR 10.115(f)(5)). The CDRH lists, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site at the beginning of each

fiscal year from 2013 to 2017. To access the lists of guidance documents CDRH is intending to publish in FY 2013, visit FDA's Web site http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm

II. Request for Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: November 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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