4164-01-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 2017 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) 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 or the Center) intends to publish in fiscal year (FY) 2017. In addition, FDA has established a docket where interested persons may comment on the priority of topics for guidance, provide comments and/or propose draft language for those topics, suggest topics for new or different guidance documents, comment on the applicability of guidance documents that have issued previously, and provide any other comments that could benefit the CDRH guidance program and its engagement with stakeholders. This feedback is critical to the CDRH guidance program to ensure that we meet stakeholder needs.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-N-1021 for "Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of

Fiscal Year 2017 Proposed Guidance Development." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket

number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration,10903 New Hampshire Ave., Bldg. 66, rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations on the Medical Device User Fee Amendments of 2012 (MDUFA III), Title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112-114), FDA agreed to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. Among these commitments included:

- Annually posting a list of priority 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
- Annually posting 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").

FDA welcomes comments on any or all of the guidance documents on the lists as explained in 21 CFR 10.115(f)(5). FDA has established Docket No. FDA-2012-N-1021 where comments on the FY 2017 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted and shared with the public (see ADDRESSES). FDA believes this docket is a valuable tool for receiving information from interested persons and will update these lists after

considering public comments, where appropriate. FDA anticipates that feedback from interested persons will allow CDRH to better prioritize and more efficiently draft guidances to meet the needs of the Agency and our stakeholders.

In addition to posting the 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.

Fulfillment of these commitments 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 the A-list and B-list announced in this notice.

II. CDRH Guidance Development Initiatives

A. Finalization of Draft Guidance Documents

CDRH has identified as a priority, and has devoted resources to, finalization of draft guidance documents. To assure the timely completion or re-issuance of draft guidances, in FY 2015 CDRH committed to performance goals for current and future draft guidance documents. For draft guidance documents issued after October 1, 2014, CDRH committed to finalize, withdraw, re-open the comment period, or issue another draft guidance on the topic for 80 percent of the documents within 3 years of the close of the comment period and for the remaining 20 percent, within 5 years. In FY 2016, CDRH finalized 2 and withdrew 5 of 12 draft guidances issued prior to October 1, 2010, and has been continuing to work towards finalizing the remaining draft guidances. Looking forward, in FY 2017, CDRH will strive to finalize, withdraw, or re-open the comment period for 50 percent of existing draft guidances issued prior

to October 1, 2011. CDRH expects to renew or modify, as appropriate, these performance goals in FY 2017 and subsequent years.

B. Earlier Stakeholder Involvement in Guidance Development

CDRH has received feedback that stakeholders desire earlier involvement in the guidance process and has taken steps to create a mechanism to address this request. In FY 2016, in anticipation of guidance documents expected to be developed, CDRH sought stakeholder input regarding electromagnetic compatibility of electrically powered medical devices and regarding utilizing animal studies to evaluate the safety of organ preservation devices and solutions. FDA appreciated the feedback received and considered it in the development of these guidances. Demonstrating commitment to incorporating stakeholder input, CDRH has included these guidances topics on the FY 2017 B-List as we progress toward issuance of draft policies reflecting early stakeholder input as appropriate.

We also welcome any additional feedback for improving the guidance program and the quality of CDRH guidance documents.

C. Applicability of Previously Issued Final Guidance

CDRH has issued over 500 final guidance documents to provide stakeholders with the Agency's thinking on numerous topics. Each guidance reflected the Agency's current position at the time that it was issued. However, the guidance program has issued these guidances over a period of 30 years, raising the question of how current previously issued final guidances remain. CDRH has resolved to address this concern through a staged review of previously issued final guidances in collaboration with stakeholders. At the Web site where CDRH has posted the "A-list" and "B-list" for FY 2017, CDRH has also posted a list of final guidance documents that

issued in 2007, 1997, 1987, and 1977.[1] CDRH is interested in external feedback on whether any of these final guidances should be revised or withdrawn. In addition, for guidances that are recommended for revision, information explaining the need for revision, such as, the impact and risk to public health associated with not revising the guidance, would also be helpful as the Center considers potential action with respect to these guidances. CDRH intends to provide these lists of previously issued final guidances annually through FY 2025 so that by 2025, FDA and stakeholders will have assessed the applicability of all guidances older than 10 years. For instance, in the annual notice for FY 2018, CDRH expects to provide a list of the final guidance documents that issued in 2008, 1998, 1988, and 1978; the annual notice for FY 2019 is expected to provide a list of the final guidance documents that issued in 2009, 1999, 1989, and 1979, and so on. CDRH will consider the comments received from this retrospective review when determining priorities for updating guidance documents and will revise these as resources permit.

In FY 2016, CDRH received comments regarding guidances issued in 2006, 1996, and 1986, and has withdrawn 12 guidance documents in response to comments received and because these guidance documents were determined to no longer represent the Agency's current thinking. One guidance on this retrospective review list was revised, and revision of several guidance documents is also being considered as resources permit.

Consistent with Good Guidance Practices regulation at 21 CFR 10.115(f)(4), CDRH would appreciate suggestions that CDRH revise or withdraw an already existing guidance document. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. While we are requesting

[1] The retrospective list of final guidances does not include the following: (1) Documents that are not guidances but were inadvertently categorized as guidance such as scientific publications, advisory opinions, and interagency agreements; (2) guidances actively being revised by CDRH; and (3) special controls documents.

feedback on the list of previously issued final guidances located in the annual agenda Web site, feedback on any guidance is appreciated and will be considered.

III. Web Site Location of Guidance Lists

This notice announces the Web site location of the document that provides the A and B lists of guidance documents, which CDRH is intending to publish during FY 2017. To access these two lists, visit FDA's Web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm529396.htm. We note that the topics on this and past guidance priority lists may be removed or modified based on current priorities, as well as comments received regarding these lists. Furthermore, FDA and CDRH priorities are subject to change at any time (e.g., newly identified safety issues). Topics on this and past guidance priority lists may be removed or modified based on current priorities. 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. In addition, the Agency is not precluded from issuing guidance documents that are not on either list.

Stakeholder feedback on guidance priorities is important to ensure that the CDRH guidance program meets the needs of stakeholders. The feedback received on the FY 2016 list was mostly in agreement, and CDRH continued to work toward issuing the guidances on this list. In FY 2016, CDRH issued 20 of 33 guidances on the FY 2016 list (14 from the A-list, 6 from the B-list). In addition, for the guidances that were on the FY 2016 A or B list but could not be published within FY 2016, and for which we received feedback that these guidances were of high priority, CDRH has recommitted to publish these guidances by placing them on the annual agenda for FY 2017, as appropriate.

Dated: December 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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