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 2015 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) is intending to publish in Fiscal Year (FY) 2015. In addition, FDA has established a docket, identified in brackets in the heading of this document, where stakeholders 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, and comment on the applicability of guidance documents that have issued previously.

DATES: You may submit either electronic or written comments at any time. FDA would appreciate if stakeholders provide feedback by [INSERT 60 DAYS FROM ISSUANCE OF THIS NOTICE IN THE FEDERAL REGISTER].

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: Paul Gadiock, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993-0002, 301-796-5736.

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 (Pub. L. 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 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 invites interested persons to submit comments on any or all of the guidance documents on the lists as explained in 21 CFR 10.115(f)(5). FDA has established the docket number (FDA-2012-N-1021) where comments on the FY 2015 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. 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 these lists each year.

Similar information about planned guidance development is included in the annual Agency-wide notice issued under its good guidance practices (GGPs) (§ 10.115(f)(5)). The CDRH lists, however, are 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.

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, and notation of guidance documents that are under review by the Agency.

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. Guidance Development Process Workshop

On June 5, 2014, CDRH held a public workshop to provide stakeholders an opportunity to actively engage with Center representatives about the guidance development process, provide transparency into guidance priority development, promote dialogue on guidance process improvements, and generate ideas for assessing the impact of guidance (http://www.fda.gov/medicaldevices/newsevents/workshopsconferences/ucm394821.htm). The workshop also provided a forum to discuss best practices in guidance development, including public participation in guidance development. CDRH carefully considered the comments and

suggestions provided by stakeholders. The following is a summary of the issues discussed at the workshop, actions the Center has taken to date in response to the discussions, and plans for implementation.

A. Draft Guidance Documents

A concern raised by external stakeholders was CDRH's use of recommendations contained in draft guidance documents to make regulatory and enforcement decisions before the recommendations were established through issuance of a final guidance document. CDRH reaffirmed that the Center's policy has always been consistent with the Agency's GGPs, which state that a draft guidance document is issued for public comment purposes only and may not be implemented until finalized (§ 10.115(g)). However, CDRH agreed additional steps should be taken.

Stakeholders requested that draft guidance documents be more clearly identified as "draft" to indicate to CDRH stakeholders and staff that they are not for implementation. CDRH revised its templates for new draft guidance documents by adding the watermark "DRAFT" to all pages in order to more conspicuously mark the guidance as not for implementation. CDRH implemented the use of the new templates effective August 6, 2014. CDRH also added the watermark "DRAFT" to draft guidance documents issued prior to August 6, 2014.

Stakeholders also recommended that CDRH's guidance documents Web page (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm) list draft guidances separately from those that had been finalized, which would enhance searchability. CDRH revised its guidance document Web page to include a new left navigation item for "Draft Guidance." In addition, CDRH removed draft guidance documents from the office guidance document lists and separated the link to "Recent Medical Device Guidance

Documents" into two separate links: "Recent Medical Device Final Guidance Documents" and "Recent Medical Device Draft Guidance Documents."

CDRH is aware there are some draft guidance documents that have not yet been finalized. In order to assure the timely completion or reissuance of draft guidances, CDRH is committing to performance goals for current and future draft guidance documents. For draft guidance documents issued after October 1, 2014, CDRH will finalize, withdraw, reopen 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. For draft guidances for which CDRH does not take action within the initial 3 years, CDRH will finalize, withdraw, reopen the comment period, or issue another draft guidance on the topic within 5 years. In addition, in FY 2015, CDRH will finalize, withdraw, or reopen the comment period for 50 percent of existing draft guidances issued prior to October 1, 2009. CDRH expects to renew or modify, as appropriate, these performance goals in FY 2016 and subsequent years.

B. Earlier Stakeholder Involvement

CDRH representatives discussed various ways in which the Center currently encourages participation by external stakeholders in the guidance development process. In addition to those described in the Background section, recently the Center has taken some new approaches to developing guidance documents. CDRH has held public workshops and panel meetings to solicit stakeholder feedback on both device-specific and policy-related issues. For example, this model was utilized for the development of the Design Considerations for Devices intended for Home Use Guidance (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM331681.pdf) prior to the draft guidance's issuance. However, because the resource

implications for public meetings or workshops and panel meetings are very high, CDRH can only use these venues in limited cases. CDRH must judiciously balance various approaches to guidance development with meeting quantitative review timelines and other statutory obligations.

In the case of emerging technologies, CDRH is using "leapfrog" guidances to provide initial recommendations regarding the type of information that would be appropriate in the review of emerging technologies. Information from external stakeholders helps CDRH formulate its initial thinking on the data necessary to support marketing approval or clearance of these devices.

In anticipation of guidances that are expected to be developed, CDRH is posing the following questions to stakeholders for consideration and comment so that relevant future draft guidances on these technologies can be as complete and useful as possible. CDRH believes that stakeholder input at this stage and again after a draft guidance is issued on the topic will lead to a comprehensive and informed final guidance on the Agency's policy for the technologies and processes listed below:

1. Patient Matched Instrumentation for Orthopedics

These devices are patient-specific instrumentation, created from patient imaging scans with the use of segmentation and planning software, to affect a surgeon's surgical plan intraoperatively. A guidance document addressing the basic elements to be addressed in a 510(k) submission for patient matched instrumentation for all joint replacement product areas will help provide transparency to industry as to the level and types of information requested for review of these devices.

- What methods are used to determine that all phases of the design process, including those that rely on execution by a trained employee and/or by software, function as intended? How is variability controlled across planning personnel and across different patient pathologies?
- What impact does preoperative planning of the surgical procedure to create a guide have on implant performance? What parameters are critical to creating an effective preoperative plan with respect to device performance? Please provide a justification for your response.
- How extensive is the interaction among the approving surgeon and the planning personnel when developing and approving a preoperative plan?
- When the manufacturers of patient-matched instruments do not manufacture the implant system or have a formal business agreement with the implant manufacturer, what information requires monitoring to ensure that modifications to the implant system or implantation recommendations do not affect the performance of the patient-matched instrumentation?

2. Medical Devices Intended for Aesthetic Use

As the U.S. population continues to age, use of medical devices for aesthetic purposes is expanding. Given the absence of generally accepted metrics for selecting patients and evaluating medical device performance for aesthetic uses, there are many challenges in collecting and interpreting clinical data that might support clearance or approval of aesthetic- use devices. Another difficulty in such studies is understanding patients' perspectives on product safety and effectiveness, which are important in defining the benefit/risk ratio for any new treatment. A

guidance document on this topic would address development and validation of methods for quantitative measure of aesthetic improvement with minimal bias.

Objective measures of device effectiveness can be difficult to develop and validate for endpoints involving aesthetic outcomes. However, tools to measure device effectiveness in an objective manner are needed in order to reduce bias in interpretation of study results.

- Do the use of validated scales that depict varying degrees of change in body features (e.g., wrinkle severity, mid-face volume) result in clinically meaningful assessment of product effectiveness? Under what circumstances would the use of a validated scale not be clinically meaningful?
- How can gender or ethnicity-specific tools be developed in order to gather clinically meaningful assessment of product effectiveness?
- To what extent should emphasis be placed on the use of validated patient-reported outcome measures in order to demonstrate product effectiveness? Should assessment of the primary endpoint using a validated patient reported outcome measure be routine?
- Can photography methods find utility in assessment of product effectiveness and be comparable to live assessment when evaluating three-dimensional changes in tissue volume? If so, are there such methods in clinical use?
- Is there a role for creative or non-traditional methods (e.g., crowd sourcing, use of social media) in clinically meaningful assessment of product effectiveness? If so, how can this be accomplished?

3. Dual 510(k) and Clinical Laboratory Improvements Amendments (CLIA) Waiver by Application

A Dual 510(k) and CLIA Waiver by Application ("Dual") is a regulatory submission requesting both 510(k) clearance and CLIA Waiver approval. Under the Dual program, a Dual must be preceded by a presubmission during which the strategy for addressing both regulatory requirements is discussed. After the presubmission, the Dual 510(k) and Waiver by Application are submitted as a single regulatory submission. A guidance document addressing considerations for the design of clinical studies used to support both CLIA Waiver approval and 510(k) clearance will provide transparency on the level and types of information to provide FDA. FDA anticipates this will help focus the Dual presubmissions and potentially shorten the review process for the Dual submission.

- Of what challenges should FDA be aware in drafting this guidance document?

Stakeholders are strongly encouraged to suggest guidance topics as well. In order to support their concept, commenters should state the potential guidance topic, reasons the guidance is needed, and proposed policy for FDA to consider on the topic. See § 10.115(f)(2). Ideally, commenters would develop a comprehensive policy in the form of a proposed guidance document that CDRH could then consider issuing as draft guidance, as explained in § 10.115(f)(2).

C. Applicability of Previously-Issued Final Guidance

CDRH has issued over 1,000 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 greater than 20 years, raising the question of how current do 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 2015, CDRH has also posted a list of final guidance documents that issued in 2005, 1995, and 1985.[1] The Center would appreciate external feedback on whether any of these final guidances should be revised or withdrawn. CDRH intends to provide such lists annually through FY 2025 so that by FY 2025, FDA and stakeholders will have assessed the applicability of all guidances older than 10 years. For instance, in the annual notice for FY 2016, CDRH expects to provide a list of the final guidance documents that issued in 2006, 1996, and 1986; the annual notice for FY 2017 is expected to provide a list of the final guidance documents that issued in 2007, 1997, and 1987, and so on. CDRH will consider the information received from this retrospective review when determining priorities for updating guidance documents. Based upon this experience, CDRH will establish a process for ongoing periodic review of final guidance that takes into account the value provided by the review and the resource implications to conduct the review.

Under the GGPs regulation at § 10.115(f)(4), the public may, at any time, suggest that CDRH revise or withdraw an already existing guidance document. The suggestion should address why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. Stakeholders are advised to examine the list or previously issued final guidances provided by CDRH on the annual agenda Web site but feedback on any guidance is appreciated.

[1] The retrospective list of final guidances does not include: (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.

III. Web Site Location of Guidance Lists

This notice announces the Web site location of the two lists of guidance documents which CDRH is intending to publish during FY 2015. To access these two lists, visit FDA's Web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm321367.htm. 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 guidances it undertakes. Staffs 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 may involve newly identified public health issues.

IV. Request for Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). 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: January 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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