Monday, December 28, 2015

FY 2016 Proposed Guidance Development and Focused Retrospective Review of Final Guidance

Today's Federal Register announces that FDA's Center for Devices and Radiological Health (CDRH) has posted a list of guidance documents that we intend to publish this fiscal year (FY2016). In addition, we commit to reviewing previously published final guidance documents, including updating or deleting guidance documents that no longer represent the Agency's current thinking on a regulatory issue, as well as committing to performance goals in finalizing current and future draft guidance documents. The notice also seeks early stakeholder involvement by posing targeted questions to stakeholders for consideration and comment in anticipation of guidances that are expected to be developed, so that relevant future draft guidances on these technologies can be as complete and useful as possible. Finally, we also seek feedback to enhance the CDRH guidance program.

We have posted three lists:
(1) guidance documents that the Agency fully intends to publish (the "A-list");
(2) guidance documents that the Agency intends to publish as resources permit (the "B-list"); and
(3) final guidance documents that issued in 2006, 1996, 1986, and 1976 that are subject to focused retrospective review and for which we would appreciate external feedback.

Although resource constraints and new issues that emerge over the course of the year may preclude CDRH from issuing every guidance document on the A-list and B-list and CDRH may issue guidance documents not on the lists, the lists are intended to provide helpful information about CDRH's current priorities for the upcoming fiscal year. CDRH plans to update all three lists every year.

We invite you to submit comments on any or all of the guidance document topics to docket FDA-2012-N-1021. Comments may include feedback on the proposed A and B-list topics, such as suggestions for new or different guidance documents, the relative priority of guidance documents, and/or draft language on the proposed A-list and B-list topics. Comments may also include suggestions that CDRH revise or withdraw a final guidance document that issued previously as part of its retrospective review. If you recommend guidances for revision, please also include an explanation of the need for revision, such as the impact and risk to public health associated with not revising the guidance. We also encourage responses to topic-specific questions posed in the FR to aid us in the drafting of new guidances expected to be developed, as well as feedback to enhance the guidance program.

Your feedback is critical in shaping CDRH's guidance development plans. For additional information, please see: Federal Register: Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2016 Proposed Guidance Development.