From: U.S. Food & Drug Administration (FDA) [mailto:fda@service.govdelivery.com]
Sent: Thursday, January 08, 2015 7:16 AM
Subject: CDRH FY 2015 Proposed Guidance Development and Focused Retrospective Review of Final Guidance AND Website Improvements for Industry Education

FY 2015 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 (FY2015). 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to reviewing previously published final guidance documents, including updating or deleting guidance documents that no longer represent the Agency's current thinking on a regulatory issue as well as committing to performance goals in finalizing current and future draft guidance documents. Finally, the notice 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.

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 2005, 1995, and 1985 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 draft language on the proposed A-list and B-list topics, suggestions for new or different guidance documents, the relative priority of guidance documents and/or suggestions that CDRH revise or withdraw a final guidance document that issued previously as part of its retrospective review.

For additional information, see: Federal Register: Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2015 Proposed Guidance Development.

Additional Website Improvements

Over the past few months, CDRH has taken several steps to make it easier for you to find and use information on our websites.

CDRH Guidance Documents Web page: We redesigned our CDRH Guidance Document Web page to include separate sections for Draft Guidance, Final Guidance, and Withdrawn Guidance. We also updated all PDF versions of draft guidance documents with the watermark "DRAFT" in order to identify the guidance as "not for implementation." Finally, we have included a link to a new FDA Guidance Search page that allows the user to search all FDA guidance documents by features including date, subject, and comment period.

CDRH Learn: We redesigned our CDRH Learn multimedia industry education Web page to make it easier for you to browse and find training and to identify new training modules.

Website Cleanup: We reviewed much of our content and archived over 700 pages of outdated information.

Transition to Mobile-Friendly: We converted over 50% of our Web pages to mobile-responsive design to make it easier for you to browse our site with your cellphone or tablet.

For questions about the FY 2015 Proposed Guidance Development and Focused Retrospective Review of Final Guidance, or to provide feedback about the new Web updates, please contact CDRH's Division of Industry and Consumer Education (DICE) at dice@fda.hhs.gov, 1-800-638-2041, or 301-796-7100.