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CDRH Releases 2015 Guidance Document Agenda, Announces Retrospective Guidance Document Review -- Center for Devices and Radiological Health

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On January 9, FDA announced the availability of a website that includes two lists of guidance documents that the Center for Devices and Radiological Health ("CDRH" or the "Center") plans to publish in Fiscal Year ("FY") 2015. The first is a list of draft and final guidance documents that the Agency "fully intends" to publish (the "A-list"), while the second is a list of draft and final guidance documents that the Agency "intends to publish as resources permit" (the "B-list"). These lists resulted from the Medical Device User Fee Amendments of 2012 ("MDUFA III"), enacted as part of the Food and Drug Administration Safety and Innovation Act.

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Examples from the A-list include final guidances:

- Applying Human Factors & Usability Engineering to Optimize Medical Device Design
- Framework for Regulatory Oversight of Laboratory Developed Tests
- Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval
- FDA Notification and Medical Device Reporting for Laboratory Developed Tests
- Intent to Exempt Certain Class II and Class I Reserved Medical Devices From Premarket Notification Requirements
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- Submission and Review of Sterility Information in 510(k) Submissions for Devices Labeled as Sterile

A-list draft guidance topics include:

- General Wellness Products
- Medical Device Accessories
- Medical Device Decision Support Software
- Benefit-Risk Factors to Consider When Reviewing IDE Submissions
- UDI Direct Marking
- Informed Consent: Policy for Observational Data Used to Fulfill Device Requirements
- Adaptive Design for Medical Device Clinical Studies
- UDI FAQs

As part of the final guidances for the B-list, the Center plans to finalize existing draft guidance documents, and

potential draft guidance examples from the B-list include: “3D Printing (Technical),” “Direct Access Genetic In Vitro Diagnostics Testing,” and “Patient Access to Information.”

The Agency noted that not all guidances on the two lists will actually be published in FY 2015, since staff often have to focus on other activities outside of guidance development, like premarket submissions or postmarket issues. Additionally, the Agency stated that certain guidances not described on the lists may be published during the year in response to “newly identified public health issues” or the “classification of de novo devices.”

Furthermore, CDRH has committed that for draft guidance documents issued after October 1, 2014, the Center will finalize, withdraw, reopen the comment period, or issue another draft guidance for 80% of the documents within three years of the close of the comment period. If the Center does not take action within the initial three years, it will act within five years. Also, in 2015, the Center plans to finalize, withdraw, or reopen the comment period for 50% of existing draft guidances issued before October 1, 2009.

On the website, the Agency also published a third list, containing final guidance documents that were issued in 2005, 1995, and 1985 and are now subject to focused retrospective review. This review responds to concerns that have been raised about the length of time final guidances remain current. Accordingly, CDRH announced plans to conduct “a staged review of previously issued final guidances in collaboration with stakeholders.” The Agency plans to provide a retrospective list annually through FY 2025. Thus, by 2025, the Agency and stakeholders “will have assessed the applicability of all guidances older than 10 years.”

Finally, given workload and time constraints, the Agency created a docket, where stakeholders can submit comments related to the lists, including the relative priority of A-list and B-list guidance topics, new guidance document topics, and/or suggestions concerning the revision or withdrawal of a final guidance document as part of the retrospective review. The Agency advises that stakeholders should provide timely feedback to the Agency by March 10, 2015.