CDRH Fiscal Year 2013 (FY 2013) Proposed Guidance Development

U.S. Food & Drug Administration

The lists below include guidance documents that CDRH intends to publish this fiscal year (FY2013). We have provided two lists: (1) a list of guidance documents that the Agency fully intends to publish (the “A-list”); and (2) a list of guidance documents that the Agency intends to publish as resources permit (the “B-list”). Although resource constraints and new issues that emerge over the course of the year may preclude CDRH from issuing every guidance document on the lists and may require that CDRH 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 these lists every year.

CDRH invites interested persons to submit comments on any or all of the guidance documents on the list to docket FDA-2012-N-1021. Comments may include draft language on the proposed topics, suggestions for new or different guidance documents, and/or the relative priority of guidance documents. CDRH believes this docket is an important tool for receiving information from interested parties and for making information available to the public. Current FDA and CDRH guidance documents can be found on the CDRH Guidance Document [1] Web page.

Why is CDRH posting a list of guidance documents it intends to issue?

During negotiations over the Medical Device User Fee Amendments of 2012 (MDUFA III) (Public Law 112-114), FDA agreed, in return from 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. Among other things, FDA agreed to:

- post annually a list of prioritized device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (FY) (the “A-list”);
- post annually a list of device guidance documents that the Agency intends to publish as resources permit each fiscal year (the “B-list”);
- update our website 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the Agency’s review of previously published guidance documents, including the deletion of guidance documents that no longer represent the Agency’s interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency; and
- provide stakeholders an opportunity to provide feedback, including draft language for guidance documents.

Does CDRH expect to complete the list?

Our experience over the years has shown that there are many reasons why CDRH does not complete the entire annual agenda of guidance documents it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, CDRH is required each year to issue a number of guidance documents we cannot know about in advance. These may involve newly identified public health issues as well as special control guidance documents that are necessary for the classification of de novo devices. It will be helpful, therefore, to receive comments indicating the relative priority of different guidance topics to interested stakeholders. In addition, we intend to consider stakeholder feedback to the docket to help prioritize our allocation of resources to specific guidance topics on the list.

How do I comment on this list or a particular guidance document?

FDA has established docket FDA-2012-N-1021 for comments on any or all of the proposed fiscal year 2013 guidance documents. FDA invites interested persons to submit comments, draft language on the proposed topics, suggestions for new or different guidance documents, and/or relative priority of guidance documents. FDA believes this docket is an important tool for receiving information from interested parties and for making information available to the public.

Interested persons may submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov [2]. It is only necessary to send one set of comments. Identify comments with docket number FDA-2012-N-1021. Received comments may be viewed 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 [2].

What guidance documents does CDRH intend to issue or develop during FY 2013?

CDRH is considering developing a variety of guidance documents in fiscal year 2013. Specific topics and status as final and draft guidance document, are provided in the two lists:

Prioritized medical device guidance documents that the Agency intends to publish in FY 2013 ("A-list")

Final Guidance Topics

- Refuse to Accept (RTA) Policy for 510(k) Submissions
- Acceptance and Filing Review for Premarket Approval Applications
- Investigational Device Exemptions (IDE) for Early Feasibility Medical Device

Clinical Studies, Including Certain First in Human (FIH) Studies
- In Vitro Companion Diagnostic Devices
- Design Considerations for Pivotal Clinical Investigations for Medical Devices
- De Novo Classification Process (Evaluation of Automatic Class III Designation)
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications
- CDRH Appeals Processes
- Medical Device Classification Product Codes
- The Pre-Submission Program and Meetings with FDA Staff
- Mobile Medical Applications
- eCopy
- Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents

Draft Guidance Topics

- Distinguishing and Reporting Medical Device Recalls from Product Enhancements
- Types of Communication During the Review of Medical Device Submissions
- FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations
- eCopy
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions

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Device guidance documents that the Agency intends to publish, as the Agency’s guidance-development resources permit each in FY 2013 ("B-list")

Final Guidance Topics

- Finalizing existing draft guidance documents.

Draft Guidance Topics

- Benefit-Risk Determinations in Premarket Notifications (510(k)s)
- Direct to Consumer (DTC) Genetic Testing: IVDs
- Transfer of Ownership of a Premarket Notification (510(k)) - Questions and Answers
- Custom Devices

Guidance documents withdrawn by CDRH in FY 2013

- The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program

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http://www.mdtmag.com/news/2012/11/cdrh-fiscal-year-2013-fy-2013-proposed-guidance-development?qt-recent_content=0&qt-most_popular=0

Links:
[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
[2] http://www.regulations.gov