Documents the Center for Devices and Radiological Health is Considering for Development (FY12)

U.S. Food & Drug Administration

This is the list of guidance documents CDRH is considering for development this year (2012). CDRH plans to update this list every year. CDRH invites interested persons to submit comments on any or all of the guidance documents on the list to docket FDA-2007-N-0270. Comments may include draft language on the proposed topics and/or suggestions for new or different guidance documents. CDRH believes this docket is an important tool for receiving information from interested parties and for making information available to the public.

The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued Level 1 drafts that may be finalized following review of public comments. This list of proposed guidance documents is not binding. CDRH is not required to issue every guidance document on the list and may issue guidance documents not on the list.

Current FDA and CDRH guidance documents can be found on the CDRH Guidance Document page [1].

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed to meet a variety of goals in return for additional funding from industry. The goals are quantitative and qualitative commitments intended to help get safe and effective medical devices to market more quickly. Among other things, FDA agreed to:

- annually post a list of the guidance documents FDA's Center for Devices and Radiological Health (CDRH) is considering for development; and
- provide stakeholders an opportunity to provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

Our experience over the years has shown that there are many reasons CDRH staff does not complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the Center is required each year to issue a number of guidances it 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 that indicate the relative priority of different guidance topics to interested stakeholders. In addition, we

intend to consider stakeholder feedback to the docket to help us prioritize our allocation of resources to specific guidance topics on the list.

FDA has established docket FDA-2007-N-0270 for comments on any or all of the proposed fiscal year 2012 guidance documents. FDA invites interested persons to submit comments, draft language on the proposed topics, and/or suggestions for new or different 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. It is no longer necessary to send two copies of mailed comments. Identify comments with docket number FDA-2007-N-0270. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

CDRH is considering developing a variety of guidance documents in fiscal year 2012:

- General Premarket Issues [3]
- Postmarket and Compliance Guidance [4]
- Device Specific Guidances [5]
- Global Harmonization or Standards Related Guidances [6]
- Cross-Cutting, Process, and Other Guidances [7]

Specific topics are listed below:

General Premarket Issues

- Pre-Submission Interactions
- Early Feasibility Studies
- Decisions for Investigational Device Exemption Clinical Investigations
- 510(k) Modifications
- Design Considerations for Pivotal Clinical Investigations
- Evaluation of Automatic Class III Designation (De Novo)
- 510(k) Paradigm (510(k) Program Guidance)
- Enforcement Policy for 510(k) for Certain IVDs and Radiology Devices
- In Vitro Companion Diagnostic Devices

Postmarket and Compliance Guidance

- Distinguishing and Reporting Medical Device Recalls from Product Enhancements
- Medical Device Reporting

- Annual Reports for Approved Premarket Approval Applications
- Electronic Medical Device Reporting

Device Specific Guidances

- Infusion Pump
- Artificial Pancreas
- Blood Lancets
- Pediatric Information for X-ray Imaging 510(k)s
- Live Case Presentations During Investigational Device Exemption Clinical Trials
- Borrelia burgdorferi (Lyme Disease)
- Medical Devices that Include Antimicrobial Agents
- Low Glucose Suspend Devices
- Computer-Assisted Detection Devices

Global Harmonization or Standards Related Guidances

- Appropriate Use of Consensus Standards in Premarket Submissions
- Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

Cross-Cutting, Process, and Other Guidances

- CDRH Appeals Processes
- Medical Device Classification Product Codes
- Design Considerations for Devices Labeled for Home Use
- Framework for Regulatory Oversight of Laboratory Developed Tests
- FDA Notification and Medical Device Reporting for Laboratory Developed Tests
- Quality System Requirements Guide for Laboratory Developed Tests
- 513(g) Procedures
- 513(g) User Fee
- Radio Frequency Wireless Technology

SOURCE [8]

Source URL (retrieved on *07/10/2014 - 2:52am*):
http://www.mdtmag.com/news/2011/09/documents-center-devices-and-radiological-health-considering-development-fy12

Links:
[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm
[2] http://www.regulations.gov
[3] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA#a
[4] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/Me

dicalDeviceUserFeeandModernizationActMDUFMA#b
[5] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA#c
[6] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA#d
[7] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA#e
[8] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm