U.S. Food and Drug Administration

Medical Devices

Documents the Center for Devices and Radiological Health is Considering for Development (FY11)

Introduction

This is the list of guidance documents CDRH is considering for development this year (2011). 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].

Why is CDRH posting a list of guidance documents it is considering for development?

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.

Does CDRH expect to complete the list?

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.

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

FDA has established docket FDA-2007-N-0270 for comments on any or all of the proposed fiscal year 2011 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.

What guidance documents is CDRH considering for development during fiscal year 2011?

CDRH is considering developing a variety of guidance documents in fiscal year 2010:

- Guidance Related to FDAAA or General Premarket Issues
- Guidance on Postmarket and Compliance Issues
- Device Specific Guidances
- Radiation Emitting Products Guidances
- Global Harmonization or Standards Related Guidances
- Cross-Cutting, Process, and Other Guidances

Specific topics are listed below:

Guidance Related to FDAAA or General Premarket Issues

- Tracking Pediatric Device Approvals
- 30-Day Notices and 135-day PMA Supplements
- Annual Reports for PMAs
- Medical Device Premarket Clinical Studies: Levels of Evidence

Guidance on Postmarket and Compliance Issues

- Manufacturing Site Change Supplements: Content and Inspectional Considerations
- Medical Device Reporting for Manufacturers
- Postmarket Surveillance Under Section 522 of the Federal Food, Drug and Cosmetic Act
- "510k Actions"-FDA and Industry Actions on Premarket Notification Submissions
- Research Use Only
- Distinguishing Medical Device Enhancements from Product Recalls and Corrections
- Electronic Medical Device Reporting

Device Specific Guidances

- Topical Oxygen Chamber for Extremities
- Transcranial Magnetic Stimulation Systems
- Ovarian Adnexal Mass Surgery Referral Index
- Electroconvulsive Therapy Device
- Premarket Notification Submissions for Medical Devices that Include Antimicrobial Agents
- Suction Apparatus Device Intended for Negative Pressure Wound Therapy
- Focused Ultrasound Stimulator System for Aesthetic Use
- Tissue Adhesive with Adjunct Wound Closure Device
- Urinary Incontinence
- Bacillus spp. Serological Reagents
- Yersinia
- Full Field Digital Mammography
- Computed Tomography
- Implantable Cardiovascular Defibrillators
- Coronary Drug Eluting Stents
- Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data
- Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data
- Pediatric Information in Diagnostic Medical Device Premarket Submissions
- Endosseous Implants
- Troponin
- "HGC" Pregnancy Tests

Radiation Emitting Products Guidances

- Non-Medical Lasers

Global Harmonization or Standards Related Guidances

- Global Harmonization Task Force: Quality Management System; Process Validation
- Global Harmonization Task Force: Post Market Surveillance; National Competent Authority Report Exchange Criteria and Report Form
- Application of IEC 60601-1 Third Edition
- Medical Device ISO 13485

Cross-Cutting, Process, and Other Guidances

- Radio-Frequency Wireless Technology in Medical Devices
- Mammography Quality Standards Act: Modifications and Additions to Policy Guidance Help System #13
- Quality Systems for Laboratory Developed Tests
- Medical Device Appeals and Complaints: Guidance on Dispute Resolution
- Medical Devices Containing Materials from Animal Sources (except IVDs)
- Medical Device Home Use

Links on this page:

1. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm
2. http://www.regulations.gov