CDRH Fiscal Year 2016 (FY 2016) Proposed Guidance Development and Focused Retrospective Review of Final Guidance

Introduction

The lists below include guidance documents that CDRH intends to publish this fiscal year (FY2016), as well as previously-issued final guidances for which CDRH is interested in receiving external feedback regarding whether these final guidances should be revised or withdrawn. We have provided three lists: (1) a list of guidance documents that the Agency fully intends to publish (the "A-list"); (2) a list of guidance documents that the Agency intends to publish as resources permit (the "B-list"); and (3) a list of final guidance documents that issued in 2006, 1996, 1986, and 1976 subject to focused retrospective review. 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 may require that CDRH issue guidance documents not on the lists, the A-list and B-list 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.

CDRH invites interested persons to submit comments on any or all of the guidance documents on the three lists 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, for which commenters should state the potential guidance topic, reasons the guidance is needed, and proposed policy or information for FDA to consider on the topic, or the relative priority of guidance documents. Comments may also include suggestions that CDRH revise or withdraw a final guidance document that issued previously as part of its retrospective review, for which commenters should address why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. 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 Web page.

Why is CDRH posting lists 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 A-list and B-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.

Why is CDRH posting a list of guidance documents as part of its retrospective review?

On June 5, 2014, CDRH held a public workshop to provide stakeholders an opportunity to actively engage with Center representatives about the guidance development process, provide transparency into guidance priority development, promote dialogue on guidance process improvements, and generate ideas for assessing the impact of guidance (Public Workshop - Center for Devices and Radiological Health Guidance Development and Prioritization Public Workshop, June 5, 2014). One question that was raised was how current previously issued final guidances remain. CDRH has resolved to address this concern through a staged review of previously issued final guidances in collaboration with stakeholders. CDRH would appreciate external feedback on whether any final guidances that issued in 2006, 1996, 1986, or 1976 should be revised or withdrawn. CDRH intends to provide such lists annually through fiscal year 2025 so that by 2025, FDA and stakeholders will have assessed the applicability of all guidances older than 10 years. For instance, in the annual notice for fiscal year 2017, CDRH expects to provide a list of the final guidance documents that issued in 2007, 1997, 1987, and 1977; the annual notice for fiscal year 2018 is expected to provide a list of the final guidance documents that issued in 2008, 1998, 1988, and 1978, and so on. CDRH will consider the information received from this retrospective review when determining priorities for updating guidance documents.

How do I comment on these lists or a particular guidance document?

FDA has established docket FDA-2012-N-1021 for comments on any or all of the proposed fiscal year 2016 guidance documents or guidance documents subject to CDRH's focused retrospective review. FDA invites interested persons to submit comments on all three lists, draft language on the proposed A-list and B-list topics, suggestions for new or different guidance documents (for which commenters should state the potential guidance topic, reasons the guidance is needed, and proposed policy or information for FDA to consider on the topic), 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 which commenters should address why the guidance document should be revised or withdrawn and, if applicable, how it should be revised). 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. It is only necessary to send one set of comments. Identify comments with docket number FDA-2012-N-1021. Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. For more detailed information on submission of comments, please refer to the Federal Register notice entitled "Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2016 Proposed Guidance Development."

What guidance documents does CDRH intend to issue or develop during FY 2016?

CDRH is considering developing a variety of guidance documents in fiscal year 2016. 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 2016 ("A-list")

Final Guidance Topics

- General Wellness Products
- Medical Device Accessories
- Benefit-Risk Factors to Consider when Reviewing IDE Submissions
- UDI Direct Marking
- Adaptive Design for Medical Device Clinical Studies
- Incorporating Patient Preferences into Medical Devices Premarket Approvals, Humanitarian Device Exemptions, and De Novo Classifications
- Applying Human Factors & Usability Engineering to Optimize Medical Device Design
- Policy for Regulatory Oversight of Laboratory Developed Tests (LDTs)
- Submission and Review of Sterility Information for Devices Labeled as Sterile
- Use of ISO 10993-1, Biological Evaluation of Medical Devices Part I: Evaluation and Testing (Biocompatibility)
- Postmarket Surveillance Studies Under Section 522 of the Food, Drug, and Cosmetic Act

- Medical Device Reporting (MDR) for Manufacturers

Draft Guidance Topics

- Medical Device Decision Support Software
- Use of Symbols in Labeling
- 510(k) Modifications
- Software Modifications
- 510(k) Third Party Review Program
- Companion Diagnostics Co-Development
- Use of Real-World Observational Patient Data to Support Decision Making for Medical Devices
- UDI Convenience Kit
- Public Notification of Emerging Postmarket Medical Device Signals

Device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each in FY 2016 ("B-list")

Final Guidance Topics

- Reporting of Computational Modeling Studies in Medical Device Submissions
- Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use
- Self-Monitoring Blood Glucose Meters for Over-the-Counter Use
- Radiation Biodosimetry Devices
- Finalizing existing draft guidance documents.

Draft Guidance Topics

- Medical Device Interoperability
- Patient Access to Information
- Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies
- Patient Matched Instrumentation for Orthopedics
- Dual 510(k) and Clinical Laboratory Improvement Amendments Act (CLIA) Waiver by Application
- Defining the Unique Device Identifier (UDI)
- Critical to Quality Information for Abdominal Surgical Mesh Devices
- Critical to Quality Information for Hydrophilic Coated and Hydrophobic Coated

Vascular and Neurological Devices

What guidance documents are subject to CDRH's focuses retrospective review during FY2016?

1976 Final Guidances

- Emission Indicators – Brightness
- Components and Repair
- Viewing Optics - Sighting Telescope
- Certain Military Lasers Exempt From 21 CFR 1040.10 & .11
- Emission Indicator – Visibility
- Interlock Design
- Guidelines for Evaluation of Non-Drug IUDs
- Remote Interlock Connectors
- Manufacture and Certification of Laser Kits
- Lasers Manufactured and Used In-House
- Certain Military Lasers Exempt From 21 CFR 1040.10 & .11

1986 Final Guidances

- Panel Report and Recommendations on PMA Approvals #P86-5 (blue book memo)
- Policy on Lamp Compatibility (sunlamps)

1996 Final Guidances

- Statistical Guidance for Clinical Trials of Non Diagnostic Medical Devices
- Indications for Use Statement
- Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic)
- Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery
- Hysteroscopes and Gynecology Laparoscopes - Submission Guidance for a 510(k)
- Thermal Endometrial Ablation Devices (Submission Guidance for an IDE)
- Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices
- 510(k) Quality Review Program (Blue Book Memo I96-1)

- Medical Device Reporting: An Overview
- Guidance Document For Testing Bone Anchor Devices
- Guidance Document for Testing Biodegradable Polymer Implant Devices
- Letter to Manufacturers and Initial Distributors of Hemodialyzers
- Suggested Format for IDE Progress Report
- Effective Visual Control of Laser Projections
- Continued Access to Investigational Devices During PMA Preparation and Review July 15, 1996 (Blue Book Memo D96-1)
- Variance from Manufacturer Report Number Format [MDR letter]
- Guide for Preparing Product Reports for Ultrasonic Therapy Products (physical therapy only)
- MDR Guidance Document No. 1 - IOL - E1996004
- Memorandum of Understanding Regarding Patient Labeling Review (Blue Book Memo #G96-3)
- Variance from Manufacturer Report Number Format - No. 5
- Shielded Trocars and Needles used for Abdominal Access during Laparoscopy
- Guide for Preparing Annual Reports for Ultrasonic Therapy Products
- Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use
- Letter to Manufacturers of Falloposcopes
- Emitted Laser Beam as Emission Indicator for Class II and Class IIIa Laser Products
- Letter to Manufacturers of Prescription Home Monitors for Non-Stress Tests
- Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA
- Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers [excimer]
- Carotid Stent - Suggestions for Content of Submissions to the Food and Drug Administration in Support of Investigational Devices Exemption (IDE) Applications
- Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs
- Prospective Manufacturers of Barrier Devices Used During Oral Sex for STD Protection
- Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)
- Do It By Design - An Introduction to Human Factors in Medical Devices

2006 Final Guidances

- Exemption from Reporting and Recordkeeping Requirements for Low Power Laser Products
- Guidance on Pharmacogenetic Tests and Genetic Tests for Heritable Markers
- The Establishment and Operation of Clinical Trial Data Monitoring Committees for Clinical Trial Sponsors
- Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment
- Dental Curing Lights - Premarket Notification [510(k)]
- Guidance for Industry and FDA Staff: Tonometers - Premarket Notification [510(k)] Submissions
- Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable
- Postmarket Surveillance Under Section 522 of the Federal Food, Drug and Cosmetic Act
- Real-Time Premarket Approval Application (PMA) Supplements
- Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended - Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices
- Preparing a Color Additive Petition for Submission to the Center for Food Safety and Applied Nutrition for Color Additives Used in or on Contact Lenses
- Keratome and Replacement Keratome Blades Premarket Notification [510(k)] Submissions
- Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices
- Exemption from Certain Reporting and Recordkeeping Requirements for Television Receivers and Computer Monitors with Cathode Ray Tubes
- Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography
- Saline, Silicone Gel, and Alternative Breast Implants
- Decorative, Non-corrective Contact Lenses

More in Guidance Documents (Medical Devices and Radiation-Emitting Products)

Cross-Center Final Guidance

- Office of Compliance Final Guidance
- Office of the Center Director Final Guidance
- Office of Communication and Education Final Guidance
- Office of Device Evaluation Final Guidance 2010 - 2015
- Office of Device Evaluation Final Guidance 1998 - 2009
- Office of Device Evaluation Final Guidance 1976 - 1997
- Office of In Vitro Diagnostics and Radiological Health Final Guidance
- Office of Surveillance and Biometrics Final Guidance
- Office of Science and Engineering Laboratories Final Guidance
- Draft Guidance
- Radiation-Emitting Products Guidance
- Withdrawn Guidance

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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