Registration: Registration is $250 for members of AAO, AAOpt, AAPOS, AOA, ASCRS, or CLAO; and $400 for non-members and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online. The deadline for online registration is September 23, 2016, at 4 p.m. EDT. There will be no onsite registration on the day of the public workshop. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Ms. Susan Monahan at *susan.monahan@fda.hhs.gov* or 301–796–5661 no later than September 16, 2016.

To register for the public workshop, please visit *http://www.cfom.info/meetings/myopia/.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone number, and membership in the cosponsoring organizations. If there are any questions with registration, please contact Mrs. Bobbi Hahn at *bhahn@cfom.info.* Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Food may be purchased in advance for $45 on the registration Web site (*http://www.cfom.info/meetings/myopia/*). Food and beverages will also be available for purchase by participants during the workshop breaks.

For more information on the workshop, please see the FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Those without Internet access should contact Bobbi Hahn to register at 651–731–7257.

Streaming Webcast of the Public Workshop: The public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by September 23, 2016. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 23, 2016. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

III. References

The following references are on display in the Division of Dockets Management (see *Transcripts*) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses. U.S. Department of Health and Human Services, Food and Drug Administration. May 1994. *http://www.fda.gov/RegulatoryInformation/Guidances/ucm080928.htm.*
2. Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. U.S. Department of Health and Human Services, Food and Drug Administration. December 2009. *http://www.fda.gov/downloads/Drugs/.../Guidances/UCM193282.pdf.*
3. Draft Guidance: Patient Preference Information—Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Device Labeling. U.S. Department of Health and Human Services, Food and Drug Administration. Posted March 2015. *http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm446680.pdf.*

Dated: July 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16353 Filed 7–8–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3787]

Information To Support a Claim of Electromagnetic Compatibility of Electrically-Powered Medical Device; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Device.'' This guidance describes the types of information that should be provided to support a claim of EMC in a premarket submission for an electrically powered medical device. Electromagnetic disturbance is electronic product radiation that may interfere with the performance of an electrically powered medical device in its intended environment (*i.e.,* cause an electromagnetic interference (EMI)). EMC assessment helps to ensure that a device is able to function in its intended environment without introducing excessive electromagnetic disturbances that might interfere with other devices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted,

such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3787 for ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Device.'' 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.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Device'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Donald Witters, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1130, Silver Spring, MD 20993–0002, 301–796–2483.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance to provide FDA's current thinking about the information that should be provided in a premarket submission to support a claim of EMC for an electrically powered medical device. The assessment of EMC helps to ensure that the risks associated with performance degradation of electrically powered medical devices due to EMI are adequately mitigated. This guidance is intended to ensure that clear and consistent information regarding medical device EMC are provided in premarket submissions to facilitate the review of submissions with EMC claims associated with safety and effectiveness.

The guidance includes information consistent with specifications described in FDA-recognized consensus national or international standards for EMC such as in the International Electrotechnical Commission (IEC) 60601–1–2: Edition 3: 2007–03, Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests; IEC 60601–1–2: Edition 4.0: 2014–01, Medical Electrical Equipment, Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Disturbances—Requirements and Tests; Association for the Advancement of Medical Instrumentation (AAMI)/American National Standards Institute (ANSI)/IEC 60601–1–2: 2007/(R) 2012 Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests; and AAMI/ANSI/IEC 60601–1–2: 2014, Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Disturbances—Requirements and Tests Standards that sponsors and manufacturers of electrically powered medical devices often reference.

The draft guidance of ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Device'' was posted November 2, 2015, for public comment, and the comment period ended on December 17, 2015. Three sets of comments were received during the comment period.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the information that should be provided to support a claim of EMC of electrically-powered medical device. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological

Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Device'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400057 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332. The collections of information in the guidance document ''Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff—Humanitarian Device Exemption (HDE) Regulation: Questions and Answers'' have been approved under OMB control number 0910–0661.

Dated: July 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16350 Filed 7–8–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–N–0221; FDA–2012–N–0559; FDA–2015–N–3287; FDA–2015–N–3815; FDA–2007–D–0429; FDA–2012–N–0447; FDA–2011–D–0597; FDA–2011–D–0164; FDA–2013–N–0013; FDA–2011–N–0146; FDA–2014–N–1533; FDA–2011–N–0921; FDA–2015–N–2163]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Food Labeling: Notification Procedures for Statements on Dietary Supplements	0910–0331	6/30/2019
PHS Guideline on Infectious Disease Issues in Xenotransplantation	0910–0456	6/30/2019
MDUFMA Small Business Qualification Certification	0910–0508	6/30/2019
Electronic Submission of Medical Device Registration and Listing	0910–0625	6/30/2019
Guidance for Industry on Q & A Regarding Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement & Nonprescription Drug Consumer Protection Act	0910–0641	6/30/2019
Antimicrobial Animal Drug Distribution Reports and Recordkeeping	0910–0659	6/30/2019
Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring	0910–0733	6/30/2019
Guidance for Industry on Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act	0910–0734	6/30/2019
Accreditation of Third Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications	0910–0750	6/30/2019
Sanitary Transportation of Human and Animal Food	0910–0773	6/30/2019
National Panel of Tobacco Consumer Studies	0910–0815	6/30/2019
Standards for the Growing, Harvesting, Packaging, and Holding of Produce for Human Consumption	0910–0816	6/30/2019
Hearing, Aging, and Direct-to-Consumer Television Advertisements	0910–0818	6/30/2019

Dated: July 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16349 Filed 7–8–16; 8:45 am]

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