ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Eric A. Mann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–5620.

SUPPLEMENTARY INFORMATION:

I. Background

Since issuance of the February 25, 2009 guidance entitled, ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products'' FDA has become aware of a lack of clarity regarding how the Agency defines a hearing aid versus a personal sound amplification product (PSAP), which has also led, in some cases, to inappropriate application of regulatory requirements for such products. These inconsistent interpretations of the definitions may inadvertently result in hearing-impaired consumers bypassing safeguards that were implemented to promote the prompt diagnosis of treatable medical conditions causing hearing loss. To ensure consistent interpretation, consistent application of relevant regulatory requirements, and adequate protection of the public health, FDA seeks to further clarify the definitions of hearing aids and PSAPs.

This draft guidance, when finalized, will supersede the guidance entitled ''Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,'' dated February 25, 2009.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the definitions and regulatory requirements for hearing aids and PSAPs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1832 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 801 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen 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*.

Dated: November 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26691 Filed 11–6–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0567]

Design Considerations for Pivotal Clinical Investigations for Medical Devices; Guidance for Industry, Clinical Investigators, Institutional Review Boards and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Design Considerations for Pivotal Clinical Investigations for Medical Devices.'' This document is intended to provide guidance to those involved in designing clinical studies intended to support premarket submissions for medical devices and for FDA staff who review those submissions. This guidance document describes different study design principles relevant to the development of medical device clinical studies that can be used to fulfill premarket clinical data requirements.

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: Submit written requests for single copies of the guidance document entitled ''Design Considerations for Pivotal Clinical Investigations for Medical Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For devices regulated by CDRH: Gregory Campbell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2110, Silver Spring, MD 20993–0002, 301–796–5750.

For devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

I. Background

The guidance document is intended to provide guidance to those involved in designing clinical studies that support premarket submissions for medical devices and FDA staff who review those submissions. Although the Agency has articulated policies related to design of studies intended to support specific device types, and a general policy of tailoring the evidentiary burden to the regulatory requirement, the Agency has not attempted to describe the different clinical study designs that may be appropriate to support a device premarket submission, or to define how a sponsor should decide which pivotal clinical study design should be used to support a submission for a particular device. The guidance document describes different study design principles relevant to the development of medical device clinical studies that can be used to fulfill premarket clinical data requirements. The guidance is not intended to provide a comprehensive tutorial on the best clinical and statistical practices for investigational medical device studies.

A medical device pivotal study is a definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use. Evidence from one or more pivotal clinical studies generally serves as the primary basis for the determination of reasonable assurance of safety and effectiveness of the medical device of a premarket approval application (PMA) and FDA's overall risk-benefit assessment. In some cases, a PMA may include multiple studies designed to answer different scientific questions.

The guidance describes principles that should be followed for the design of premarket clinical studies that are pivotal in establishing the safety and effectiveness of a medical device. Practical issues and pitfalls in pivotal clinical study design are discussed, along with their effects on the conclusions that can be drawn from the studies concerning safety and effectiveness.

In the **Federal Register** of August 15, 2011 (76 FR 50484), FDA announced the availability of the draft guidance. Interested persons were invited to comment by November 14, 2011. FDA considered the comments and revised the guidance, as appropriate.

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 Agency's current thinking on pivotal clinical investigations for medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.* To receive ''Device Considerations for Pivotal Clinical Investigations for Medical Devices,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1776 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 807, subpart E have been approved under 0910–0120; the collections of information in 21 CFR part 812 have been approved under 0910–0078; the collections of information in 21 CFR part 814 have been approved under 0910–0231.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen 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.*

Dated: November 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 12, 2013, from 8 a.m. to 6:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1643, Silver Spring, MD 20993, *Sara.Anderson@fda.hhs.gov,* 301 796–7047; or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC