information are sponsors that develop drugs and biological products.

Burden Estimate: This guidance outlines FDA's policies and procedures related to the following expedited programs for serious conditions: (1) Fast track designation including rolling review, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. In addition, this guidance describes threshold criteria generally applicable to these expedited programs.

This guidance refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR parts 202.1, 314, and 601, and sections 505(a), 506(a)(1), 735, and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a), 356(a)(1), 379(g), and 379(h)) have been approved under OMB control numbers 0910–0686, 0910–0001, 0910–0338, 0910–0014, and 0910–0297.

This guidance proposes the following new collections of information:

Priority Review Designation Request. The guidance describes that a sponsor may expressly request priority review of an application. Based on information from FDA's databases and information available to FDA, we estimate that approximately 47 sponsors will prepare and submit approximately 1 priority review designation submission in accordance with the guidance and that the added burden for each submission will be approximately 30 hours to develop and submit to FDA as part of the application (totaling 1,410 hours).

Breakthrough Therapy Designation Request. The guidance describes the process for sponsors to request breakthrough therapy designation in an application. Based on information available to FDA, we estimate that approximately 24 sponsors will prepare approximately 1 breakthrough therapy designation submission in accordance with the guidance and that the added burden for each submission will be approximately 70 hours to prepare and submit (totaling 1,680 hours).

Promotional Materials for Accelerated Approval Under Part 314. The guidance describes section 506(b)(2)(B) of the FD&C Act and FDA's accelerated approval regulations (§§ 314.550 and 601.45). These provisions authorize FDA to require sponsors to submit copies of all promotional materials to the Agency for consideration prior to their dissemination. The regulations provide that copies of all promotional materials including promotional labeling as well as advertisements intended for dissemination or publication within 120 days following marketing approval must be submitted to FDA during the preapproval period. The regulations further provide that after 120 days following marketing approval, unless otherwise informed by the Agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement. Currently, FDA has OMB approval for the submission of copies of all promotional materials under part 601 (OMB control number 0910–0338) but does not have approval for the submission of copies of all promotional materials under part 314.

Based on information from FDA's databases and information available to FDA, we estimate that approximately 20 sponsors will submit promotional materials for accelerated approval 7 times annually in accordance with § 314.550 and that the burden for each submission will be approximately 120 hours (a total of 16,800 hours).

In the **Federal Register** of June 26, 2013 (78 FR 38349), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 26 comments. However, these comments did not address the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance on expedited programs	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Designation Request	47	1	47	30	1,410
Breakthrough Therapy Designation Request	24	1	24	70	1,680
Promotional Materials for Accelerated Approval Under § 314.550	20	7	140	120	16,800
Total hours					19,890

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26695 Filed 11–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1295]

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry 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 draft guidance entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.'' This draft guidance clarifies the distinction between hearing aids and personal sound amplification products (PSAPs), as well as the regulatory controls that apply to each. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 5, 2014.

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]

BILLING CODE 4160–01–P

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.