Dated: March 10, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–05796 Filed 3–12–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0397]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice invites comments on reporting requirements contained in existing FDA regulations governing State enforcement notifications.

DATES: Submit either electronic or written comments on the collection of information by May 12, 2015.

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

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910–0275)—Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in their own name and within their own jurisdiction. However, before doing so, a State must provide notice to FDA according to 21 CFR 100.2. The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondents	Total annual responses	Average burden per response	Total hours
100.2(d)	1	1	1	10	10

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

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, we have not received any new enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually. Although we have not received any new enforcement notifications in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: March 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05668 Filed 3–12–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Ear, Nose, and Throat 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: Ear, Nose, and Throat 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 April 30 and May 1, 2015 from 8 a.m. to 6 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: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring MD 20993–0002, *Patricio.Garcia@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On April 30, 2015, the committee will discuss and make recommendations regarding the classification of Hearing Protectors, Circumaural Hearing Protectors, Middle Ear Inflation Devices, Tactile Hearing Aid Devices, and Vestibular Analysis Apparatuses. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Hearing Protectors are currently regulated under the heading, ''Protector, Hearing (Insert),'' Product Code EWD, as unclassified under the 510(k) premarket notification authority. Circumaural Hearing Protectors are currently regulated under the heading, ''Protector, Hearing (Circumaural),'' Product Code EWE, as unclassified under the 510(k) premarket notification authority. Middle Ear Inflation Devices are currently regulated under the heading, ''Device, Inflation, Middle Ear,'' Product Code MJV, as unclassified under the 510(k) premarket notification authority. Tactile Hearing Aid Devices are currently regulated under the heading, ''Hearing Aid, Tactile,'' Product Code LRA, as unclassified under the 510(k) premarket notification authority. Vestibular Analysis Apparatuses are currently regulated under the heading, ''Apparatus, Vestibular Analysis,'' Product Code LXV, as unclassified under the 510(k) premarket notification authority. FDA is seeking committee input on the risks, safety and effectiveness and the regulatory classification of Hearing Protectors, Circumaural Hearing Protectors, Middle Ear Inflation Devices, Tactile Hearing Aid Devices, and Vestibular Analysis Apparatuses.

On May 1, 2015 the committee will discuss key issues related to a potential pre- to post-market shift in clinical data requirements for modifications to cochlear implants in pediatric patients. These issues are categorized into three broad areas for discussion:

1. Cochlear implant changes (*e.g.* sound processing features, patient characteristics) that may be suitable for this pre- to post-market shift in clinical data requirements.

2. Appropriate premarket clinical data requirements to support pre- to post-market shift (*e.g.* leveraging clinical data from adults and/or older children).

3. Clinical study design considerations (*e.g.* study endpoints and test metrics, subject characteristics) for post market studies to confirm safety and effectiveness and inform future labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 22, 2015. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. on April 30, 2015 and between approximately 1 p.m. and 2 p.m. on May 1, 2015. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 14, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 16, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact at James Clark at *James.Clark@fda.hhs.gov,* or 301–796–5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05675 Filed 3–12–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Organizations To Serve as Non-Voting Liaison Representatives to the Chronic Fatigue Syndrome Advisory Committee (CFSAC)

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

Authority: 42 U.S.C. 217a, Section 222 of the Public Health Service (PHS) Act, as amended. The committee is governed