TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total					1,320

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

We base our estimate of burden for the recordkeeping provisions of § 179.25(e) on our experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. We estimate that there are four irradiation plants whose business is devoted primarily (*i.e.,* approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. We estimate that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on four facilities devoting 100 percent of their business to food irradiation (4 × 300 hours = 1200 hours for recordkeeping annually), and four facilities devoting 10 percent of their business to food irradiation (4 × 30 hours = 120 hours for recordkeeping annually).

No burden has been estimated for the labeling requirements in §§ 179.21(b)(1), 179.21(b)(2), and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act.

Dated: March 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07263 Filed 3–30–15; 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; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of March 13, 2015. The amendment is being made to reflect a change in the April 30th *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: 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), code EN. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 13, 2015 (80 FR 13392), FDA announced that a meeting of the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee would be held on April 30 and May 1, 2015. On page 13393, in the first and second columns, the *Agenda* portion of the document is changed to read as follows:

On April 30, 2015, the Agency is adding three Agenda items to the original five agenda items posted in the March 13, 2015, **Federal Register** document. The three additional items are: Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient), Speech Training Aids for the Hearing Impaired (AC-powered and Patient-Contact), and Nasal Septal Button Devices. The committee will discuss and make recommendations regarding the classification of Hearing Protectors, Circumaural Hearing Protectors, Tactile Hearing Aids, Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient), Speech Training Aids for the Hearing Impaired (AC-powered and Patient-Contact), Vestibular Analysis, Middle Ear Inflation Devices, and Nasal Septal Button Devices. 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. 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. Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient) are currently regulated under the heading, ''Aids, Speech Training For The Hearing Impaired (Battery-Operated or Non-Patient),'' Product Code LFA, as unclassified under the 510(k) premarket notification authority. Speech Training Aids for the Hearing Impaired (AC-Powered and Patient-Contact) are currently regulated under the heading, ''Aids, Speech Training For The Hearing Impaired (AC-Powered and Patient-Contact),'' Product Code LEZ, 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. 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. Nasal Septal Button Devices are currently regulated under the heading, ''Button, Nasal Septal,'' Product Code LFB, 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, Tactile Hearing Aids, Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient), Speech Training Aids for the Hearing Impaired (AC-Powered and Patient-Contact), Vestibular Analysis, Middle Ear Inflation Devices, and Nasal Septal Button Devices.

On May 1, 2015, the committee will discuss key issues related to a potential pre- to postmarket 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 postmarket shift in clinical data requirements.

2. Appropriate premarket clinical data requirements to support pre- to postmarket 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 postmarket 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.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 24, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–07300 Filed 3–30–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–F–0171]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Labeling; Calorie Labeling of Articles of Food in Vending Machines

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Labeling; Calorie Labeling of Articles of Food in Vending Machines'' has 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 5, 2015, the Agency submitted a proposed collection of information entitled ''Food Labeling; Calorie Labeling of Articles of Food in Vending Machines'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0782. The approval expires on March 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07265 Filed 3–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0868]

Development and Submission of Near Infrared Analytical Procedures; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Development and Submission of Near Infrared Analytical Procedures.'' This draft guidance provides recommendations to applicants of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) regarding the development and submission of near infrared (NIR) analytical procedures used during the manufacture and analysis of pharmaceuticals. This draft guidance only pertains to the development and validation of NIR analytical procedures and does not provide recommendations concerning the set up and qualification of NIR instruments or their maintenance and calibration.

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 June 1, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

FOR FURTHER INFORMATION CONTACT: John L. Smith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1757.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Development and Submission of Near Infrared Analytical Procedures.'' This draft guidance provides recommendations to applicants of NDAs and ANDAs regarding the development and submission of NIR analytical procedures used during the manufacture and analysis of pharmaceuticals (including raw materials, in-process materials and intermediates, and finished products). It also provides recommendations regarding how the concepts described in the International Conference on Harmonisation (ICH) guidance for industry, ''Q2(R1) Validation of Analytical Procedures: Text and Methodology'' (*http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm265700.htm*) and ''PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance'' (*http://www.fda.gov/downloads/Drugs/Guidances/ucm070305.pdf*) can be applied to the development, validation,