

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]

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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,