

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,

and submission of NIR analytical procedures.

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.

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 current thinking of FDA on the submission and development of NIR analytical procedures. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 314 for NDAs, ANDAs, supplements to applications, and annual reports have been approved under OMB control number 0910–0001.

III. 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>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07266 Filed 3–30–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice for Public Comment on the Title IV–E Adoption Assistance Program's Suspension and Termination Policies

AGENCY: Children's Bureau; Administration on Children, Youth and Families; ACF, HHS

ACTION: Notice.

SUMMARY: In accordance with title IV–E of the Social Security Act (42 U.S.C. 673), the Children's Bureau (CB) announces the opportunity for public comment on our suspension and termination policies for the title IV–E adoption assistance program, articulated in the Child Welfare Policy Manual. We similarly announce the opportunity to provide public comment about any other policy areas of concern relating to the title IV–E adoption assistance program.

DATES: Submit written or electronic comments on or before June 29, 2015.

ADDRESSES: Interested persons may submit comments to <http://www.regulations.gov>. We urge you to submit comments electronically to ensure they are received in a timely manner. Written comments may also be submitted to Kathleen McHugh, United States Department of Health and Human Services, Administration for Children and Families, Policy Division, 8th Floor, 1250 Maryland Avenue SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kathleen McHugh, United States Department of Health and Human Services, Administration for Children and Families, Policy Division, 8th Floor, 1250 Maryland Avenue SW., Washington, DC 20024. Email address: cbcomments@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: The Social Security Act only permits a title IV–E agency to terminate a child or youth's title IV–E adoption assistance subsidy under three delineated circumstances: (1) The child has attained the age of 18, or the age that the agency has chosen pursuant to sec. 475(8)(B)(iii) and (iv) of the Social Security Act (or the age of 21 if the title IV–E agency has determined that the child has a mental or physical disability which would warrant continuation of assistance); (2) the title IV–E agency determines that the adoptive parents are no longer legally responsible for support of the child; or (3) the title IV–E agency determines that the adoptive parents are no longer providing any support to the child.

CB has interpreted the law to prohibit a title IV–E agency from automatically suspending a title IV–E adoption assistance payment on the basis that suspending title IV–E adoption assistance is equivalent to terminating title IV–E adoption assistance. See Child Welfare Policy Manual, section 8.2D.5, Question and Answer #3 (available at http://www.acf.hhs.gov/cwpm/programs/cb/laws_policies/laws/cwpm/policy_dsp.jsp?citID=82#747).

The statute also requires adoptive parents to keep the title IV–E agency apprised of any circumstances that would impact a child's continued eligibility for title IV–E adoption assistance, or would impact the appropriate amount of the payment. See the Social Security Act at sec. 473(a)(4)(B). However, the statute does not specify a recourse for title IV–E agencies if a parent does not provide such information. CB has explained in the Child Welfare Policy Manual that title IV–E agencies may not suspend or terminate title IV–E adoption assistance if adoptive parents do not respond to requests for information about whether the parents are providing any support to the child, or whether the adoptive parents remain legally responsible for their adopted child. See Child Welfare Policy Manual, section 8.2, Question and Answer #1 (http://www.acf.hhs.gov/cwpm/programs/cb/laws_policies/laws/cwpm/policy_dsp.jsp?citID=63).

We seek comment from title IV–E agencies and other stakeholders about the title IV–E adoption assistance suspension and termination policies. We invite agencies and stakeholders to share their experiences and concerns about how title IV–E agencies implement the suspension and termination policies, and any difficulties they have had ensuring that they are paying title IV–E adoption assistance funds appropriately.

In particular, we encourage respondents to address the following questions:

(1) Should jurisdictions have authority to suspend adoption assistance payments under any circumstances? If so, what specific circumstances should be the basis for suspension?

(2) If suspension was to be permitted, what processes should be required in connection with suspension, and what processes should be required for reinstatement?

More generally, we invite title IV–E agencies and other stakeholders to share their broader concerns about the title IV–E adoption assistance program that are unrelated to suspending or