the Best Pharmaceuticals for Children Act (BPCA), on adverse event reports for Serevent (SALMETEROL), Provigil (MODAFINIL), Azopt (BRINZOLAMIDE), Bextaxon (LEVOBETAXOLOL), Emtrivia (EMTRICITABINE), and Gleevec (IMATINAB MESYLATE). The Pediatric Advisory Committee will also hear about and discuss the Pediatric Initiatives between FDA and the European Medicines Agency.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee 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 November 5, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2: p.m. on November 27, 2007 and 11 a.m. to 11:30 a.m. and 3 p.m. to 3:30 p.m. on November 28, 2007. Those desiring to make 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 October 26, 2007. 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 October 29, 2007.

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 Dr. Carlos Peña 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/oc/advisory/default.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: October 8, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–20302 Filed 10–12–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric 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: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services , when that research is also regulated by FDA.

Date and Time: The meeting will be held on Thursday, November 29, 2007, from 8 a.m. to 4 p.m.

Location: Hilton, Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Carlos Peña, Office of Science and Health Coordination, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–3340, e-mail: *Carlos.Peña@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The Pediatric Advisory Committee will hear and discuss issues related to FDA's draft guidance for Industry entitled ''Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling,'' that published in the **Federal Register** of Tuesday, February 8, 2005 (70 FR 6697). As part of the review and consideration of public comments received by FDA in response to this draft guidance, the Pediatric Advisory Committee will hear and discuss information on: Labeling of drugs for use by lactating women; breastfeeding physiology, benefits, and current research; the physiology and pharmacology of drug transfer into breast milk; and ethical issues related to studying breastfeeding mother/infant pairs.

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 will be available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee 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 November 5, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Those desiring to make 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 October 26, 2007. 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 October 29, 2007.

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FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at*http://www.fda.gov/oc/advisory/default.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: October 8, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–20304 Filed 10–12–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0367]

Draft Guidance for Industry on Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval; 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 ''Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval.'' The purpose of this guidance is to inform industry of FDA's current thinking regarding appropriate clinical study designs to evaluate antibacterial drugs, and to ask sponsors to amend ongoing or completed studies accordingly. This guidance is in response to a number of public discussions in recent years regarding the use of active-controlled studies designed to show noninferiority as a basis for approval of antibacterial drug products.

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 written or electronic comments on the draft guidance by December 14, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Edward Cox, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6412, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval.'' Most antibacterial drugs have been approved based on active-controlled noninferiority trials. There have been a number of public discussions in recent years on the use of noninferiority studies to support regulatory approval of antibacterial drug products. Some of these discussions have focused on specific diseases such as acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. These public discussions have contributed to FDA's evolving understanding of the science of clinical trials and, in particular, the appropriate role of active-controlled studies designed to show noninferiority in the development of antibacterial drug products.

This draft guidance recommends that sponsors provide justification for the treatment effect size and the proposed noninferiority margin for all antibacterial development programs for which approval will rely on noninferiority studies.

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 use of noninferiority studies to support approval of antibacterial drug products. 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 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively, and the collection of information under the guidance for industry Special Protocol Assessment has been approved under OMB control number 0910–0470.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–20282 Filed 10–12–07; 8:45 am]

BILLING CODE 4160–01–S