

subject to the requirement that the product be studied further to verify and describe its clinical benefit. On November 16, 2009, Genentech submitted the results of two clinical trials intended to satisfy this requirement. CDER determined that these trials failed to verify AVASTIN's clinical benefit in the treatment of MBC and on December 16, 2010, issued a notice of opportunity for a hearing to Genentech proposing to withdraw approval of AVASTIN's MBC indication. Genentech submitted a hearing request dated December 23, 2010, followed by a submission of data and information on which it would rely at a hearing. The Agency granted Genentech's hearing request and published a notice of hearing on May 11, 2011 (76 FR 27332). The hearing was held on June 28 and 29, 2011. Following the hearing, on November 18, 2011, the Commissioner issued a final decision withdrawing approval of AVASTIN's MBC indication.

II. Electronic Access

Persons with access to the Internet may obtain the final decision at <http://www.fda.gov/downloads/NewsEvents/Newsroom/UCM280546.pdf>. The final decision, a transcript of the hearing, and other documents pertaining to the withdrawal of Avastin's MBC indication are available at <http://www.regulations.gov> under the docket number found in brackets in the heading of this document.

Dated: February 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0605]

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Institutional Review Board Continuing Review After Clinical Investigation Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled, "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval." The guidance

announced in this document finalizes the draft guidance of the same title dated January 2010. This document also supersedes the Information Sheet, Continuing Review After Study Approval. The guidance is intended to assist institutional review boards (IRBs) in carrying out their continuing review responsibility by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations.

DATES: Submit either electronic or written comments at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002 (1-888-463-6332 or 301-796-3400); or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448 (1-800-835-4709 or 301-827-1800); or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993 (1-800-638-2041 or 301-796-7100). Send one self-addressed adhesive label to assist the office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Sara Goldkind, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002. 301-796-8342.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled, "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval." This guidance is intended to assist IRBs in carrying out their continuing review responsibility under 21 CFR 56.108(a) and 56.109(f) by providing recommendations regarding

the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations. The guidance should also help clinical investigators and sponsors better understand their responsibilities related to continuing review. This guidance supersedes the Information Sheet, "Continuing Review After Study Approval" (September 1998, Office of Health Affairs, Food and Drug Administration). To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services, Office for Human Research Protections (OHRP) and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts.

In the **Federal Register** of January 13, 2010 (75 FR 1790), FDA announced the availability of the draft guidance of the same title, dated January 2010. FDA received numerous comments on the draft guidance. All comments received during the comment period and questions received by Agency staff related to implementation of the regulations have been carefully reviewed and, where appropriate, incorporated into the guidance. Changes from the draft guidance include more detailed discussion about what should be submitted to assist the IRB in conducting continuing review, clarification of recommendations regarding submission of study-wide information for multi-site studies, discussion of the circumstances in which expedited review procedures may be used for continuing review, and revised guidance about how continuing review dates should be determined. In addition, FDA's draft guidance, "IRB Continuing Review after Clinical Investigation Approval", did not address IRB approval of research with conditions. Subsequent to OHRP's issuance of its guidance, "IRB Approval of Research with Conditions" (November 2010), FDA received multiple inquiries and comments recommending that FDA adopt the same policy. In response to these comments, FDA is including a discussion of IRB approval of research with conditions in the guidance.

This guidance is part of the Information Sheet Guidance Initiative, announced in the **Federal Register** of February 3, 2006 (71 FR 5861), which describes FDA's intention to update the process for developing, issuing, and making available guidances intended for IRBs, clinical investigators, and

sponsors. Known as "Information Sheets," these guidances have provided recommendations to IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by the FDA. The Information Sheet Guidance Initiative is intended to ensure that the Information Sheets are updated, consistent with the FDA's good guidance practices (GGPs). As part of the initiative, which will be ongoing, the Agency plans to rescind Information Sheets that are obsolete, revise and reissue guidances that address current issues, and develop new guidance documents as needed.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.regulations.gov> or <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>.

Dated: February 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0918]

Pediatric Studies of Meropenem Conducted in Accordance With Section 409I of the Public Health Service Act; Establishment of Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a public docket to make available to the public a report of the pediatric studies of meropenem that were conducted in accordance with section 409I of the Public Health Service Act (PHS Act) and submitted to the Director of the National Institutes of Health (NIH) and the Commissioner of Food and Drugs.

DATES: Submit either electronic or written comments by March 28, 2012.

ADDRESSES: You may submit comments, identified by FDA-2011-N-0918, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise Pica-Branco, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6402, Silver Spring, MD 20993-0002, Email: denise.picabranco@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under section 409I of the PHS Act (42 U.S.C. 284m), the Secretary of the Department of Health and Human Services (the Secretary) acting through the Director of the NIH, in consultation with FDA and experts in pediatric research, must develop, prioritize, and publish a list of priority needs in pediatric therapeutics, including drugs and indications that require study.¹ For drugs and indications on this list, FDA, acting in consultation with NIH, is authorized to issue a written request to holders of a new drug application (NDA) or abbreviated new drug application (ANDAs) for a drug for which pediatric studies are needed to provide safety and efficacy information for pediatric labeling. If the sponsors receiving the written request decline to conduct the studies or if FDA does not receive a response to the written request within 30 days of the date the written request was issued, the Secretary, acting through the Director of NIH and in consultation with FDA, must publish a request for proposals to conduct the pediatric studies described in the written request and award funds to an entity with appropriate expertise for the conduct of the pediatric studies described in the written request. Upon completion of the pediatric studies, a study report that includes all data generated in connection with the studies must be submitted to FDA and NIH and placed in a public docket assigned by FDA.

Meropenem, an antibiotic medication, is labeled for pediatric patients from 3 months of age through adolescence as a single agent antimicrobial therapy for meningitis and complicated intra-abdominal infections, and is a recommended option for monotherapy of high severity complicated intra-abdominal infections in adults. Off-label use of meropenem in newborn and infant patients younger than 3 months of age is significant, despite the lack of adequate pharmacokinetic, dosing, tolerability, and safety data for this age group.

On August 13, 2003, NIH published a **Federal Register** notice (68 FR 48402) announcing the addition of several drugs, including meropenem, to the priority list of drugs most in need of

¹ Prior to the 2007 reauthorization of the Best Pharmaceuticals for Children Act (Pub. L. 107-109), the priority list included specific drugs instead of therapeutic areas.