DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2342]

Pediatric Studies of Ampicillin Conducted in Accordance With the Public Health Service Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is making available to the public a report, submitted by Duke Clinical Research Institute on December 15, 2015, of the pediatric studies of ampicillin that were conducted in accordance with 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. This notice is to announce the 30-day open public comment period on the report.

DATES: Submit either electronic or written comments by May 25, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 25, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of May 25, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–2342 for ''Pediatric Studies of Ampicillin Conducted in Accordance With Section 409I of the Public Health Service Act.'' Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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: Lori Gorski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6466, Silver Spring, MD 20993–0002, email: *Lori.Gorski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

1. Background

Under section 409I of the PHS Act (42 U.S.C. 284m), the Secretary of Health and Human Services (the Secretary), acting through the Director of 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, under the Best Pharmaceuticals for Children Act, to holders of a new drug application or an abbreviated new drug application for a drug for which pediatric studies are needed, to provide safety and efficacy information for pediatric labeling. If the applicants or application holders 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

[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.

NIH and placed in a public docket assigned by FDA.

Neonates are at risk for serious bacterial infections including meningitis, bacteremia, sepsis, and urinary tract infections. Most of these children are admitted to a hospital, where they receive antibiotics. Early onset of bacterial infection (less than 7 days of life) reflects vertical transmission, usually caused by group B streptococci (GBS), *Escherichia coli, Listeria monocytogenes,* or *enterococcus* species, and is a significant cause of illness and death among low birth weight infants. Late onset infections suggest nosocomial, community-acquired infections or late onset GBS; these may be caused by gram-negative organisms as well as staphylococcal species. The first line of antibiotic therapy is ampicillin in combination with gentamicin or a third-generation cephalosporin.

In the **Federal Register** of February 13, 2004 (71 FR 23931), NIH published a notice announcing the addition of several drugs, including ampicillin, to the priority list of drugs most in need of study for use by children to ensure the drugs' safety and efficacy. A written request for pediatric studies of ampicillin was issued on August 5, 2005, to the holders of applications for ampicillin. FDA did not receive a response to the written request. Accordingly, NIH issued a request for proposals to conduct the pediatric studies described in the written request in 2006, and awarded funds to Pediatric Trials Network in December 2011 to complete the studies described in the written request. Upon completion of the pediatric studies, a report of the pediatric studies of ampicillin was submitted to NIH and FDA. As required under section 409I of the PHS Act, FDA opened a public docket and NIH placed in the docket the report of pediatric studies of ampicillin that was submitted to NIH and FDA. The report includes all data generated in connection with the study, including the written request.

II. Availability of Report for Public Comment

FDA is announcing the 30-day open public comment period for the report of the pediatric studies of ampicillin that were conducted in accordance with section 409I of the PHS Act and submitted to NIH and FDA. We invite interested parties to review the Duke Clinical Research Institute report, which was posted to the docket on December 15, 2015, and submit comments to the docket (see **ADDRESSES**).

Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–08301 Filed 4–24–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Food and Drug Administration Small Business and Industry Assistance Regulatory Education for Industry Spring Conference; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), together with the Center for Devices and Radiological Health (CDRH), is sponsoring a 2-day public conference entitled ''FDA Small Business and Industry Assistance Regulatory Education for Industry (REdI) Spring Conference.'' The goal of this public conference is to provide direct, relevant, and helpful information on the key aspects of drug and medical device regulations in order to increase regulatory certainty and predictability for pharmaceutical and/or medical device industry. Our primary audience is that of small manufacturers of drug and/or medical devices who want to learn about how FDA approaches the regulation of drugs and medical devices and for whom increased certainty and predictability will help to decrease the regulatory burdens that can be associated with a lack of understanding of, or familiarity with, FDA's drug and medical device regulations. However, anyone involved in the pharmaceutical and/or medical device industry may attend.

DATES: The public conference will be held May 9 and 10, 2017, from 8:30 a.m. to 4:30 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public conference will be held in the High Ballroom, located on the Lobby Level of the Renaissance Atlanta Midtown Hotel, 866 W. Peachtree St. NW., Atlanta, GA 30308. The hotel's phone number is 678–412–2400.

FOR FURTHER INFORMATION CONTACT: Brenda Stodart, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6707, email: *cdersbia@fda.hhs.gov;* or Elias Mallis, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–7100, email: *DICE@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public conference entitled ''FDA Small Business and Industry Assistance Regulatory Education for Industry Spring Conference.'' This public conference is intended to increase the drug and medical device industry's awareness of applicable FDA regulations. There will be an opportunity for questions and answers following each presentation.

II. Topics for Discussion at the Conference

This 2-day, FDA-led forum offers the opportunity to interact with FDA subject matter experts from across CDER and CDRH. The following information will be discussed:

- CDER Investigational New Drug Application (IND) Review Process: Types of IND; Content and Format of an IND; Chemistry Manufacturing and Controls; Pharmacology/Toxicology; Drug Inspections
- CDRH: 510(k); Biocompatibility in Premarket Submissions; Non-Conforming Product; Device Inspections

III. Participating in the Public Conference

Registration: There is no fee to attend the public conference. Space is limited, and registration will be on a first-come, first-served basis. To register, please complete registration online at: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm545309.htm.* Early registration is recommended. Registrants will receive email confirmation when they have been accepted, and reminder emails will be sent to registrants 2 days before the conference. If time and space permit, onsite registration will be available beginning at 7:30 a.m. on each day of the public conference. If you need special accommodations due to disability, please contact *info@sbiaevents.com* at least 7 days in advance.

Streaming Webcast of the Public Conference: This public conference will also be Webcast. Persons interested in viewing the Webcast must register to