4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3037]

Pediatric Studies of Lorazepam; Establishment of Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to make available to the public a report of the pediatric studies of Lorazepam 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.

DATES: Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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-3037 for "Pediatric Studies of Lorazepam; Establishment of Public Docket." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://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 http://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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper 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: 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, Lori.Gorski@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 or abbreviated new drug application 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.

Lorazepam is commonly used in pediatric practice as a first-line agent for the initial treatment of status epilepticus. However, there is limited information available about dosing, pharmacokinetics, effectiveness, and safety in pediatric patients treated with Lorazepam.

A written request for pediatric studies of Lorazepam was issued on July 5, 2002, to Wyeth-Ayerst Research, the holder of the new drug applications for Lorazepam. FDA did not receive a response to the written request. On January 21, 2003, NIH published a Federal

[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.

Register notice (68 FR 2789) announcing the addition of several drugs, including Lorazepam, to the priority list of drugs most in need of study for use by children to ensure their safety and efficacy. Accordingly, NIH issued a request for proposals to conduct the pediatric studies described in the written request and awarded funds to the Children's National Medical Center in September 2004, to complete the studies described in the written request. Upon completion of the pediatric studies, a report of the pediatric studies of Lorazepam 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 Lorazepam that was submitted to NIH and FDA. The report includes all data generated in connection with the study, including the written request.

We invite interested parties to review the report and submit comments to the docket. The public docket is available for public review in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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