4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0284]

Pediatric Studies of Sodium Nitroprusside 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 sodium nitroprusside that were conducted in accordance with the Public Health Service Act (the 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, identified by FDA-2012-N-0284, 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:

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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 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, biological products, and indications that require study.[1] For drugs and biological products 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 (ANDA) for a drug, or holders of a biologics license application (BLA) for a biological product, 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.

Sodium nitroprusside, a hypotensive agent, is labeled for the immediate reduction of blood pressure of patients in hypertensive crises, for producing controlled hypotension in order to reduce bleeding during surgery, and for the treatment of acute congestive heart failure. Off-

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

label use of sodium nitroprusside in pediatric patients is significant, despite the lack of adequate pharmacokinetic, dosing, tolerability, and safety data for this age group.

On January 21, 2003, NIH published a Federal Register notice (68 FR 2789) announcing the addition of several drugs, including sodium nitroprusside, to the priority list of drugs most in need of study for use by children to ensure their safety and efficacy. A written request for pediatric studies of sodium nitroprusside was issued on July 8, 2002, to Abbott Laboratories, the holder of the NDA for sodium nitroprusside. 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 July 2004, and awarded funds to Duke University and Stanford University 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 sodium nitroprusside 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 sodium nitroprusside 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: September 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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