4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3132]

General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products." This draft guidance is intended to assist sponsors of new drug applications (NDAs), biologics license applications (BLAs) for therapeutic biologics, and supplements who are planning to conduct clinical studies in neonatal populations. The issuance of this draft guidance on clinical pharmacology considerations for neonatal studies for drugs and biological products is stipulated under the FDA Reauthorization Act of 2017 (FDARA).

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2019-D-3132 for " General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and

Biological Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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 Dockets Management Staff. 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Rajnikanth Madabushi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2173, Silver Spring, MD 20993, 301-796-1537 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products." This draft guidance is intended to assist sponsors of NDAs, BLAs for therapeutic biologics, and supplements who are planning to conduct clinical studies in neonatal populations. This draft guidance is adjunctive to the December 2014 draft FDA guidance entitled *General Clinical*

Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products, as it addresses general clinical pharmacology considerations in neonates, a pediatric subpopulation. The issuance of this draft guidance on clinical pharmacology considerations for neonatal studies for drugs and biological products is stipulated under section 505 of FDARA.

Given that most drugs used in Neonatal Intensive Care Units are used in an off-label capacity, studies of therapeutic products need to be conducted in neonates. In addition, therapies need to be developed for conditions unique to neonates. This draft guidance addresses: (1) subgroup classifications of neonates; (2) general pharmacokinetic, pharmacodynamic, and pharmacogenomic considerations for clinical pharmacology studies in neonates; and (3) clinical pharmacology considerations for any planned studies in neonates whether the studies are conducted pursuant to the Best Pharmaceuticals for Children Act, the Pediatric Research Equity Act, or neither. This draft guidance does not discuss the timing to initiate neonatal studies. Questions regarding the appropriate timing for the initiation of neonatal studies should be discussed with the relevant FDA review division.

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 current thinking of FDA on "General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 for submitting of NDAs in 21 CFR 314.50(d)(7), including pediatric use information and the submission of waiver requests in § 314.90, have been approved under OMB control number 0910-0001. The collections of information for submitting BLAs, including pediatric use information and waiver requests under 21 CFR 601.27, have been approved under OMB control number 0910-0338. The collections of information for submitting investigational new drug applications in § 312.47(b)(1)(iv), including plans for pediatric studies and the submission of waiver requests in § 312.10, have been approved under OMB control number 0910-0014. The collections of information for requesting meetings with FDA about drug development programs in §§ 312.47 and 312.82 have been approved under OMB control number 0910-0014. The collections of information for prescription drug labeling in 21 CFR 201.56 and 21 CFR 201.57 have been approved under OMB control number 0910-0572. The collections of information related to expedited review programs for serious conditions have been approved under OMB control number 0910-0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov. Guidance documents are also available at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics or http://www.regulations.gov.

Dated: July 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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