4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-4693]

Postapproval Pregnancy Safety Studies; 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 final guidance for industry titled "Postapproval Pregnancy Safety Studies." The purpose of this guidance will be to provide sponsors and investigators with recommendations on how to design investigations to assess the outcomes in pregnant women exposed to drug and biological products regulated by FDA (i.e., pregnancy safety studies) in the postapproval setting. This guidance finalizes the draft guidance of the same name issued on May 9, 2019.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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-2018-D-4693 for "Postapproval Pregnancy Safety Studies." 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

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

Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6469, Silver Spring, MD 20993, 301-796-6169; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry titled "Postapproval Pregnancy Safety Studies." The purpose of this guidance is to provide sponsors and investigators with recommendations on how to design investigations to assess the safety outcomes in pregnant women exposed to drug and biological products regulated by FDA, in the postapproval setting. Currently, collection of safety data in drug and biological products used during pregnancy usually occurs after approval. Pregnancy registries have been used to collect these data. However, in the years since FDA first issued guidance on this topic, scientific methodologies for assessing the safety of drug and biological products used during pregnancy in the postmarketing setting have evolved.

This guidance finalizes the draft guidance titled "Postapproval Pregnancy Safety Studies" issued on May 9, 2019 (84 FR 20371). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include the following: (1) clarifying the section on pregnancy registries, including the addition of a subsection on statistical methods; (2) broadening the scope of the complementary study methods sections; (3) expanding the discussion on data collection in situations when rare exposure to a drug during pregnancy is anticipated; and (4) updating terminology to include descriptive pregnancy safety studies. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Postapproval Pregnancy Safety Studies." 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. FDA considered the applicability of Executive Order 14192, per OMB guidance in M-25-20, and finds this action to be an EO 14192 deregulatory action.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information

are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR 314.50(d), 314.80(c)(2)(iii), and 314.81(b)(2)(vii) pertaining to submissions of new drug applications for submitting postmarketing safety reports, postmarketing study updates in annual reports, and formal meetings between sponsors or applicants and FDA have been approved under OMB control number 0910-0001. The collections of information in 21 CFR 312.23(a)(6) pertaining to submitting pregnancy registry design considerations in a protocol for investigational new drug applications have been approved under OMB control number 0910-0014. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practices have been approved under OMB control number 0910-0139. The collections of information in 21 CFR parts 310.305(c) and 314.80(c)(2)(iii) and (e) for submitting postmarketing safety reports have been approved under OMB control number 0910-0230. The collections of information in 21 CFR parts 310, 314, 600, and 803 for submitting postmarketing safety reports under MedWatch have been approved under OMB control number 0910-0291. The collections of information in 21 CFR 601 pertaining to biologics license applications have been approved under OMB control number 0910-0338. The collections of information in 21 CFR 201.56 and 201.57 pertaining to human prescription drug labeling have been approved under OMB control number 0910-0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-09268 Filed: 5/8/2026 8:45 am; Publication Date: 5/11/2026]