Dated: July 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0559]

Postmarketing Studies and Clinical Trials: Determining Good Cause for Noncompliance With Section 505(o)(3)(E)(ii) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Postmarketing Studies and Clinical Trials: Determining Good Cause for Noncompliance with Section 505(o)(3)(E)(ii) of the Federal Food, Drug, and Cosmetic Act.'' The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to require certain postmarketing studies and clinical trials for prescription drugs at the time of approval or after approval if FDA becomes aware of new safety information. This draft guidance describes the factors FDA considers when determining whether an applicant has demonstrated good cause for failure to comply with the timetable for completion of studies or clinical trials required under the provisions. This draft guidance also provides information on relevant procedures, including how an applicant should communicate with FDA regarding compliance with these required studies and trials and describes actions FDA may take for noncompliance with the requirements.

DATES: Submit either electronic or written comments on the draft guidance by September 12, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2023–D–0559 for ''Postmarketing Studies and Clinical Trials: Determining Good Cause for Noncompliance with Section 505(o)(3)(E)(ii) of the Federal Food, Drug, and Cosmetic Act.'' 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 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 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: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993, 301–796–6054, or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Postmarketing Studies and Clinical Trials: Determining Good Cause for Noncompliance with Section 505(o)(3)(E)(ii) of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance provides information for holders of applications for human prescription drugs that are required to conduct postmarketing studies or clinical trials under section 505(o)(3) of the FD&C Act (21 U.S.C. 355(o)(3). Section 505(o), added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), authorizes FDA to require certain postmarketing studies for prescription drugs at the time of approval or after approval if FDA becomes aware of new safety information. These postmarketing studies and clinical trials are also referred to as postmarketing requirements (PMRs) or FDAAA PMRs.

An applicant required to conduct a PMR must provide certain information to FDA, including a timetable for study or clinical trial completion and periodic reports on the status of the study or clinical trial. If an applicant fails to comply with the timetable or fails to submit periodic status reports, FDA considers the applicant to be in violation of section 505(o)(3) of the FD&C Act, unless the applicant has demonstrated good cause for its PMR noncompliance. Under section 505(o)(3)(E)(ii) of the FD&C Act, FDA is responsible for determining what constitutes good cause for PMR noncompliance. Violations of requirements under this section are subject to enforcement action, including pursuant to sections 505(o)(1) (charges under section 505 of the FD&C Act), 502(z) (21 U.S.C. 332(z)) (misbranding charges), and 303(f)(4)(A) (21 U.S.C. 333(f)(4)(A)) (civil monetary penalties).

This draft guidance describes the factors FDA considers when determining whether an applicant has demonstrated good cause for its noncompliance with the timetable for PMR completion. This draft guidance also provides information on relevant procedures including how to communicate with FDA regarding PMR compliance, submission of an explanation of the circumstances that led to noncompliance, and how FDA notifies an applicant of a determination of noncompliance, and describes the enforcement actions FDA can take for PMR noncompliance. Although this draft guidance primarily addresses noncompliance with the timetable for completion of PMR milestones, any violation of a requirement under section 505(o)(3)(E)(ii) of the FD&C Act is subject to enforcement action, in the absence of a demonstration of good cause.

Section 505(o) of the FD&C Act applies only to prescription drugs approved under section 505(b) of the FD&C Act and biological drug products approved under section 351 of the Public Health Service Act.[1] This draft guidance does *not* apply to nonprescription drugs, including nonprescription drugs that are approved under a new drug application, or to generic drugs approved under section 505(j) of the FD&C Act.

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 ''Postmarketing Studies and Clinical Trials: Determining Good Cause for Noncompliance with Section 505(o)(3)(E)(ii) of the Federal Food, Drug, and Cosmetic Act.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314, including the submission of status reports of postmarketing study commitments under § 314.81(b)(2)(vii), have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft 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.*

[1] See section 505(o)(2)(B) of the FD&C Act.

Dated: July 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3402]

Advisory Committee; National Mammography Quality Assurance Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the National Mammography Quality Assurance Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the National Mammography Quality Assurance Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the July 7, 2025, expiration date.

DATES: Authority for the National Mammography Quality Assurance Advisory Committee will expire on July 7, 2025, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: James Swink, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301–796–6313, email: *James.Swink@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the National Mammography Quality Assurance Advisory Committee (the Committee). The Committee is a non-discretionary Federal advisory committee established to provide advice to the Commissioner.

The Commissioner is charged with the administration of the Federal Food, Drug, and Cosmetic Act and various provisions of the Public Health Service Act. The Mammography Quality Standards Act of 1992 amends the Public Health Service Act to establish national uniform quality and safety