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FDA is announcing the availability of a draft guidance for industry entitled ''Postmarketing Studies and Clinical Trials: Determining Good Cause for Noncompliance with Section 505(o)(3)(E)(ii) of the Federal Food,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 This draft guidance provides information for holders of applications for human prescription drugs that are required to conduct postmarketing studies or clinical trials under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This draft guidance describes the factors FDA considers when determining whether an applicant has demonstrated good cause for its noncompliance with the timetable for PMR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 This draft guidance also provides information on relevant procedures including how to communicate with FDA regarding PMR compliance, submission of an explanation of the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 Although this draft guidance primarily addresses noncompliance with the timetable for completion of PMR milestones, any violation of a requirement under section 505(o)(3)(E)(ii) of the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

standards for mammography facilities. The National Mammography Quality Assurance Advisory Committee advises the Secretary and, by delegation, the Commissioner of Food and Drugs or designee in discharging their responsibilities with respect to establishing a mammography facilities certification program. The Committee shall advise the HHS Secretary and the Commissioner or designee on:

(A) developing appropriate quality standards and regulations for mammography facilities;

(B) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program;

(C) developing regulations with respect to sanctions;

(D) developing procedures for monitoring compliance with standards;

(E) establishing a mechanism to investigate consumer complaints;

(F) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities;

(G) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas;

(H) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and

(I) determining the costs and benefits of compliance with these requirements.

The Committee shall consist of a core of 15 members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. Members will be invited to serve for overlapping terms of up to 4 years. Almost all members of this committee serve as Special Government Employees. The core of voting members shall include at least four individuals from among national breast cancer or consumer health organizations with expertise in mammography, and at least two practicing physicians who provide mammography services. In addition to the voting members, the Committee shall include two nonvoting industry representative members who have expertise in mammography equipment. The Committee may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/radiation-emitting-products/national-mammography-quality-assurance-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

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–N–0008]

Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its public advisory committees for the Center for Drug Evaluation and Research (CDER) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on CDER's public advisory committees. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by August 14, 2023, (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by August 14, 2023.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to Nicholas Marsh (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Division of Advisory Committee and Consultant Management, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2418, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Nicholas Marsh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2418, Silver Spring, MD 20993–0002, 240–402–5357, email: *Nicholas.Marsh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative to the following advisory committees:

I. CDER Advisory Committees

A. Anesthetic and Analgesic Drug Products Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery.

B. Antimicrobial Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

C. Arthritis Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases.