Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993–0002, 301–796–6287 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's standards recognition program furthers the aim of international harmonization because the same standards (or international equivalents) are relied upon by sponsors to meet other countries' regulatory requirements when appropriate. This guidance describes the procedures that FDA follows and the actions FDA may take to recognize and withdraw recognition from voluntary consensus standards. This guidance provides further clarity and explanation about the regulatory framework, policies, and practices when evaluating requests for recognition. This guidance also responds to section 3053 of the Cures Act by updating published guidance on these topics (Pub. L. 114–255).

FDA generally considers for recognition voluntary consensus standards, which are created by standards development organizations that follow a consensus process. A document issued by the Office of Management and Budget (OMB) entitled ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,'' commonly called OMB Circular A–119, defines the attributes or elements of a consensus process (Ref. 1). This guidance explains those elements and how they pertain to FDA's consideration of a standard for recognition.

The guidance describes the process leading up to and including recognition. We list common purposes to recognize voluntary consensus standards as well as the essential information that FDA will provide in the supplemental information sheet for the recognition of a standard. This guidance also discusses when FDA may withdraw recognition.

Any interested party may also request that FDA recognize a specific voluntary consensus standard. This guidance recommends the information that should be included in a request for recognition of a standard, and it summarizes the actions we may take to act on such a request.

A notice of availability of the draft guidance appeared in the **Federal Register** of September 14, 2018 (83 FR 46740). FDA considered comments received and revised the guidance as appropriate in response to the comments, including specifying that FDA will provide the rationale for complete and partial recognition and describing considerations for determining the timing of a transition period between versions of standards. This guidance supersedes the guidance ''CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition,'' issued on September 17, 2007.

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 ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff.'' 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*. Persons unable to download an electronic copy of ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 616 and full title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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. 3501–3521). The collections of information in the following FDA guidance have been approved by OMB control number 0910–0120.

Dated: September 3, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–20308 Filed 9–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1861]

Generic Drug User Fees; Stakeholder Meetings on Generic Drug User Fee Amendments of 2017 Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Generic Drug User Fee Amendments of 2017 (GDUFA). At the end of September 2022, new legislation will be required for FDA to continue collecting generic drug user fees for subsequent fiscal years for the generic drug program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program. The FD&C Act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by October 8, 2020. Stakeholder meetings will be held monthly, and it is anticipated that they will commence in October 2020.

ADDRESSES: The meetings will take place virtually and will be held by webcast only. Submit notification of intention to participate in monthly stakeholder meetings by email to *GenericDrugPolicy@fda.hhs.gov*. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240–402–8926, *Dat.Doan@fda.hhs.gov;* or Tiana Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6196, Silver Spring, MD 20993, 301–796–2882, *Tiana.Barnes@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of GDUFA. GDUFA authorizes FDA to collect user fees from the regulated industry for the current program (GDUFA II). At the end of September 2022, new legislation will be required for FDA to continue collecting user fees for subsequent fiscal years for the generic drug program. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund human generic drug activities. Section 744C(f) (21 U.S.C. 379j–43(f)) of the FD&C Act requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program, including representatives from patient and consumer groups, healthcare professionals, and scientific and academic experts. FDA initiated this process by holding a public meeting on July 21, 2020, at which stakeholders and other members of the public were given an opportunity to present their views on reauthorization (85 FR 38378). The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in October 2020.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer groups, healthcare professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic stakeholder consultation meetings on GDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed. Stakeholders who identify themselves through this notice will be included in all stakeholder discussions while FDA negotiates with the regulated industry. Stakeholders who decide to participate in these monthly meetings at a later time may still participate in remaining monthly meetings by notifying FDA (see **ADDRESSES**). These stakeholder discussions will satisfy the consultation requirement in section 744C(f)(3) (21 U.S.C. 379j–43(f)(3)) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding GDUFA reauthorization, please provide notification by email to *GenericDrugPolicy@fda.hhs.gov* by October 8, 2020. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification. Information concerning GDUFA, including the text of the law, the GDUFA II Commitment Letter, key **Federal Register** documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA website at *https://www.fda.gov/gdufa*.

Dated: September 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20334 Filed 9–14–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0618, FDA–2010–N–0601, FDA–2010–N–0598, FDA–2013–N–1155, FDA–2010–N–0118, FDA–2020–N–0145, FDA–2010–N–0597, FDA–2014–N–0086, FDA–2016–N–2836, FDA–2019–N–5841, and FDA–2019–N–5973]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain*. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025	8/31/2023
Current Good Manufacturing Practice Regulations for Medicated Feed	0910–0152	8/31/2023
Good Manufacturing Practice Regulations for Type A Medicated Articles, 21 CFR Part 226	0910–0154	8/31/2023
Food Labeling Regulations	0910–0381	8/31/2023
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–0520	8/31/2020