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: Karen Takahashi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm, 6686, Silver Spring, MD 20993–0002, 301–796–3191.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Facility Readiness: Goal Date Decisions Under GDUFA.'' This guidance provides information to applicants on how FDA intends to assign a goal date based on a facility's readiness for inspection as certified on Form FDA 356h submitted as part of an original ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). This guidance explains how FDA incorporates a performance enhancement in the GDUFA III commitment letter as part of its goal date assignments.

Under the commitment letter related to the GDUFA authorization for fiscal years 2018 through 2022 (under the Generic Drug User Fee Amendments of 2017), a goal date was assigned without regard to facility readiness for inspection. In contrast, under the GDUFA III commitment letter, FDA agreed to assign a longer goal date if a facility is not ready for an inspection at the time of application submission. An application containing a facility not ready for inspection is more likely to require more than one assessment cycle, extending the time required for possible approval and potentially delaying patient access to quality generic drugs. This change in goal date assignment will help FDA to focus resources on applications with facilities ready for inspection.

This guidance finalizes the draft guidance of the same title issued on October 7, 2022 (87 FR 61039). No public comments were received on the draft guidance. Only minor editorial changes were made.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Facility Readiness: Goal Date Decisions Under GDUFA.'' 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. 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 part 314 for ANDAs have been approved under OMB control number 0910–0001. The collections of information in Form FDA 356h have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 11 for electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information pertaining to the GDUFA III commitment letter have been approved under OMB control number 0910–0727.

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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13391 Filed 6–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2602]

First Annual Animal Drug User Fee Educational Conference; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following educational conference (public meeting) entitled ''First Annual Animal Drug User Fee Educational Conference.'' This is the first of five annual educational conferences FDA will host as described in the ''Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028.'' The purpose of this series of conferences is to provide educational sessions for stakeholders who are interested in the new animal drug approval process.

DATES: The first educational conference will be held on July 17, 2024, from 9 a.m. to 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. You may submit comments at any time for this series of educational conferences. We request that you submit either electronic or written comments by 90 days after each annual educational conference to ensure that the Agency considers your comment on a topic discussed at that conference.

ADDRESSES: The first educational conference will be available in person and virtually. The in-person conference will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Great Room Conference Center, Silver Spring, MD 20993–0002. Entrance for conference participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.* Persons interested in attending this educational conference must register at: *https://fda.zoomgov.com/webinar/register/WN_cSFEyfDpQK6RuGrwPznG9A.*

You may submit comments 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–2024–N–2602 for ''First Annual Animal Drug User Fee Educational Conference.'' 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.

FOR FURTHER INFORMATION CONTACT: Walter Ellenberg, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–0885, *adufa_v_edu_conference@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Drug User Fee Act (Pub. L. 108–130) (ADUFA or the Act) was originally signed into law in 2003 and was subsequently reauthorized by Congress in 2008, 2013, 2018, and 2023. ADUFA authorizes FDA to collect fees for certain new animal drug applications, products, establishments, and sponsors. Resources generated under ADUFA supplement the Agency's funding to enhance the performance of the drug review process, ensuring that new animal drug products are safe and effective for animals, and that food derived from treated animals will be safe for consumption. FDA considers the timely review of the safety and effectiveness of new animal drug applications to be central to the Agency's mission to protect and promote human and animal health.

The Animal Drug User Fee Amendments of 2023 (ADUFA V), the most recent reauthorization of the Act, authorizes FDA to collect user fees through fiscal year 2028. ''The Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028'' (Performance Goals Letter) sets forth the Agency's performance goals for the period covered by ADUFA V. Among other goals, the document commits the Agency to hosting triannual meetings (three meetings per calendar year) with Animal Health Institute (AHI) members. Each year, during one of these meetings, the Agency will commit up to 8 hours for an educational conference intended for the animal drug industry. This notice announces the first of these annual Animal Drug User Fee Educational Conferences. These conferences are open to the public. The educational conference being announced in this notice is the first annual conference of this series.

II. Topics for Discussion at the Educational Conference

As described in the Performance Goals Letter, FDA will plan a series of topics for the educational conferences during the 5 years of ADUFA V. While the agenda for each educational conference is determined by the Agency with input from AHI, all stakeholders are welcome to submit comments to the docket requesting topics to be included for future educational conferences (see **ADDRESSES**).

This initial conference will provide a high-level overview in the following areas:

(1) Overview of the Approval Process
(2) Communication Pathways with the Center for Veterinary Medicine

(3) Best Practices in the Approval Process
(4) Target Animal Safety Technical Section Overview
(5) Effectiveness Technical Section Overview
(6) Chemistry, Manufacturing, and Controls Technical Section Overview
(7) Human Food Safety Technical Section Overview
(8) Environmental Impact Technical Section Overview
(9) Minor Technical Sections Overview

The conference will also contain Q&A sessions during which FDA will address specific questions from the in-person and virtual audience as time allows. Future educational conferences will take a more in-depth approach to these and other topics based on questions and comments received during this conference, as well as questions and comments submitted to the docket.

III. Participating in the Educational Conference

Registration: This educational conference is open to the public and will be available virtually and in-person. When registering, please provide complete contact information for each attendee, including name, title, affiliation (if any), address, email, and telephone number. Also, please self-identify as a member of one of the stakeholder categories: regulated industry, scientific or academic experts, veterinary professionals, consumer advocacy groups, press/media relations, FDA, other government/congress, or other.

Early registration is recommended for persons who wish to attend the conference. Registrants will receive confirmation when their registration has been received and they will be provided the webcast link. Persons interested in attending this conference virtually may register until the start time of the conference. Persons interested in attending this conference in person are encouraged to register online at *https://fda.zoomgov.com/webinar/register/WN_cSFEyfDpQK6RuGrwPznG9A* no later than July 10, 2024. Onsite registration will be provided on the day of the conference on a first-come, first-served basis, until the room capacity is reached. Onsite registration will open at the conference site at 8 a.m. on July 17, 2024. If room capacity is reached, individuals will be offered the opportunity to observe the conference from an overflow room located at the conference site.

If you need special accommodations due to a disability, please contact Walter Ellenberg (see **FOR FURTHER INFORMATION CONTACT**) no later than July 10, 2024.

Transcript: Transcripts of the educational conference will be available on FDA's website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings* approximately 30 days after the conference. Please be advised that as soon as a transcript of the educational conference is available, it will be accessible at *https://www.regulations.gov,* and may also be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

Recording of Conference: Please be advised that as soon as a recording of this conference is available, it will be accessible at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

Dated: June 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13303 Filed 6–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5656]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 18, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

State Enforcement Notifications—21 CFR 100.2(d)

OMB Control Number 0910–0275—Extension

This information collection supports Agency regulations. Specifically, section 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in their own name and within their own jurisdiction. However, before doing so, a State must provide notice to FDA according to § 100.2 (21 CFR 100.2). The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the **Federal Register** of January 23, 2024 (89 FR 4315), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows: