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.

A transcript of the public meeting will be made available in the docket, as well as on the FDA website at: *https://www.fda.gov/industry/animal-generic-drug-user-fee-act-agdufa/agdufa-meetings.*

FOR FURTHER INFORMATION CONTACT: Lisa Kable, Center for Veterinary Medicine, Food and Drug Administration, 240–402–6888, *lisa.kable@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The authority for AGDUFA expires September 30, 2023. Without new legislation, FDA will no longer have the authority to collect user fees to fund the new animal generic drug review process for future fiscal years. Prior to beginning negotiations with the regulated industry on AGDUFA reauthorization, section 742(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-22(d)(2)) requires FDA to: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization including specific suggestions for changes to the goals referred in section 742(a) of FD&C Act; (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes; and (4) publish the comments on FDA's website. FDA is holding a public meeting to gather information on what FDA should consider including in the reauthorization of AGDUFA. FDA is interested in responses from the public on the following two general questions and welcomes other pertinent information that stakeholders would like to share:

1. What is your assessment of the overall performance of the AGDUFA program thus far?

2. What aspects of AGDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

II. Background

FDA considers the timely review of generic new animal drug submissions to be central to the Agency's mission to protect and promote human and animal health. The AGDUFA program began in FY 2009 and is currently in the third authorization (AGDUFA III). FDA has published a number of reports that provide useful background on AGDUFA I, AGDUFA II, and AGDUFA III. AGDUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports can be found at: *https://www.fda.gov/industry/fda-user-fee-programs/animal-generic-drug-user-fee-act-agdufa.*

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register no later than midnight Eastern Time on May 18, 2021, by emailing complete contact information for each attendee, including name, title, affiliation, address, email, telephone number, and if you need reasonable accommodations due to a disability (*e.g.,* Closed Captioning) to *cvmagdufa@fda.hhs.gov.* Early registration is recommended. Registrants will receive confirmation when their registration has been received and will be provided the webcast link.

Requests for Oral Presentations: During online registration you may indicate if you wish to make an oral presentation during the public meeting. To facilitate agenda development, registrants requesting to present will be contacted to provide information regarding which topics they intend to address and the title of their presentation. We will do our best to accommodate requests to make an oral presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate. All requests to make oral presentations must be received by May 7, 2021.

We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will notify participants by May 11, 2021. Selected presenters planning to use an electronic slide deck must submit an electronic copy of their presentation to Lisa Kable (see **FOR FURTHER INFORMATION CONTACT**) with the subject line ''AGDUFA Public Meeting Presentation'' on or before May 17, 2021. If presenters choose not to use a slide deck, they are requested to submit a single slide with their name, affiliation, title of their presentation, and contact information. No commercial or promotional material will be permitted to be presented at the public meeting.

Dated: April 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07375 Filed 4–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0655]

Animal Generic Drug User Fee Act; Stakeholder Consultation Meetings on the Animal Generic Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice: Request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this notice to request that public stakeholders notify FDA of their intent to participate in periodic consultation meetings on reauthorization of the Animal Generic Drug User Fee Act (AGDUFA). The statutory authority for AGDUFA expires September 30, 2023. The Federal Food,

Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders—including patient and consumer advocacy groups, veterinary professionals, and scientific and academic experts—in developing recommendations for the next AGDUFA program and hold discussions with these stakeholders at least once every 4 months during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure consistent stakeholder representation at the consultation meetings.

DATES: Submit notification of intention to participate in continued periodic stakeholder consultation meetings regarding AGDUFA reauthorization by May 20, 2021. These stakeholder meetings are expected to commence on July 2021 and will continue at least once every 4 months during reauthorization negotiations with the regulated industry. See the **SUPPLEMENTARY INFORMATION** section for further information regarding notification of intention to participate.

ADDRESSES: The stakeholder meetings will be held virtually.

FOR FURTHER INFORMATION CONTACT: Lisa Kable, Center for Veterinary Medicine, Food and Drug Administration, 240–402–6888, *Lisa.Kable@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

In 2018 Congress passed the Animal Generic Drug User Fee Amendments of 2018 (Pub. L. 115–234; AGDUFA III). The authority for AGDUFA III expires September 30, 2023. Without new legislation to reauthorize the program, FDA will no longer be able to collect user fees for future fiscal years to fund the generic new animal drug review process. Section 742(d)(1) of the FD&C Act (21 U.S.C. 379j–22(d)(1)) requires that FDA consult with a range of stakeholders in developing recommendations for consideration for the next AGDUFA program, including representatives from patient and consumer advocacy groups, veterinary professionals, and scientific and academic experts. To initiate this process of consultation, elsewhere in this issue of the **Federal Register**, we are announcing a public meeting to be held on May 20, 2021, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. The meeting and written comments submitted to the docket will provide critical input as the Agency prepares for reauthorization discussions. Section 742(d)(3) of the FD&C Act further requires that FDA continue meeting with these stakeholders at least once every 4 months during negotiations with the regulated industry to continue discussions of their views on the reauthorization, including suggested changes to the AGDUFA program.

FDA is issuing this **Federal Register** notice to request that stakeholders—including veterinary, patient and consumer groups, as well as scientific and academic experts—notify FDA of their intent to participate in the periodic consultation meetings on AGDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings is essential in the reauthorization process. If you wish to participate in this part of the reauthorization process, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all future stakeholder discussion while FDA negotiates with the regulated industry. If a stakeholder decides to participate in these meetings at a later time, they may still participate in remaining meetings by notifying FDA (see **FOR FURTHER INFORMATION CONTACT**). These stakeholder discussions will satisfy the requirement in section 742(d)(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 AGDUFA reauthorization, please submit notification by email to: *cvmagdufa@fda.hhs.gov* by May 18, 2021. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, telephone number, and notice of any special accommodations required due to a disability (*e.g.,* Closed Captioning). Stakeholders will receive confirmation and additional information about the first meeting, and subsequent meeting when scheduled, after FDA receives this notification of intent to participate.

Dated: April 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07374 Filed 4–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1736]

Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and request for comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice announcing a public meeting and requesting comments that appeared in the **Federal Register** of October 13, 2020. In that notice, FDA announced a public meeting, which was held on November 16, 2020, and requested public input on a potential revised approach for considering the human medical importance of antimicrobial new animal drugs when assessing and managing the antimicrobial resistance risks associated with the use of antimicrobial drugs in animals. Specifically, the Agency requested comments on the potential revised process for ranking antimicrobials according to their relative importance in human medicine, on the potential criteria for their ranking, and on the resulting ranked list of antimicrobial drugs. We are taking this action in response to technical difficulties submitting comments to the Federal eRulemaking portal.

DATES: Submit either electronic or written comments by April 22, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 22, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 22, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the