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

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–2020–N–1736 for ''Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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: Kelly Covington, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5661, *Kelly.Covington@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 13, 2020, FDA published a notice announcing a public meeting and requesting comments on a concept paper entitled ''Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs,'' giving interested persons until January 15, 2021, to comment on the public meeting and request for comments. In a notice published in the **Federal Register** on November 27, 2020 (85 FR 76081), the Agency extended the comment period to March 16, 2021. The Agency has received several comments from stakeholders of technical difficulties submitting comments to the Federal eRulemaking portal. In consideration of these difficulties, FDA is reopening the comment period for 10 days to allow these stakeholders the opportunity to submit comments. All comments previously submitted, do not need to be resubmitted.

Dated: April 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07452 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–0656]

Animal Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public meeting entitled ''Animal Drug User Fee Act.'' The purpose of the public meeting is to invite public comment on the Animal Drug User Fee Act (ADUFA) program and suggestions regarding the features FDA should consider for the next reauthorization of the ADUFA program. The meeting will be open to the public.

DATES: The public meeting will be hosted via a live virtual webcast on Thursday, May 20, 2021, from 2 p.m. to 4 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration dates and information. To permit the widest possible opportunity to obtain comments on all aspects of the public meeting, the docket will remain open for comment throughout the reauthorization process of ADUFA, until December 1, 2022. In addition to being publicly viewable at *http://www.regulations.gov,* comments received by June 21, 2021, suggesting changes to the program, will also be published on *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/adufa-meetings.*

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 December 1, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 1, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery