public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27428 Filed 12–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–D–0038]

Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry #152 entitled ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern.'' This draft guidance informs stakeholders about FDA's current method for evaluating potential microbiological effects of antimicrobial new animal drugs on bacteria of human health concern as part of the new animal drug application process.

DATES: Submit either electronic or written comments on the draft guidance by March 20, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–1998–D–0038 for ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ruby Singh, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0794, *ruby.singh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #152 entitled ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.'' Antimicrobial drugs have been used since the mid-20th century to control and cure infectious diseases in humans. Since their discovery, these drugs have prevented millions of human deaths worldwide, they have helped to promote animal health, and they have helped to provide an abundant and affordable supply of meat, milk, and eggs. Soon after antimicrobial drugs became widely available, scientists noted that their use could contribute to the emergence and selection of antimicrobial resistance in bacteria, thereby reducing the effectiveness of the

antimicrobial drugs. To address the human health risks surrounding the use of antimicrobial new animal drugs, in 2003, FDA issued Guidance for Industry (GFI) #152, entitled ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.''

GFI #152 outlines a qualitative risk assessment methodology as a process for evaluating foodborne antimicrobial resistance concerns related to the use of antimicrobial drugs in food-producing animals. GFI #152 also contains an appendix, commonly referred to as ''Appendix A,'' in which FDA ranks antimicrobial drugs according to their relative importance to human medicine: ''critically important,'' ''highly important,'' or ''important.''

The current list of medically important antimicrobial drugs in Appendix A reflects FDA's thinking at the time of publication, in 2003. It was envisioned at the time of publication of GFI #152 that the Agency would reassess the rankings provided in Appendix A periodically to confirm that the rankings are consistent with contemporary practices and needs. As noted in GFI #152, the development of new antimicrobial drugs for human therapy, the emergence or re-emergence of diseases in humans, and changes in prescribing practices, are some factors that may cause the human medical importance rankings to change over time.

Given the considerable advances in science that have taken place since 2003, new relevant information has become available. In light of those advances and the new information now available, FDA published a notice in the **Federal Register** of October 13, 2020 (85 FR 64481), 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.''

FDA received more than 60 comment submissions from pharmaceutical companies, academia, organizations, and private citizens on this concept paper. FDA has considered all comments and is issuing this draft guidance document, which contains revised sections in the risk assessment framework, including updated tables and figures, and a revised Appendix A based on new ranking criteria of antimicrobials according to their importance in human medicine.

This level 1 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 ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.'' 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 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27415 Filed 12–16–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0005]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 18, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sagal Musa, *sagal.musa@hhs.gov* or (202) 205–2634. When submitting comments or requesting information, please include the document identifier 4040–0005–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collections: Application for Federal Domestic Assistance—Individual.

Type of Collection: Renewal.

OMB No.: 4040–0005.

Abstract: The Application for Federal Assistance—Individual form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use Application for Federal Assistance—Individual form for grant programs not required to collect all the data that is required on the SF–424 core data set and form.

Type of respondent: The Application for Federal Assistance—Individual form is used by organizations to apply for Federal financial assistance in the form of grants. This form is submitted to the Federal grant-making agencies for evaluation and review. This IC expires on January 31, 2023. *Grants.gov* seeks a three-year clearance of these collections.