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; 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 hosting a virtual public meeting entitled "Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs." The purpose of the meeting is to obtain early input from the public 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. The Agency is seeking public input on a 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. A concept paper describing this potential revised process will be made available for discussion at the public meeting and can be obtained at the website listed in section II of this notice.

DATES: The public meeting will be held on November 16, 2020. Submit either electronic or written comments on this topic by January 15, 2021. Further information regarding the meeting, including the time the meeting will start, the agenda, and how to register to attend the meeting,

can be found at https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/fda-public-meeting-potential-approach-ranking-antimicrobial-drugs-according-their-importance-human. See the SUPPLEMENTARY INFORMATION section for registration dates and information.

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 January 15, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 15, 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 of 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," be 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.

Transcripts of the meeting will be available on the FDA website at: https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/fda-public-meeting-potential-approach-ranking-antimicrobial-drugs-according-their-importance-human approximately 30 days after the meeting.

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:

I. Background

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."[1] 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. One component of the risk assessment is the consequence assessment, which considers the medical importance of an antimicrobial drug or drug class used in human medicine.

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." In GFI #152, FDA recommends that sponsors of antimicrobial new animal drugs refer to Appendix A to initially assess the importance of the antimicrobial drug or drug class in question to human

[1] https://www.fda.gov/media/69949/download.

medicine and base their consequence assessment conclusion on this human medical importance ranking.

The current list of medically important antimicrobial drugs in Appendix A reflects FDA's thinking at the time of publication, in 2003.

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. 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.

Given the considerable advances in science that have taken place since 2003, new relevant information has become available. The purpose of the public meeting is to obtain early input on a potential revised process for ranking antimicrobial drugs according to their relative importance in human medicine, as well as potential criteria for their ranking.

II. Topics for Discussion at the Public Meeting

We will publish the public meeting agenda and related information, including a concept paper describing a potential revised ranking process, at https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/fda-public-meeting-potential-approach-ranking-antimicrobial-drugs-according-their-importance-human. We do not intend for this meeting to produce any decisions or new positions on specific regulatory questions. However, we expect this meeting to be an important step in our efforts to gather information and public feedback on a potential revised process for ranking antimicrobial

drugs according to their relative importance in human medicine, on the criteria for their ranking, and on a ranked list of antimicrobial drugs.

We are specifically interested in receiving public comments on the following questions:

1. Are the criteria and the tier-based framework described in the potential revised process for ranking antimicrobial drugs according to their relative human medical importance clear, complete, and consistent?
2. What changes do you think are needed to the criteria or tiers, if any?
3. Have the potential criteria been applied correctly to the antimicrobial classes as reflected in the resulting rankings?
4. Are there other issues we should consider regarding these criteria and the tier-based framework?
5. How often and by what process should FDA update the ranking of medically important antimicrobials?

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register no later than 11:59 p.m. Eastern Time on November 12, 2020, 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 Kelly Covington at kelly.covington@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 October 23, 2020.

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 October 27, 2020. Selected presenters planning to use an electronic slide deck must submit an electronic copy of their PowerPoint presentation to Kelly Covington (see FOR FURTHER INFORMATION CONTACT) with the subject line "Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs" on or before November 9, 2020. 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 or distributed at the public meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at https://www.regulations.gov. It may also be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the Agency's website at https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/fda-public-meeting-potential-approach-ranking-antimicrobial-drugs-according-their-importance-human.

Dated: October 7, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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