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; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final 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." This guidance document informs interested parties 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: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. 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: Ron Miller, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240-402-0795, ron.miller@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 2003, FDA issued 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." As stated in the guidance, the drug/drug class rankings provided in the Appendix are intended specifically to inform one component of the described qualitative risk assessment methodology, and they are not intended to be used as a standalone guide for antimicrobial use in veterinary practice or otherwise to serve as a standalone risk management tool.

The list, as published in 2003, of medically important antimicrobial drugs in Appendix A reflects FDA's thinking at the time of publication. 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 document 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. In the *Federal Register* of December 19, 2022 (87 FR 77619), FDA announced the availability of draft revised GFI #152 entitled "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern." Interested parties were originally given until March 20, 2023, to comment on the guidance. In the *Federal Register* of March 7, 2023 (88 FR 14170), FDA extended the comment period for the guidance to May 19, 2023.

FDA received over 9,200 comments on the draft guidance that appear to have been the result of 2 write-in campaigns. These campaigns asked FDA to "quit delaying efforts to stop the overuse of antibiotics in meat production," "stop allowing the meat industry to use antibiotics to counter unhealthy conditions in livestock facilities," "treat all drugs used in human medicine as medically important…," and said that "FDA must make a plan for updating [the list of medically important drugs in Appendix A] more frequently." With the exception of the comment that FDA should treat all drugs used in human medicine as medically important, these comments expressed broad policy views and did not address specific recommendations in the draft guidance.

Twenty-two comments outside of the write-in campaigns were submitted by animal pharmaceutical companies, food animal producers, veterinarians, consumer and public health interest groups, a State agriculture department, and other organizations and individuals. These comments offered feedback and suggestions addressing specific recommendations in the draft guidance.

FDA considered all comments as we finalized the guidance. In the final guidance, we made several changes, including: providing a more detailed description of hazard characterization; combining sections of the guidance discussing Application of Risk Management Strategies and Risk Management; clarifying why the ranking of medically important drugs in Appendix A should not be used alone to dictate risk management decisions, but instead be used to inform one component of the risk assessment process as described in the

guidance; and addressing why FDA excludes topicals in our ranking of medically important antimicrobials. In addition, we made editorial changes to improve clarity.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M-25-20, and finds this action to be neither regulatory nor deregulatory under this E.O.

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 514 have been approved under OMB control number 0910-0032.

III. Electronic Access

Persons with access to the internet may obtain the 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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