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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-2925]

Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals; Draft Guidance for Industry; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that published in the *Federal Register* of September 26, 2023. In that notice, FDA requested comments on the draft guidance for industry (GFI) #273 entitled "Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals." The Agency is taking this action in response to requests for an extension to allow interested persons additional time to develop and submit comments.

DATES: FDA is extending the comment period on the notice of availability published September 26, 2023 (88 FR 66009). Submit either electronic or written comments on the draft guidance by January 5, 2024, to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance.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-2023-D-2925 for "Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals." 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.

FOR FURTHER INFORMATION CONTACT: John Mussman, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0589, john.mussman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 26, 2023, FDA published a notice announcing the availability of a draft guidance for industry (GFI) #273 entitled "Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals." Interested persons were originally given until December 26, 2023, to comment on the draft guidance.

The Agency received requests for extension of the comment period for the draft guidance. After considering the requests, and the fact that the original comment period is scheduled to close on December 26, 2023, FDA has decided to extend the comment period for the draft guidance until January 5, 2024. The Agency believes that this extension allows adequate time for interested persons to submit comments to ensure that FDA can consider the comments before it begins work on the final version of the guidance.

Dated: November 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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