



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1197]

The Food and Drug Administration's Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals Using a Biomass Denominator; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability for public comment of a proposed method for applying a food animal biomass denominator to annual data on antimicrobials sold and distributed for use in food animals in the United States. This method will allow us to obtain a corrected estimate of antimicrobial drug sales relative to the animal population potentially being treated with those drugs, thereby lending further context to the antimicrobial sales data we are collecting and analyzing.

DATES: Submit either electronic or written comments on the proposed method by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2017-N-1197 for “FDA’s Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals Using a Biomass Denominator.” 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.

- 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.gpo.gov/fdsys/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.

Submit written requests for single copies of the proposed method to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Persons with access to the Internet may obtain the proposed method at either

<https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042896.htm> or in this docket at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5671, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Animal drug sponsors are required to report annually to FDA the amount of antimicrobials sold or distributed for use in food-producing animals and provide species-specific estimates of the percentage of their drug product sales for use in any of the four major food-producing species (cattle, swine, chickens, and turkeys) identified on the approved product label

(21 CFR 514.87(c)). FDA is announcing the availability of a proposed method for using a biomass denominator to adjust these sales data. The proposed method will provide estimates of annual antimicrobial drug sales adjusted for the size of the animal population (the animal biomass of each such species) potentially being treated with those drugs. The adjusted estimates will provide insight into broad shifts in the amount of antimicrobials sold for use in food-producing animals and give the Agency a more nuanced view of why sales increase or decrease over time in a manner that is specific to U.S. animal production. Such analysis will also support our ongoing efforts to encourage the judicious use of antimicrobials in food-producing animals to help ensure the continued availability of safe and effective antimicrobials for animals and humans.

Application of a biomass denominator to normalize antimicrobial sales data has been used internationally. In developing this proposal for applying a biomass denominator to antimicrobial sales data in the United States, FDA has considered methods being utilized and discussed in other countries. FDA's intent in publishing the proposed method is to initiate discussion with stakeholders on the biomass correction method FDA is considering, and to seek comment on the methodology and the utility of this type of data analysis.

Dated: August 10, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
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