4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA-2012-N-0447]

Antimicrobial Animal Drug Sales and Distribution Reporting; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry #252 entitled "Antimicrobial Animal Drug Sales and Distribution Reporting Small Entity Compliance Guide." The small entity compliance guide (SECG) is intended to help small entities comply with the final rule we issued in the *Federal Register* of May 11, 2016, entitled "Antimicrobial Animal Drug Sales and Distribution Reporting."

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-2012-N-0447 for "Antimicrobial Animal Drug Sales and Distribution Reporting; Small Entity Compliance Guide." 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.

- 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." We will review this copy, including the claimed confidential information, in our 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.

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 SECG to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the SECG.

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:

I. Background

Sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient are required by section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b), as amended by section 105 of the Animal Drug Use Fee Amendments of 2008 (ADUFA 105) (Pub. L. 110-316), to submit to us an annual report on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. We are also required by ADUFA 105 to publish annual summary reports of the data we receive from animal drug sponsors. In accordance with the law, sponsors of the affected antimicrobial new animal drug products began submitting their sales and distribution data to us on an annual basis, and we have published summaries of such data for each calendar year beginning with 2009.

In the *Federal Register* of May 11, 2016 (81 FR 29129), we published a final rule entitled "Antimicrobial Animal Drug Sales and Distribution Reporting" that amended our existing records and reports regulation in part 514 (21 CFR part 514) to incorporate the sales and distribution data reporting requirements specific to antimicrobial new animal drugs that were added to the FD&C Act by ADUFA 105. The rule also added an additional reporting provision intended to improve our understanding of antimicrobial animal drug sales intended for use in specific food-producing animal species. In accordance with the new rule, the sponsor of each approved or conditionally approved new animal drug product that contains an antimicrobial active ingredient must submit an annual report to us on the amount of each such ingredient in the drug product that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. The final rule, which is codified at §§ 514.80 and 514.87, became effective July 11, 2016.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule will not have a significant economic impact on a substantial number of small entities (81 FR 29129 at 29138). Nonetheless, we determined not to certify that finding due to the remote possibility that, in the future, a very small company could enter the market and sponsor an application for an antimicrobial new animal drug product that would be sold or distributed for use in food-producing animals. Thus, in compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28), we are making available this SECG to explain the actions that a potential future market entrant small entity must take to comply with the rule.

We are issuing this SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 514.87 have been approved under OMB control number 0910-0659. The collections of information in § 514.80 have been approved under OMB control number 0910-0284.

III. Electronic Access

Persons with access to the internet may obtain the SECG at either https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or https://www.regulations.gov.

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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