4160-01-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

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or Agency) is soliciting comments regarding potential changes to its regulations relating to records and reports for approved new animal drugs. FDA is considering revisions to this regulation to incorporate the requirements of section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 105). As part of that process, FDA is reviewing other reporting requirements applicable to antimicrobial new animal drug sponsors to determine whether additional information should be reported. Collecting data on antimicrobial drugs used in food-producing animals will assist FDA in tracking antimicrobial use trends and examining how such trends may relate to antimicrobial resistance.

DATES: Submit electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0447, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0447 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(l)) requires sponsors of approved or conditionally approved new animal drug applications to establish and maintain records and make such reports of data relating to experience with uses and other data or information received or obtained by the sponsor with respect to such animal drugs as required by regulation or order. FDA's regulation relating to records and reports for approved new animal drugs is found at 21 CFR 514.80. This regulation requires an animal drug sponsor to submit a number of different reports, including periodic drug experience reports, which must contain, among other things, drug distribution data showing the amount of the drug distributed domestically and the amount exported.

In 2008, ADUFA 105 directed the Agency to collect additional data and information about approved antimicrobial new animal drugs by amending section 512(l) of the FD&C Act to include new reporting requirements for sponsors of approved antimicrobial new animal drugs. Under section 512(l) of the FD&C Act, as amended by ADUFA 105, antimicrobial new animal drug sponsors must now also submit to FDA on an annual basis a report specifying the amount of each antimicrobial active ingredient in the sponsor's drug that is sold or distributed for use in food-producing animals. Specifically, sponsors are required to report the amount of each antimicrobial active ingredient as follows: (1) By container size, strength, and dosage form; (2) by quantities distributed domestically and quantities exported; and (3) for each dosage form, a listing of the target animals, indications, and production classes that are specified on the

approved label of the product. Currently, sponsors of antimicrobial drugs that are approved and labeled for multiple animal species, including both food-producing and nonfood-producing animals, do not report sales and distribution information for each individual animal species. Only total product sales information is reported. The information must be reported for the preceding calendar year, and include separate information for each month of the calendar year, and be submitted to FDA each year by no later than March 31. ADUFA 105 also requires FDA to publish an annual summary report of the antimicrobial drug sales and distribution data it receives.

The sales and distribution information that is currently being collected from antimicrobial new animal drug sponsors in accordance with ADUFA 105 is important in supporting efforts such as the National Antimicrobial Resistance Monitoring System (NARMS), a surveillance program that tracks trends related to antimicrobial resistance in food-producing animals and humans.

A recent Government Accountability Office (GAO) report addressing antibiotic resistance concluded that sales and distribution information as currently collected by FDA does not provide sufficient data needed to analyze trends in antimicrobial resistance, such as information on actual drug use in specific food-producing animal species (Ref. 1). Having improved data would enable the Agency to better correlate resistance data in NARMS with drug exposure, thereby providing improved information for science-based decisionmaking in the approval and monitoring of safe and effective antimicrobial drugs. In addition, such information would further enhance FDA's ongoing activities related to antimicrobial resistance and is consistent with the recommendations in guidance recently issued by this Agency addressing the judicious use of medically important antimicrobial drugs in food-producing animals (Ref. 2).

II. Agency Request for Comments

A. Sales and Distribution Data by Species

FDA is considering revisions to the requirements in this Agency's regulation at § 514.80 to incorporate the requirements of ADUFA 105 and, as part of that process, is reviewing other reporting requirements applicable to antimicrobial new animal drug sponsors to determine whether additional information should be reported. FDA is soliciting public comment on whether, consistent with its authority under section 512(l) of the FD&C Act to collect information relating to approved new animal drugs, it should amend its regulations to require the submission of additional sales and distribution information including, for antimicrobial animal drug products that are approved and labeled for more than one food-producing animal species, an estimate of the amount of each active antimicrobial ingredient sold or distributed for use in each approved food-producing animal species. Specifically, comments should address how sponsors can both practically and accurately provide separate sales and distribution information for each species.

B. FDA's Annual Summary Report

ADUFA 105 directs FDA to issue on an annual basis a summary report of the sales and distribution data collected from sponsors of antimicrobial new animal drugs and further provides that such data must be reported by antimicrobial class. ADUFA 105 also directs FDA to independently report only those antimicrobial drug classes with three or more distinct sponsors, so as to protect confidential business information. Within these statutory parameters, FDA is seeking public comment on how best to compile and present this summary information.

C. Alternative Methods for Obtaining Antimicrobial Use Data

FDA is seeking public comment on alternative methods available to the Agency for obtaining additional data and information about the extent of antimicrobial drug use in food-producing animals. Specifically, the Agency is requesting public input on alternative methods for assessing antimicrobial use the Agency can employ within its existing authority that may further support the analysis of factors related to the development and spread of antimicrobial resistance in connection with the use of medically important antibiotics in food-producing animals.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This advanced notice of proposed rulemaking is issued under section 512 of the FD&C Act (21 U.S.C. 360b) and under the authority of the Commissioner of Food and Drugs.

IV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. U.S. General Accounting Office, “Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals,” GAO-11-801, Washington, DC, General Accounting Office, 2011 (http://www.gao.gov/new.items/d11801.pdf).

2. Guidance for Industry #209, entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm).

Dated: June 29, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-18366 Filed 07/26/2012 at 8:45 am; Publication Date: 07/27/2012]