§ 1708.111 Sequestration of witnesses.
(a) Witnesses shall be sequestered during interviews, or during the taking of testimony, unless otherwise permitted by the Investigating Officer(s), or by the Board, as the case may be.
(b) No witness, or counsel accompanying any such witness, shall be permitted to be present during the examination of any other witness called in such proceeding, unless permitted by the Investigating Officer(s), or the Board, as the case may be.

§ 1708.112 Appearance and practice before the Board.
(a) Counsel appearing before the Board or the Investigating Officer(s) must conform to the standards of ethical conduct required of practitioners before the Courts of the United States.
(b) The Board may suspend and deny, temporarily or permanently, the privilege of appearing or practicing before the Board in any way to a person who is found:
1. To not possess the requisite qualifications to represent others;
or
2. To have engaged in unethical or improper professional conduct; or
3. To have engaged in obstructionism or contumacy; or
4. To be otherwise not qualified.
(c) Obstructionist or contumacious conduct in an investigation before the Board or the Investigating Officer(s) will be grounds for exclusion of any person from such safety investigation proceedings and for summary suspension for the duration of the course of the investigation.
(d) A witness may retain replacement counsel if original counsel is suspended or excluded.

§ 1708.113 Right to submit statements.
At any time during the course of an investigation, any person may submit documents, statements of facts, or memoranda of law for the purpose of explanation or further development of the facts and circumstances relevant to the safety matter under investigation.

§ 1708.114 Official transcripts.
(a) Official transcripts of testimony of witnesses, whether or not compelled by subpoena, to appear before a Board safety investigation, shall be recorded either by an official reporter, or by any other person or means designated by the Investigating Officer or the Board’s General Counsel.
(b) Such witness, after completing the completeness of testimony may file a request with the Board’s General Counsel to procure a copy of the official transcript of that witness’s testimony. The General Counsel shall rule on the request, and may deny for good cause.
(c) Good cause for denying a witness’s request to procure a transcript may include, but shall not be limited to, the protection of a trade secret, non-disclosure of confidential or proprietary business information, security sensitive operational or vulnerability information, safety privileged information, or the integrity of Board investigations.
(d) Whether or not a request is made, the witness and his or her attorney shall have the right to inspect the official transcript of the witness’s own testimony, in the presence of the Investigating Officer or his designee, for purposes of conducting an errata review.
(e) Transcripts of testimony are otherwise considered confidential and privileged safety information and in no case shall a copy or any reproduction of such transcript be released to any other person or entity, except as provided in paragraph (2) above or as required under the Freedom of Information Act or the Sunshine Act, or any procedures or requirements contained in Board regulations issued pursuant to those Acts.

§ 1708.115 Final report of safety investigation.
(a) The Board will complete a final report of the safety investigation fully setting forth the Board’s findings and conclusions.
(b) The final report of the safety investigation is confidential and protected by the safety privilege, and is therefore not releasable.
(c) The Board in its discretion may judge and take the necessary steps, in connection with the Board’s findings and conclusions, in order to conserve the public’s health and safety and the integrity of Board investigations.
(d) Nothing in this section or otherwise displaces the Board’s legal obligations with respect to compliance with the Freedom of Information Act, the Sunshine Act, any procedures or requirements contained in Board regulations issued pursuant to those Acts.

§ 1708.116 Procedure after safety investigations.
(a) If a formal safety investigation results in a finding that an event or practice has adversely affected, or may adversely affect, public health and safety, the Board may take any appropriate action authorized to it under its enabling statute, including, but not limited to, making a formal recommendation to the Secretary of Energy, convening a hearing, or establishing a reporting requirement.
(b) If a safety investigation yields information relating to violations of Federal criminal law involving Government officers and employees, the Board shall expeditiously refer the matter to the Department of Justice for disposition.
(c) If in the course of a safety investigation a safety issue or concern is found to be outside the Board’s jurisdiction, that safety issue or concern shall be referred to the appropriate entity with jurisdiction for disposition.
(d) Statements made in connection with testimony provided to the Board in an investigation are subject to the provisions of 18 U.S.C. 1001.

Dated: July 20, 2012.

Jesse H. Roberson,
Vice Chairman.

[FR Doc. 2012–18180 Filed 7–26–12; 8:45 am]

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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 September 25, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–0447, by any of the following methods:
data showing the amount of the drug experience reports, which must contain, reports for approved new animal drugs FDA’s regulation relating to records and sponsor with respect to such animal information received or obtained by the establish and maintain records and new animal drug applications to approved or conditionally approved Drug, and Cosmetic Act (the FD&C Act)) requires sponsors of antimicrobial new animal drugs and cosmetic act to include new reporting requirements for sponsors of approved antibi microbial new animal drugs. Under section 512(j) 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 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(j) 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.)


Dated: June 29, 2012.

Leslie Kux,
Assistant Commissioner for Policy.