prohibit that attorney from being present during testimony.

§ 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) Not to 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 compelled 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 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 Government in 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 sanitize the final report of the safety investigation by redacting confidential and safety privileged information so that the report is put in a publically releasable format.

(d) Nothing in this section voids or otherwise displaces the Board's legal obligations with respect to compliance with the Freedom of Information Act, the Government in the Sunshine Act, or any procedures or requirements contained in the Board's 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.

Jessie H. Roberson,

Vice Chairman.

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

BILLING CODE 3670–01–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 September 25, 2012.

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: Neal Bataller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9062, email: *Neal.Bataller@fda.hhs.gov*.

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 7–26–12; 8:45 am]

BILLING CODE 4160–01–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 201 and 210

[Docket No. 2012–7]

Mechanical and Digital Phonorecord Delivery Compulsory License

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Copyright Office of the Library of Congress is proposing to amend its regulations for reporting Monthly and Annual Statements of Account for the making and distribution of phonorecords under the compulsory license, 17 U.S.C. 115, to bring the regulations up to date to reflect recent and pending rate determinations by the Copyright Royalty Judges, which among other things provide new rates for limited downloads, interactive streaming and incidental digital phonorecord deliveries, and to harmonize these reporting requirements with the existing regulations for reporting the making and distribution of physical phonorecords, permanent downloads and ringtones.

DATES: Comments are due no later than September 25, 2012. Reply comments are due October 25, 2012.

ADDRESSES: The Copyright Office strongly prefers that comments be submitted electronically. A comment submission page is posted on the Copyright Office Web site at *http://www.copyright.gov/docs/section115/soa/comments/*. The Web site interface requires submitters to complete a form specifying name and other required information, and to upload comments as an attachment. To meet accessibility standards, all comments must be uploaded in a single file in either the Adobe Portable Document File (PDF) format that contains searchable, accessible text (not an image); Microsoft Word; WordPerfect; Rich Text Format (RTF); or ASCII text file format (not a scanned document). The maximum file size is 6 megabytes (MB). The name of the submitter and organization should appear on both the form and the face of the comments. All comments will be posted publicly on the Copyright Office Web site exactly as they are received, along with names and, if provided, organizations. If electronic submission of comments is not feasible, please contact the Copyright Office at (202) 707–XXXX for special instructions.

FOR FURTHER INFORMATION CONTACT: Tanya Sandros, Deputy General Counsel, or Stephen Ruwe, Attorney Advisor, Office of the General Counsel, PO Box 70400, Washington, DC 20024–0400 Telephone: (202) 707–1673. Telefax: (202) 252–3423.

SUPPLEMENTARY INFORMATION:

Background

Section 115 of the Copyright Act provides a compulsory license for reproducing and distributing phonorecords of a musical work. The mechanical license limits the exclusive rights granted to copyright owners by enabling anyone to make a phonorecord of an eligible musical work for the purpose of distributing it to the public for private use.

The mechanical license may be used once phonorecords of a nondramatic musical work have been distributed to the public in the United States under the authority of the copyright owner. In order to legally use the mechanical license, the licensee has to comply with the requirements in the statute and pay a royalty fee to the copyright owner. The mechanical license has its limitations; it is only available to make and distribute phonorecords of a musical work and it does not allow the licensee to reproduce and distribute another's sound recording, or change the ''basic melody or fundamental character of the work.'' 17 U.S.C. 115(a)(2).

The mechanical license was established in the 1909 Copyright Act as the first compulsory license in United States copyright law. Congress created the license because it wanted to make musical compositions available for public use, prevent monopoly, and at the same time ensure that compensation is provided to copyright owners. The first mechanical license was established in response to the 1908 Supreme Court holding in *White-Smith Music Publishing Co.* v. *Apollo Co.,* 209 U.S. 1 (1908). The Court decided that piano rolls were not considered 'copies' of a musical work because they did not contain a system of notation that could be read. Instead, the Court held they were merely mechanical reproductions made for the purpose of performing music. This decision prompted Congress to extend copyright protection to include the right to make mechanical devices which embody the musical work. H.R. Rep. No. 60–2222, at 9 (1909). However, Congress was concerned that extending the right of reproduction to include mechanical devices like piano rolls would enable a cartel of music publishers to exercise monopoly power over the recording of music to the possible detriment of the copyright owners of the musical work. To ensure a balance, Congress created