obtained through an audit of the market agencies' records. Such records are already being maintained as a normal business practice. This will include such records or documents that evidence payment of an assessment pursuant to the requirements in § 1280.225(b). In addition, market agencies must certify, as required by regulations prescribed by the Department, that the provisions of § 1280.217(b) have been met. This final rule includes these regulations.

Comments

On June 7, 2002, the Department published in the **Federal Register** (67 FR 39249) an interim final rule with request for comments. The comment period ended August 6, 2002.

The Department received 10 comments in a timely manner. In addition, five late comments were received. The late comments generally reflected the substance of comments timely received. Comments were received from producers, auction market operators, general farm and sheep organizations, and an association representing marketing agents. The changes suggested by the commenters are discussed below.

One commenter suggested that remitters should be allowed to remit the assessment and appropriate paperwork via the Internet. Currently, the Board does not have the ability to accept the transfer of funds or required forms via the Internet. The Board may choose to explore this option after an analysis of the current collection procedures. Accordingly, this suggestion is not adopted.

One commenter urged the Department to embark on an educational campaign aimed at the marketing agencies so there is a better understanding of what is required of them and to recommend procedures that can be used to meet those requirements. The Department agrees that a continuing educational program is warranted. Since the Board was seated in November 2002, Board representatives have attended annual meetings of several industry groups in order to better inform industry representatives about the program. Additionally, Board representatives have visited individual marketing agencies (*i.e.*, auction markets) to better educate them regarding their responsibilities for collecting the assessment, passing the assessment on to the subsequent buyer, and remitting the assessment to the Board. The Board has made these types of outreach activities a staple of their client communications program. Accordingly, no change is needed as a result of this comment.

Some commenters recommended that the Department suspend the program until the Board is in place to allow sale and auction markets time to become fully educated and compliant with the Federal checkoff procedures. An extensive educational and outreach program was conducted beginning at least 2 years before the implementation of the program with the creation of the Exploration Team. In addition, in July 2002, the Department distributed informational packets to nearly 1,000 auction markets explaining the program. Further, the Board has been in place since November 2002. Accordingly, this suggestion is not adopted.

One commenter suggested that auction markets should not be required to complete a Non-Producer Status Form (LS–78). Auction markets generally facilitate the transaction between the seller and buyer and, usually, do not take ownership of the lambs. Under the Lamb Checkoff Program, auction markets are not required to complete the form unless they are seeking non-producer status. The Non-Producer Status form is intended for those market agents that are subject to § 1280.217 of the Order. Form LS–78 is intended to be completed only by those persons who buy and resell lambs within 10 days from the date of purchase on which the market agency acquired ownership. If an auction market buys animals in the company's name (taking title to the lambs) and resells them within 10 days from the date of purchase, they would be required to complete the form.

The Department received several comments regarding issues that were previously subject to public comment in connection with implementation of the Order and not part of the rules and regulations that are the subject of this rulemaking. The following comments were received: two commenters suggested that those persons who remit a small amount of assessment should be afforded the opportunity to remit the assessment when the amount reaches a certain dollar amount or be allowed to remit less often than required by the interim final rule; several commenters recommended assessing animals on a per head basis; one commenter suggested that ewes should be exempt from the assessment; several commenters suggested that the assessments should be collected and remitted at each transaction similar to other commodity checkoff programs; one commenter suggested that the Board should include one or two representatives from an association or organization representing livestock markets that sell sheep; and one commenter suggested that auction markets remit the assessment directly to the Board.

On September 21, 2001, the proposed Order was published in the **Federal Register** with a request for public comment. The final Order was published and became effective on April 12, 2002. The interim final rule was published in the **Federal Register** on June 7, 2002, with a request for public comment. The comment period ended on August 6, 2002. The purpose of this final rule is to implement provisions of the Order provisions concerning the collection and remittance of assessments, procedures for obtaining a refund, reporting, and books and records. The aforementioned comments were not within the scope of this final rule and would require a change to the Order and further rulemaking. Accordingly, these suggestions are not adopted in this action.

Accordingly, after consideration of all comments, the interim final rule, as published in the **Federal Register** (67 FR 39249, June 7, 2002) is finalized without change.

List of Subjects in 7 CFR Part 1280

Administrative practice and procedure, Advertising, Consumer Information, Marketing agreements, Lamb and lamb products, Reporting and record keeping requirements.

PART 1280—LAMB PROMOTION, RESEARCH, AND INFORMATION

■ Accordingly, the interim final rule amending 7 CFR part 1280 which was published at 67 FR 39249 on June 7, 2002, is adopted as a final rule without change.

Dated: June 2, 2004

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 04–12786 Filed 6–4–04; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clindamycin Liquid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for an expanded dose range and revised indications for the use of clindamycin hydrochloride oral liquid in both dogs and cats for the treatment of certain bacterial diseases.

DATES: This rule is effective June 7, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed a supplement to ANADA 200–193 for Clindamycin Hydrochloride Oral Liquid. The supplemental ANADA provides for an expanded dose range and revised indications for the use of clindamycin hydrochloride oral liquid in both dogs and cats for the treatment of certain bacterial diseases. The supplemental application is approved as of April 21, 2004, and the regulations are amended in 21 CFR 520.447 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.447 is amended by revising paragraphs (b)(1) and (b)(2) to read as follows:

§ 520.447 Clindamycin liquid.

* * * * *

(b) * * *

(1) Nos. 000009 and 059130 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), (d)(2)(i)(A), and (d)(2)(ii)(A) of this section.

(2) No. 059079 for use as in paragraphs (d)(1)(i)(B), (d)(1)(ii)(B), (d)(2)(i)(B), and (d)(2)(ii)(B) of this section.

* * * * *

Dated: May 19, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–12718 Filed 6–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin and Clorsulon Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for an increased period of protection from reinfection with three species of internal parasites following administration of an ivermectin and clorsulon injectable solution to cattle.

DATES: This rule is effective June 7, 2004.

FOR FURTHER INFORMATION CONTACT: Janis Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: *janis.messenheimer@fda.gov*.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed a supplement to NADA 140–833 for IVOMEC Plus (ivermectin and clorsulon) Injection for cattle. The application extends the period of persistent effectiveness for *Oesophagostomum radiatum* to 28 days after treatment, and for *Cooperia punctata* and *Trichostrongylus axei* to 21 days after treatment. A veal calf warning statement is being added because residue depletion data for this class of cattle has not been submitted to the application. The supplemental NADA is approved as of April 21, 2004, and 21 CFR 522.1193 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning April 21, 2004. Exclusivity applies only to the extension of the persistent effectiveness claims for the three species of parasites listed previously in this document.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows: