animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Phibro Animal Health. The supplemental NADA provides for label revisions associated with a previous change of sponsorship and other minor changes for amprolium concentrate solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis. The product approval is being codified for the first time.

DATES: This rule is effective August 6, 2008.

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660, filed a supplement to NADA 13–663 that provides for the use of COCCIPROL (amprolium) 9.6% Oral Solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis. The supplemental NADA provides for label revisions associated with a previous change of sponsorship and other minor changes. The supplemental NADA is approved as of July 8, 2008, and the regulations are amended in 21 CFR 520.100 to reflect the approval. The product approval is being codified for the first time. Also, § 520.100 is revised to reflect current pathogen spelling.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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 Subject 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. In § 520.100, revise paragraph (b), remove paragraph (d), redesignate paragraph (e) as paragraph (d), and revise new paragraphs (d)(2)(i)(A) and (d)(2)(i)(B) to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) *Sponsors.* See sponsors in 510.600(c) of this chapter.

(1) No. 016592 for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(2) Nos. 051311 and 066104 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(3) No. 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(2) of this section.

* * * * *

(d) * * *

(2) * * *

(i) * * * (A) As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*, administer 5 mg per kilogram (mg/kg) body weight for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard.

(B) As an aid in the treatment of coccidiosis caused by *E. bovis* and *E. zurnii*, administer 10 mg/kg body weight for 5 days.

* * * * *

Dated: July 28, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–18093 Filed 8–5–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2008–N–0039]

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Hydrochloride

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 new animal drug application (NADA) filed by Pharmacia and Upjohn Co., a Division of Pfizer, Inc. The NADA provides for the veterinary prescription use of a ceftiofur hydrochloride injectable suspension for treatment of various bacterial infections in swine and cattle.

DATES: This rule is effective August 6, 2008.

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–288 that provides for veterinary prescription use of EXCENEL RTU EZ (ceftiofur hydrochloride) Sterile Suspension, used for treatment of various bacterial infections in swine and cattle. The NADA is approved as of July 1, 2008, and the regulations are amended in 21 CFR 522.313b to reflect the approval. A swine pathogen is also being revised to reflect current scientific nomenclature.

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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under § 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 Subject 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:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. In § 522.313b, revise paragraphs (a), (e)(1)(ii), and (e)(2)(i) to read as follows:

§ 522.313b Ceftiofur hydrochloride.

(a) *Specifications.* Each milliliter of ceftiofur hydrochloride suspension contains 50 milligrams (mg) ceftiofur equivalents in either a peanut oil or caprylic/capric triglyceride suspension.

* * * * *

(e) *Conditions of use*—

(1) * * *

(ii) *Indications for use.* For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella* Choleraesuis, and *Streptococcus suis*.

* * * * *

(2) * * *

(i) *Amount.* For bovine respiratory disease and acute bovine interdigital necrobacillosis, administer 1.1 to 2.2 mg/kg of body weight at 24-hour intervals for 3 to 5 consecutive days. For bovine respiratory disease only, 2.2 mg/kg of body weight may be administered twice at a 48-hour interval. For acute metritis only, administer 2.2 mg/kg of body weight at 24-hour intervals for 5 consecutive days. Product in peanut oil suspension may be administered by either intramuscular or subcutaneous injection. Product in caprylic/capric triglyceride suspension may be administered by subcutaneous injection only.

* * * * *

Dated: July 28, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–18094 Filed 8–5–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9415]

RIN 1545–BB84

REMIC Residual Interests—Accounting for REMIC Net Income (Including Any Excess Inclusions) (Foreign Holders)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 9415), that were published in the **Federal Register** on Monday, July 14, 2008 (73 FR 40171). The final regulations relates to income that is associated with a residual interest in a Real Estate Mortgage Investment Conduit (REMIC) and that is allocated through certain entities to foreign persons who have invested in those entities.

DATES: This correction is effective on August 6, 2008.

FOR FURTHER INFORMATION CONTACT: Arturo Estrada, (202) 622–3900 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9415) that is the subject of this correction is under section 1441 of the Internal Revenue Code.

Need for Correction

As published, TD 9415 contains an error that may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.1441–2 is amended by revising paragraph (f) to read as follows:

§ 1.1441–2 Amounts subject to withholding.

* * * * *

(f) *Effective/applicability date.* This section applies to payments made after December 31, 2000. Paragraphs (b)(5) and (d)(4) of this section apply to payments made after August 1, 2006.

Cynthia E. Grigsby,

Senior Federal Register Liaison Officer, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. E8–17954 Filed 8–5–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2008–0763]

RIN 1625–AA00

Special Local Regulation; Chris Craft Silver Cup Regatta, St. Clair River, Algonac, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for an area on the St. Clair River, Algonac, Michigan. This temporary special local regulation is intended to restrict vessels from a portion of the St. Clair River during the Chris Craft Silver Cup Regatta. This temporary special local regulation is necessary to protect spectators and vessels from the hazards associated with boat race operations.

DATES: This rule is effective from 9 a.m. on August 8, 2008 until 8 p.m. on August 10, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0763 and are available online at *http://www.regulations.gov*.

They are also available for inspection or copying at two locations: The Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and at U.S. Coast Guard Sector Detroit, 110 Mt. Elliot Ave., Detroit, MI 48207 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call CDR Joseph Snowden, Prevention, U.S. Coast Guard Sector