final Commerce's regulations governing the offset of Commerce-issued payments to collect debts owed to other Federal agencies.

DATES: This rule is effective October 9, 2007.

FOR FURTHER INFORMATION CONTACT: Lisa Casias, Deputy Chief Financial Officer and Director for Financial Management, Office of Financial Management, at (202) 482–1207, Department of Commerce, 1401 Constitution Avenue, NW., Room 6827, Washington, DC 20230. This document is available for downloading from the Department of Commerce, Office of Financial Management's Web site at the following address: *http://osec.doc.gov/ofm/OFM%20Publications.htm.*

SUPPLEMENTARY INFORMATION:

Background

This rule revises and replaces Department of Commerce debt collection regulations found at 15 CFR Parts 19, 21 and 22 to conform to the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104–134, 110 Stat. 1321, 1358 (Apr. 26, 1996), the revised Federal Claims Collection Standards, 31 CFR Chapter IX (Parts 900 through 904), and other laws applicable to the collection of non-tax debt owed to the Government. The Department of Commerce made additions and revisions to 15 CFR Part 19, and deleted 15 CFR Parts 21 and 22 to consolidate and streamline the debt collection regulations.

This regulation provides procedures for the collection of non-tax debts owed to Commerce Department entities. Commerce adopts the Government-wide debt collection standards promulgated by the Departments of the Treasury and Justice, known as the Federal Claims Collection Standards (FCCS), as revised on November 22, 2000 (65 FR 70390), and supplements the FCCS by prescribing procedures consistent with the FCCS, as necessary and appropriate for Commerce operations. This regulation also provides the procedures for the collection of debts owed to other Federal agencies when a request for offset is received by Commerce.

This regulation does not contain a section regarding the delegation of debt collection authority within the Commerce Department. The delegation is contained in the Department of Commerce Credit and Debt Management Operating Procedures Handbook (currently available at *http://www.osec.doc.gov/ofm/credit/cover.htm*), and does not need to be included in the regulation.

Nothing in this regulation precludes the use of collection remedies not contained in this regulation. For example, Commerce entities may collect unused travel advances through offset of an employee's pay under 5 U.S.C. 5705. Commerce entities and other Federal agencies may simultaneously use multiple collection remedies to collect a debt, except as prohibited by law.

Commerce entities may, but are not required to, promulgate additional policies and procedures consistent with this regulation, the FCCS, and other applicable Federal laws, policies, and procedures, subject to the approval of the Deputy Chief Financial Officer.

Section Analysis

The Department of Commerce published the Interim final rule with request for comments on April 16, 2007 at 72 FR 18869. No comments were received. For section analysis of this final rule, see 72 FR 18869 on April 16, 2007.

Regulatory Analysis

E.O. 12866, Regulatory Review

This rule is not a significant regulatory action as defined in Executive Order 12866.

Regulatory Flexibility Act

Because notice of proposed rulemaking and opportunity for comment are not required pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility act (5 U.S.C. 601, *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

List of Subjects in 15 CFR Part 19

Administrative practice and procedure, Claims, Debts, Garnishment of wages, Government employee, Hearing and appeal procedures, Pay administration, Salaries, Wages.

Authority and Issuance

■ Accordingly, the interim final rule amending 15 CFR part 19 and removing 15 CFR parts 21 and 22 which was published at 72 FR 18869 on April 16, 2007, is adopted as a final rule without change.

Dated: October 1, 2007.

Lisa Casias,

Deputy Chief Financial Officer and Director for Financial Management, Department of Commerce.

[FR Doc. E7–19755 Filed 10–5–07; 8:45 am]

BILLING CODE 3510–FA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 516 and 556

New Animal Drugs; Florfenicol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect conditional approval of an application for conditional approval of a new animal drug intended for a minor species filed by Schering-Plough Animal Health Corp. The application seeks conditional approval of the use of florfenicol by veterinary feed directive for the control of mortality in catfish due to columnaris disease associated with *Flavobacterium columnare*.

DATES: This rule is effective October 9, 2007.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed an application for conditional approval (141–259) that provides for the use of AQUAFLOR-CA1 (florfenicol), a Type A medicated article, by veterinary feed directive to formulate Type C medicated feed for the control of mortality in catfish due to columnaris disease associated with *Flavobacterium columnare*. In accordance with the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act), this drug is conditionally approved as of April 13, 2007, and the regulations are amended by adding 21 CFR 516.1215 and by revising 21 CFR 556.283 to reflect the conditional approval of this application. The effect of this final rule is delayed until October 9, 2007, pending establishment of part 516 (72 FR 41010, July 26, 2007).

In accordance with the freedom of information provisions of 21 CFR part 20, a summary of safety and effectiveness data and information submitted to support conditional approval of this application for conditional approval 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.

AQUAFLOR-CA1 in the dosage form and for the intended uses conditionally approved by FDA under application number 141–259 qualifies for 7 years of exclusive marketing rights beginning on the date of approval. This new animal drug qualifies for exclusive marketing rights under section 573(c) of the act (21 U.S.C. 360ccc-2(c)) because it has been declared a designated new animal drug by FDA under section 573(a) of the act.

FDA has determined under 21 CFR 25.33(d)(4) 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

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 556

Animal drugs, Foods.

■ 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 parts 516 and 556 are amended as follows:

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 1. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–2, 371.

■ 2. Add subpart E to read as follows:

Subpart E—Conditionally Approved New Animal Drugs For Minor Use and Minor Species

§ 516.1215 Florfenicol.

(a) *Specifications.* Type A medicated article containing 500 grams (g) florfenicol per kilogram.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations.* Labeling shall bear the following: ''Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141–259. Extra-label use of this drug in or on animal feed is strictly prohibited.''

(d) *Related tolerances.* See § 556.283 of this chapter.

(e) *Conditions of use*—(1) *Catfish*—(i) *Amount.* Feed 182 to 1816 g florfenicol per ton of feed as a sole ration for 10 consecutive days to deliver 10 milligrams florfenicol per kilogram of fish.

(ii) *Indications for use.* For the control of mortality due to columnaris disease associated with *Flavobacterium columnare.*

(iii) *Limitations.* Feed containing florfenicol shall not be fed to catfish for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 12 days prior to slaughter. Federal law limits this drug to use under the professional supervision of a licensed veterinarian. The expiration date of veterinary feed directives (VFDs) for florfenicol must not exceed 15 days from the date of prescribing. VFDs for florfenicol shall not be refilled. See § 558.6 of this chapter for additional requirements.

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 4. In § 556.283, revise paragraph (c) to read as follows:

§ 556.283 Florfenicol.

* * * * *

(c) *Related conditions of use.* See §§ 516.1215, 520.955, 522.955, and 558.261 of this chapter.

Dated: September 27, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–19853 Filed 10–5–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP MIAMI 07–142]

RIN 1625–AA00

Safety Zone; Monthly Biscayne Bay Yacht Racing Association Cruising Races, Biscayne Bay, Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Monthly Biscayne Bay Yacht Racing Association (BBYRA) Cruising Races, which will temporarily limit the movement of non-participant vessels in Biscayne Bay near Miami, FL. This temporary safety zone is intended to restrict vessels from entering the waters where the event will be held unless specifically authorized by the Captain of the Port, Miami, Florida or his designated representative. This regulation is needed to protect the safety of participants, marine spectators and recreational and professional mariner traffic.

DATES: This rule is effective from 11 a.m. until 4 p.m. each day on Saturday, September 8, 2007 and Sunday, October 14, 2007.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket are part of docket COTP MIAMI 07–142 and are available for inspection or copying at Sector Miami, 100 MacArthur Causeway, Miami Beach, Fl 33139 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: MSTCS R. Johnson, Coast Guard Sector Miami, Florida, at (305) 535–4317.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Notice of these events was not provided to the Coast Guard with sufficient time to publish an NPRM and receive public comment before the event dates. This temporary rule is necessary to ensure the safety of participants, spectators, and the general public from the hazards associated with a boat race.

For the same reasons, the Coast Guard also finds, under 5 U.S.C. (d)(3), that