19 CFR Part 163

Administrative practice and procedure, Customs duties and inspection, Exports, Imports, Reporting and recordkeeping requirements, Trade agreements.

19 CFR Part 178

Administrative practice and procedure, Exports, Imports, Reporting and recordkeeping requirements.

Amendments to the CBP Regulations

■ Accordingly, the interim rule amending Parts 10, 163, and 178 of the CBP regulations (19 CFR parts 10, 163, and 178), which was published at 72 FR 35154 on June 27, 2007, is adopted as a final rule without change.

W. Ralph Basham,

Commissioner, U.S. Customs and Border Protection.

Approved: March 25, 2008.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. E8–6511 Filed 3–28–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Penicillin G Benzathine and Penicillin G Procaine Suspension

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 IVX Animal Health, Inc. The supplemental NADA provides for changing scientific nomenclature for a bovine pathogen on labeling for penicillin G benzathine and penicillin G procaine injectable suspension.

DATES: This rule is effective March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to NADA 65–498 for PEN BP–48 (penicillin G benzathine and penicillin G procaine) injectable suspension used for the treatment of animal diseases associated with several bacterial pathogens. The supplemental NADA provides for changing a bovine pathogen name from *Corynebacterium pyogenes* to *Actinomyces pyogenes* on product labeling. The supplemental NADA is approved as of February 22, 2008, and the regulations in 21 CFR 522.1696a are amended to reflect the approval.

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 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:

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.

§ 522.1696a [Amended]

■ 2. In § 522.1696a, in paragraph (d)(2)(ii)(A), remove ''*Corynebacterium pyogenes*'' and ''(*C. pyogenes*)'' and in their places add ''*Actinomyces pyogenes*'' and ''(*A. pyogenes*)''.

Dated: March 21, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–6603 Filed 3–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feed; Zilpaterol

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 Intervet Inc. The NADA provides for use of approved, single-ingredient Type A medicated articles containing zilpaterol hydrochloride and melengestrol acetate in two-way combination Type B and Type C medicated feeds for heifers fed in confinement for slaughter.

DATES: This rule is effective March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Gerald L. Rushin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8103, e-mail: *gerald.rushin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Intervet Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed NADA 141–284 that provides for use of ZILMAX (zilpaterol hydrochloride) and MGA (melengestrol acetate) Type A medicated articles to make dry and liquid two-way combination Type B and Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and for suppression of estrus (heat) in heifers fed in confinement for slaughter during the last 20 to 40 days on feed. The NADA is approved as of February 29, 2008, and the regulations in 21 CFR 558.665 are amended to reflect the approval.

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)(2) 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 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 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

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

■ 2. In § 558.665, add paragraph (e)(2) to read as follows:

§ 558.665 Zilpaterol.

* * * * *

(e) * * *

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* *	*	*	* *	*
(2) 6.8 to provide 60 to 90 mg/ head/day	Melengestrol acetate to provide 0.25 to 0.5 mg/ head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(1) of this section; and for suppression of estrus (heat).	As in paragraph (e)(1) of this section; see paragraph §§ 558.342(d) of this chapter. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.	057926
* *	*	*	* *	*

Dated: March 21, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–6601 Filed 3–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 41

[T.D. TTB–68; Re: T.D. ATF–444 and Notice No. 912]

RIN 1513–AB38

Puerto Rican Tobacco Products and Cigarette Papers and Tubes Shipped From Puerto Rico to the United States (2007R–368P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule (Treasury decision).

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is adopting as a final rule, with some clarifying changes and editorial corrections, the temporary regulations set forth in T.D. ATF–444. These temporary regulations eliminated the onsite preshipment inspection of, and the requirement to complete several ATF forms for, shipments to the United States of tobacco products and cigarette papers and tubes manufactured in Puerto Rico.

DATES: *Effective Date:* March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Amy R. Greenberg, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200E, Washington, DC 20220; telephone 202–927–8210; or e-mail *Amy.Greenberg@ttb.gov*.

SUPPLEMENTARY INFORMATION:

Background

Chapter 52 of the Internal Revenue Code of 1986 (IRC) pertains to the Federal excise tax on tobacco products and cigarette papers and tubes. Section 5701 of the IRC (26 U.S.C. 5701) imposes a tax on such products manufactured in, or imported into, the United States. Section 7652(a) of the IRC (26 U.S.C. 7652(a)) imposes the same tax, with certain exceptions not pertinent here, on articles of merchandise of Puerto Rican manufacture coming into the United States and withdrawn for consumption or sale. The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for administering the provisions of chapter 52 and section 7652(a) of the IRC as they pertain to the tax on tobacco products and cigarette papers and tubes, including promulgating regulations concerning payment and collection of the tax and other requirements that protect the revenue. Prior to January 24, 2003, our predecessor agency, the Bureau of Alcohol, Tobacco and Firearms (ATF) administered these regulations.

On March 8, 2001, ATF published in the **Federal Register** (66 FR 13849) a temporary rule, T.D. ATF–444, amending the regulations in 27 CFR part 275 to eliminate certain regulatory requirements related to the shipment of tobacco products and cigarette papers and tubes of Puerto Rican manufacture from Puerto Rico to the United States. Specifically, ATF amended §§ 275.105, 275.106, 275.110, and 275.111 to eliminate the requirement that persons who ship tobacco products and cigarette papers and tubes of Puerto Rican manufacture from Puerto Rico to the United States notify ATF prior to the shipment, and to eliminate the requirements that an ATF officer: (1) Inspect each shipment of such articles; (2) certify that the amount of tax on the articles has been calculated correctly; and (3) release each shipment. The amended regulations set forth recordkeeping requirements in place of the former processes of notification, physical inspection, certification, and release. Under the temporary rule, persons who ship Puerto Rican tobacco products and cigarette papers and tubes to the United States must keep and maintain records to show that the amount of tax is correctly calculated, paid (where applicable), and recorded for audit and examination purposes.

The temporary rule amendments to §§ 275.106, 275.110, and 275.111 also eliminated the requirements for the completion of four specific forms. Two forms, ATF forms 2987 (5210.8) and 3075 (5200.9), were required to be submitted to ATF by the company shipping the products to the United States, and contained information readily available from common commercial records. The elimination of these forms was intended to relieve the taxpayer of a duplicative recordkeeping requirement. The other two forms, ATF forms 2989 and 3074 (5200.6), were certificates which were prepared by ATF officers and affixed to the outside