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,