PART 141—ENTRY OF MERCHANDISE

1. The general authority citation for part 141 and the specific authority citation for subpart G continue to read, and a new specific authority citation for § 141.102(e) is added in appropriate numerical order to read, as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624; 46 U.S.C. App. 3, 91.

* * * * *

Subpart G also issued under 19 U.S.C. 1505;

* * * * *

Section 141.102(e) also issued under 19 U.S.C. 3;

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2. Section 141.102 is amended by adding a new paragraph (e) to read as follows:

§ 141.102 When deposit of estimated duties, estimated taxes, or both not required.

* * * * *

(e) *Merchandise otherwise duty-free under Andean Trade Preference Act (ATPA).* For merchandise entered or withdrawn from warehouse for consumption in the customs territory of the United States on or after February 15, 2002, an importer of eligible articles that, but for the expiration of the Andean Trade Preference Act (ATPA), would have been entitled to duty-free treatment under the ATPA, may, at the importer's option, defer the payment of estimated Customs duties and fees on the entry of those articles until May 16, 2002. Merchandise eligible for duty-free treatment under the ATPA is identified in General Note 11, Harmonized Tariff Schedule of the United States (HTSUS), and in the relevant ''Special'' rate of duty column in the HTSUS. The procedure for obtaining duty-free treatment for merchandise otherwise eligible for such treatment under the ATPA is contained in § 10.207 of this chapter. If the option is taken to deposit the estimated duties and fees more than 10 days from the date of entry, the entry and entry summary will not be accepted by Customs electronically.

Robert C. Bonner,

Commissioner of Customs.

Approved: February 13, 2002.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 02–4009 Filed 2–13–02; 4:46 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Albuterol

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 Boehringer Ingelheim Vetmedica, Inc. The NADA provides for use of an intranasal aerosol of albuterol sulfate for relief of bronchospasm and bronchoconstriction in horses.

DATES: This rule is effective February 15 2002.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002, filed NADA 141–180 that provides for use of TORPEX (albuterol sulfate) Aerosol for the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses. The NADA is approved as of November 16, 2001, and the regulations are amended in 21 CFR part 529 by adding § 529.40 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 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 Dockets Management Branch (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)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning November 16, 2001, because no active ingredient (including any ester or salt of the drug) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(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 529

Animal drugs.

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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

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

2. Section 529.40 is added to read as follows:

§ 529.40 Albuterol.

(a) *Specifications.* A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals.* See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Amount.* Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use.* For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) *Limitations.* Not for use in horses intended for food.

Dated: February 4, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–3738 Filed 2–14–02; 8:45 am]

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