

have in support of a claim for preferential tariff treatment under the United States-Korea Free Trade Agreement (UKFTA), including a UKFTA importer's certification.

■ 10. The appendix to part 163 is amended by adding a new listing under section IV in numerical order to read as follows:

Appendix to Part 163—Interim (a)(1)(A) List

* * * * *
IV. * * *

§ 10.1005 UKFTA records that the importer may have in support of a UKFTA claim for preferential tariff treatment, including an importer's certification.

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PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

■ 11. The authority citation for part 178 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 et seq.

■ 12. Section 178.2 is amended by adding new listings for “§§ 10.1003 and 10.1004” to the table in numerical order to read as follows:

§ 178.2 Listing of OMB control numbers.

Table with 3 columns: 19 CFR Section, Description, OMB Control No. Row 1: §§ 10.1003 and 10.1004, Claim for preferential tariff treatment under the US-Korea Free Trade Agreement, 1651-0117

David V. Aguilar, Acting Commissioner, U.S. Customs and Border Protection. Approved: March 14, 2012. Timothy E. Skud, Deputy Assistant Secretary of the Treasury. [FR Doc. 2012-6554 Filed 3-15-12; 8:45 am] BILLING CODE 9111-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2011-N-0003]

Oral Dosage Form New Animal Drugs; Pergolide

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 an original new animal drug application (NADA) filed by Boehringer Ingelheim Vetmedica, Inc. The NADA provides for the veterinary prescription use of pergolide mesylate tablets in horses for the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease).

DATES: This rule is effective March 19, 2012.

FOR FURTHER INFORMATION CONTACT: Amy L. Omer, Center for Veterinary Medicine (HFV-114), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8336, email: amy.omer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002, filed NADA 141-331 for the veterinary prescription use in horses of PRASCEND (pergolide mesylate) Tablets for the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease). The NADA is approved as of September 7, 2011, and 21 CFR part 520 is 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 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 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. Add § 520.1705 to read as follows:

§ 520.1705 Pergolide.

(a) Specifications. Each tablet contains 1 milligram (mg) pergolide mesylate.

(b) Sponsor. See No. 000010 in § 510.600(c) of this chapter.

(c) Conditions of use in horses—(1) Amount. Administer orally at a starting dose of 2 micrograms/kilograms (µ/kg) once daily. Dosage may be adjusted to effect, not to exceed 4 µg/kg daily.

(2) Indications for use. For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease).

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: March 14, 2012.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
[FR Doc. 2012-6544 Filed 3-16-12; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2011-N-0003]

Oral Dosage Form New Animal Drugs; Phenylpropanolamine

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 an original new animal drug application (NADA) filed by Pegasus Laboratories, Inc. The NADA provides for the veterinary prescription use of phenylpropanolamine hydrochloride chewable tablets for the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

DATES: This rule is effective March 19, 2012.

FOR FURTHER INFORMATION CONTACT: Lisa M. Troutman, Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8322, email: lisa.troutman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514, filed NADA 141-324 that provides for the veterinary prescription use of PROIN (phenylpropanolamine hydrochloride) Chewable Tablets for the control of urinary incontinence due to urethral sphincter hypotonus in dogs. The NADA is approved as of August 4, 2011, and the regulations are amended in 21 CFR part 520 to reflect the approval.

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 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

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 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. Add § 520.1760 to read as follows:

§ 520.1760 Phenylpropanolamine.

(a) *Specifications.* Each chewable tablet contains 25, 50, or 75 milligram (mg) phenylpropanolamine hydrochloride.

(b) *Sponsors.* See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer 2 mg/kg of body weight twice daily.

(2) *Indications for use.* For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

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

Dated: March 14, 2012.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2012-N-0222]

Revision of Organization and Conforming Changes to Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to amend the regulations to reflect organizational change in the Agency and to make other conforming changes. This action is editorial in nature and is intended to improve the accuracy of the Agency’s regulations.

DATES: This rule is effective April 1, 2012.

FOR FURTHER INFORMATION CONTACT: Vanessa Starks, Human Capital Management, Food and Drug Administration, 19903 New Hampshire Ave., Silver Spring, MD 20903, 301-796-8846.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this final rule to amend its regulations by updating the organizational information in part 5 (21 CFR part 5).

The portion of this final rule updating the organizational information in part 5, subpart M is a rule of Agency organization, procedure, or practice. FDA is issuing these provisions as a final rule without publishing a general notice of proposed rulemaking because such notice is not required for rules of Agency organization, procedure, or practice under 5 U.S.C. 553(b)(3)(A). For the conforming changes to the other regulations, the Agency finds good cause under 5 U.S.C. 553(b)(3)(B) to dispense with prior notice and comment, and good cause under 5 U.S.C. 553(d)(3) to make these conforming changes effective less than 30 days after publication because such notice and comment and delayed effective date are unnecessary and contrary to the public interest. These conforming changes merely update the footnotes in part 5, subpart M. These changes do not result in any substantive change in the regulations.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is