

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 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](mailto: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