

earlier CPSC application included a reference to one of the required test methods. Previously CPSC-accepted third party conformity assessment bodies for 16 CFR part 1303 (including those that had one of the specified test methods in their accreditation scope document that was supplied with their earlier CPSC application) must reapply to maintain CPSC acceptance because the CPSC did not record references to test methods. If accepted, the third party conformity assessment body will remain on the list of accepted third party conformity bodies whose accreditations the CPSC has accepted for 16 CFR part 1303.

#### **IV. Acceptance of Children's Product Certifications Based on Third Party Conformity Assessment Body Testing to 16 CFR Part 1303**

The September 22, 2008 **Federal Register** Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with Part 1303 of Title 16, Code of Federal Regulations established that each manufacturer (including the importer) or private labeler of children's products subject to the lead paint ban must have products that are manufactured after December 21, 2008 tested by a laboratory accredited (by the CPSC) and must issue a certificate of compliance with the lead paint ban based upon that testing.

This amended notice of requirements published today addresses only the CPSC acceptance criteria for a third party conformity assessment body for testing to the lead paint ban at 16 CFR part 1303. This amended notice does not affect the already-established criteria for CPSC acceptance of certificates of compliance. A product manufacturer's certificate of compliance to 16 CFR part 1303 must be based on testing by a third party conformity assessment body that is posted on the CPSC Web site as accepted for 16 CFR part 1303 at the time the product is tested. The Commission will accept a certificate of compliance with 16 CFR part 1303, Ban of Lead-Containing Paint for a children's product based on testing performed by an accredited (CPSC-accepted) third party conformity assessment body (including a government-owned or government-controlled conformity assessment body, or a firewalled conformity assessment body) if the testing was conducted on a date for which the third party conformity assessment body was listed as accepted by the CPSC for testing to the lead paint ban at 16 CFR part 1303.

Dated: March 30, 2011.

**Todd A. Stevenson,**  
*Secretary, Consumer Product Safety Commission.*

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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; Robenacoxib**

**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 Novartis Animal Health US, Inc. The NADA provides for the veterinary prescription use of robenacoxib tablets in cats for the control of postoperative pain and inflammation.

**DATES:** This rule is effective April 5, 2011.

#### **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, e-mail: amy.omer@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141-320 that provides for the veterinary prescription use of ONSIOR (robenacoxib) Tablets in cats for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration. The NADA is approved as of March 8, 2011, and the regulations are amended in 21 CFR part 520 by adding § 520.2075 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 § 520.2075 to read as follows:

#### **§ 520.2075 Robenacoxib.**

(a) *Specifications.* Each tablet contains 6 milligrams (mg) robenacoxib.

(b) *Sponsors.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats—(1) Amount.* Administer 0.45 mg per pound (/lb) (1 mg/kilogram (kg)) once daily.

(2) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats weighing at least 5.5 lb (2.5 kg) and at least 6 months of age; for up to a maximum of 3 days.

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

Dated: March 31, 2011.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

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