

employing the workers represented in the petition and the locations of their establishments in which the domestic article is produced;

(2) The percentage of domestic production of the like or directly competitive domestic article that such represented firms and/or workers account for and the basis for claiming that such firms and/or workers are representative of an industry; and

(3) The names and locations of all other producers of the domestic article known to the petitioner;

(c) *Import data.* Import data for at least each of the most recent 5 full years that form the basis of the claim that the article concerned is being imported in increased quantities in absolute terms;

(d) *Domestic production data.* Data on total U.S. production of the domestic article for each full year for which data are provided pursuant to paragraph (c) of this section;

(e) *Data showing injury.* Quantitative data for each of the most recent 5 full years indicating the nature and extent of injury to the domestic industry concerned:

(1) With respect to serious injury, data indicating:

(i) A significant idling of production facilities in the industry, including data indicating plant closings or the underutilization of production capacity;

(ii) The inability of a significant number of firms to carry out domestic production operations at a reasonable level of profit; and

(iii) Significant unemployment or underemployment within the industry; and/or

(2) With respect to the threat of serious injury, data relating to:

(i) A decline in sales or market share, a higher and growing inventory (whether maintained by domestic producers, importers, wholesalers, or retailers), and a downward trend in production, profits, wages, productivity, or employment (or increasing underemployment);

(ii) The extent to which firms in the industry are unable to generate adequate capital to finance the modernization of their domestic plants and equipment, or are unable to maintain existing levels of expenditures for research and development;

(iii) The extent to which the U.S. market is the focal point for the diversion of exports of the article concerned by reason of restraints on exports of such article to, or on imports of such article into, third country markets; and

(3) Changes in the level of prices, production, and productivity.

(f) *Cause of injury.* An enumeration and description of the causes believed to be resulting in the injury, or threat thereof, described under paragraph (e) of this section, and a statement regarding the extent to which increased imports of the subject article are believed to be such a cause, supported by pertinent data;

(g) *Relief sought and purpose thereof.* A statement describing the import relief sought, including the type, amount, and duration, and the specific purposes therefor, which may include facilitating the orderly transfer of resources to more productive pursuits, enhancing competitiveness, or other means of adjustment to new conditions of competition;

(h) *Efforts to compete.* A statement on the efforts being taken, or planned to be taken, or both, by firms and workers in the industry to make a positive adjustment to import competition.

(i) *Critical circumstances.* If the petition alleges the existence of critical circumstances, a statement setting forth the basis for the belief that there is clear evidence that increased imports (either actual or relative to domestic production) of the article are a substantial cause of serious injury, or the threat thereof, to the domestic industry, and that delay in taking action would cause damage to that industry that would be difficult to repair, and a statement concerning the provisional relief requested and the basis therefor.

■ 9. Revise § 206.35 to read as follows:

§ 206.35 Time for determinations, reporting.

(a) *In general.* The Commission will make its determination with respect to injury within 120 days (180 days if critical circumstances are alleged) after the date on which the investigation is initiated. The Commission will make its report to the President no later than 30 days after the date on which its determination is made.

(b) *Perishable agricultural product.* In the case of a request in a petition for provisional relief with respect to a perishable agricultural product that has been the subject of monitoring by the Commission, the Commission will report its determination and any finding to the President not later than 21 days after the date on which the request for provisional relief is received.

(c) *Critical circumstances.* If petitioner alleges the existence of critical circumstances in the petition, the Commission will report its determination regarding such allegation and any finding on or before the 60th day after such filing date.

■ 10. Add § 206.37 to read as follows:

§ 206.37 Limited disclosure of certain confidential business information under administrative protective order.

Except in the case of an investigation under the United States-Jordan Free Trade Area Implementation Act or the NAFTA, the Secretary shall make available to authorized applicants, in accordance with the provisions of § 206.17, confidential business information obtained in an investigation under this subpart.

By order of the Commission.

Issued: January 19, 2012.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2012–1500 Filed 1–25–12; 8:45 am]

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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; Deracoxib

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 Novartis Animal Health U.S., Inc. The supplemental NADA provides for veterinary prescription use of deracoxib tablets in dogs for the control of postoperative pain and inflammation associated with dental surgery and the addition of a 12-milligram (mg) size tablet.

DATES: This rule is effective January 26, 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: Novartis Animal Health U.S., Inc., 3200 Northline Ave., Suite 300, Greensboro, NC 27408, filed a supplement to NADA 141–203 that provides for veterinary prescription use of DERAMAXX (deracoxib) Chewable Tablets in dogs for the control of postoperative pain and inflammation associated with dental surgery and the addition of a 12-mg size tablet. The supplemental NADA is

approved as of November 23, 2011, and 21 CFR 520.538 is amended 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 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. In § 520.538, revise paragraphs (a), (d)(1), and (d)(2) to read as follows:

§ 520.538 Deracoxib.

(a) *Specifications.* Each tablet contains 12, 25, 50, 75, or 100 milligrams (mg) deracoxib.

* * * * *

(d) * * *

(1) *Amount.* Administer orally as needed, as a single daily dose based on body weight:

(i) 1 to 2 mg/kilogram (kg) (0.45 to 0.91 mg/pound (lb)), for use as in paragraph (d)(2)(i) of this section.

(ii) 1 to 2 mg/kg (0.45 to 0.91 mg/lb) for 3 days, for use as in paragraph (d)(2)(ii) of this section.

(iii) 3 to 4 mg/kg (1.4 to 1.8 mg/lb) for up to 7 days, for use as in paragraph (d)(2)(iii) of this section.

(2) *Indications for use.* (i) For the control of pain and inflammation associated with osteoarthritis.

(ii) For the control of postoperative pain and inflammation associated with dental surgery.

(iii) For the control of postoperative pain and inflammation associated with orthopedic surgery.

* * * * *

Dated: January 23, 2012.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2012-1622 Filed 1-25-12; 8:45 am]

BILLING CODE 4160-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2011-0730; FRL-9620-9]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Consumer and Commercial Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia. The SIP revision adds a new chapter (9VAC5-45—Consumer and Commercial Products) in order to control volatile organic compounds (VOC) from portable fuel containers, consumer products, architectural and industrial (AIM) coatings, adhesives and sealants, and asphalt paving operations within the Northern Virginia and Fredericksburg VOC Emissions Control Areas. The SIP revision also includes new and revised documents incorporated by reference into the Virginia regulations (9VAC5-20-21—Documents Incorporated by Reference) in order to support the new and revised regulations. This action is being taken under the Clean Air Act (CAA).

DATES: *Effective Date:* This final rule is effective on February 27, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2011-0730. All documents in the docket are listed in the www.regulations.gov Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly

available only in hard copy form.

Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT:

Gregory Becoat, (215) 814-2036, or by email at becoat.gregory@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 2011 (76 FR 69214), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Virginia. The NPR proposed approval of Virginia's consumer and commercial products regulations. The formal SIP revision was submitted by the Commonwealth of Virginia on March 18, 2010.

II. Summary of SIP Revision

The SIP revision consists of the following: (1) Amendments to Chapter 9VAC5-20-21—Documents Incorporated by Reference, in order to make administrative changes for clarity, style, format, renumbering, and incorporate by reference into the Virginia regulations the new and revised regulations; (2) adds a new chapter, 9VAC5-45—Consumer and Commercial Products (Chapter 45) for regulations pertaining to consumer and commercial products; (3) adds special provisions in Chapter 45 that specify monitoring, compliance, notification, general testing, recordkeeping and reporting requirements; (4) establishes standards for portable fuel containers for products manufactured before and after August 1, 2010; (5) establishes standards for consumer products for products manufactured before and after August 1, 2010; (6) establishes standards for architectural and industrial maintenance coatings; (7) establishes standards for adhesives and sealants; and (8) establishes standards for asphalt paving operations. These SIP revisions contain the required elements for a federally enforceable rule: emission limitations, compliance procedures and test methods, compliance dates and record keeping provisions. The Commonwealth of Virginia has adopted the standards and requirements of the consumer and commercial products regulations as recommended by the Ozone Transport Commission model