occurs [bullet] diarrhea lasts more than 2 days''.

(3) *For products containing kaolin identified in § 335.10(b).* (i) ''Ask a doctor or pharmacist before use if you are taking any other drugs. Try to use at least 3 hours before or after taking any other drugs.''

(ii) ''Stop use and ask a doctor if [bullet] symptoms get worse [bullet] diarrhea lasts more than 2 days''.

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products containing any ingredient identified in § 335.10.* The labeling states ''[bullet] drink plenty of clear fluids to help prevent dehydration caused by diarrhea''.

(2) *For products containing bismuth subsalicylate identified in § 335.10(a).* The labeling states ''[bullet] adults and children 12 years and over:'' 525 milligrams ''every 1/2 to 1 hour, or'' 1,050 milligrams ''every hour as needed [bullet] do not exceed'' 4,200 milligrams ''in 24 hours [bullet] use until diarrhea stops but not more than 2 days [bullet] children under 12 years: ask a doctor''.

(3) *For products containing kaolin identified in § 335.10(b).* The labeling states ''[bullet] adults and children 12 years and over:'' 26.2 grams ''after each loose stool [bullet] continue to take every 6 hours until stool is firm but not more than 2 days [bullet] do not exceed'' [262 grams] ''in 24 hours [bullet] children under 12 years of age: ask a doctor''.

(e) *Products that meet the criteria established in § 201.66(d)(10) of this chapter.* The information described in § 201.66(c) of this chapter shall be printed in accordance with the following specifications.

(1) The labeling shall meet the requirements of § 201.66(c) of this chapter except that the information in § 201.66(c)(3) of this chapter may be omitted, and the information in § 201.66(c)(5) and (c)(6) of this chapter may be presented as follows:

(i) The words ''Contains salicylate.'' may be omitted from the warning in § 335.50(c)(2)(i)(B).

(ii) The subheading ''When using this product'' in § 335.50(c)(2)(iv) may be omitted.

(iii) The words ''continue to'' may be omitted from the directions in § 335.50(d)(3).

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to § 201.66(c)(3) of this chapter and the bullet in the warning in § 335.50(c)(1)(i) may be omitted.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

■ 4. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

§ 369.20 [Amended]

5. Section 369.20 *Drugs; recommended warning and caution statements* is amended by removing the entry for ''DIARRHEA PREPARATIONS.''

Dated: March 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9380 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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 US, Inc. The supplemental NADA provides for the veterinary prescription use of deracoxib tablets in dogs for the control of pain and inflammation associated with osteoarthritis.

DATES: This rule is effective April 17, 2003.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 141–203 that provides for the veterinary prescription use of DERAMAXX (deracoxib) Chewable Tablets for the control of pain and inflammation associated with osteoarthritis. The supplemental NADA is approved as of February 11, 2003, and 21 CFR 520.538 is amended 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 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 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)(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 February 11, 2003.

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 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. Section 520.538 is amended by revising paragraphs (d)(1) and (d)(2) to read as follows:

§ 520.538 Deracoxib.

* * * * *

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

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

(ii) 3 to 4 mg/kg (1.4 to 1.8 mg/lb) for up to 7 days, for use as in paragraph (d)(2)(ii) 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 orthopedic surgery in dogs weighing 4 or more pounds (1.8 kg).

* * * * *

Dated: March 8, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–9532 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[WI114–01–7344a, FRL–7484–2]

Approval and Promulgation of Air Quality Implementation Plans and Designation of Areas for Air Quality Planning Purposes; Wisconsin

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is making a determination that Manitowoc and Door Counties in Wisconsin have attained the one-hour ozone National Ambient Air Quality Standard (NAAQS), and we are approving the State of Wisconsin's request to redesignate Manitowoc and Door Counties to attainment for ground level ozone. In approving this redesignation request, we are also approving the State's plan for maintaining the one-hour ozone standard for the next 10 years as a revision to the Wisconsin State Implementation Plan (SIP). We are notifying the public that we believe the motor vehicle emissions budgets for volatile organic compounds (VOC) and oxides of nitrogen (NO_X) in the maintenance plan for Manitowoc and Door Counties are adequate for conformity purposes and approvable as part of the maintenance plan. In this direct final rule, we are also approving a 1999 periodic inventory for the Milwaukee-Racine ozone nonattainment area. The Wisconsin Department of Natural Resources (WDNR) submitted the redesignation request and SIP revisions on January 28, 2003, and submitted additional information on February 5, 2003 and February 27, 2003.

DATES: This rule is effective on June 16, 2003, unless EPA receives adverse written comments by May 19, 2003. If EPA receives adverse comments, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: You may inspect copies of the documents relevant to this action during normal business hours at the following location: Regulation Development Section, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. Please contact Kathleen D'Agostino at (312) 886–1767 before visiting the Region 5 office.

Send written comments to: Carlton Nash, Chief, Regulation Development Section, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Engineer, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–1767.

SUPPLEMENTARY INFORMATION: This Supplementary Information section is organized as follows:

I. What Has Wisconsin Submitted?

On January 28, 2003, the WDNR submitted a revision to its SIP for ozone. Additional information pertaining to the SIP was submitted on February 5, 2003 and February 27, 2003. This SIP revision contained four components: (1) A request to redesignate Manitowoc and Door Counties to attainment for ozone and a plan to ensure maintenance of the ozone standard through 2013, (2) the 1999 periodic inventory for the Milwaukee-Racine area, (3) maintenance plan updates for Sheboygan and Kewaunee Counties, and (4) new transportation conformity budgets based on the MOBILE6 emissions model for the Milwaukee-Racine and Sheboygan areas. This direct final action will address the redesignation request and maintenance plan for Manitowoc and Door Counties and the 1999 periodic inventory for the Milwaukee-Racine area. The maintenance plan updates for Kewaunee and Sheboygan Counties and the new transportation conformity budgets for the Milwaukee-Racine and Sheboygan areas will be addressed in a separate action.

A. Redesignation of Manitowoc and Door Counties and SIP Revision for Maintaining the One-Hour Ozone Standard

1. Why Has the State Made This Submission?

In accordance with requirements of the Clean Air Act as amended in 1990 (Act), Manitowoc and Door Counties were designated as ozone nonattainment areas on November 6, 1991 (56 FR 56850). At that time Manitowoc was classified as a moderate ozone nonattainment area and Door County was classified as a rural transport marginal) ozone nonattainment area. The nonattainment designations were based on monitored violations of the NAAQS for ozone.

Recent air quality data shows that both counties are attaining the ozone NAAQS. Therefore, on January 28, 2003, the WDNR submitted a request to redesignate the areas to attainment for ozone and a maintenance plan to ensure attainment through 2013.

2. What Criteria Are EPA Using in Reviewing the State's Submission?

The Act establishes the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) allows for redesignation providing that:

(1) The Administrator determines that the area has attained the NAAQS;

(2) The State containing such area has met all requirements applicable to the area under section 110 and Part D;

(3) The Administrator has fully approved the applicable implementation plan for the area under section 110(k);

(4) The Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable implementation plan and applicable Federal air pollutant control regulations and other permanent and enforceable reductions; and

(5) The Administrator has fully approved a maintenance plan for the area as meeting the requirements of section 175A.

The EPA provided guidance on redesignation in the General Preamble for the Implementation of Title I of the CAA Amendments of 1990, on April 16, 1992 (57 FR 13498) and supplemented on April 28, 1992 (57 FR 18070). The