

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.

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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:

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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.