

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Phenylbutazone Paste

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 abbreviated new animal drug application (ANADA) filed by Bioniche Animal Health USA, Inc. The ANADA provides for oral use of phenylbutazone paste in horses for relief of inflammatory conditions associated with the musculoskeletal system.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601, filed ANADA 200-266 for the oral use of BUTEQUINE (phenylbutazone) Paste in horses for relief of inflammatory conditions associated with the musculoskeletal system. Bioniche Animal Health's BUTEQUINE Paste is approved as a generic copy of Schering-Plough Animal Health's PHENYLZONE (phenylbutazone) Paste, approved under NADA 116-087. The ANADA is approved as of February 21, 2003, and the regulations are amended in 21 CFR 520.1720c to reflect the approval and current format. 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.

FDA has determined under 21 CFR 25.33(a)(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 520.1720c is amended by revising paragraphs (a) and (b), by removing paragraph (c), and by redesignating paragraph (d) as new paragraph (c) to read as follows:

§ 520.1720c Phenylbutazone paste.

(a) *Specifications*—(1) Each gram of paste contains 0.2 grams phenylbutazone.

(2) Each gram of paste contains 0.35 grams phenylbutazone.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 000061 and 010797 for use of product described in paragraph (a)(1) of this section.

(2) No. 064847 for use of product described in paragraph (a)(2) of this section.

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Dated: July 3, 2003.

Andrew J. Beaulieu,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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