

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DDM

Display Date	8-16-05
Publication Date	8-17-05
Certifier	A. Corbin

Implantation or Injectable Dosage Form New Animal Drugs; Phenylbutazone Injection

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 Sparhawk Laboratories, Inc. The ANADA provides for the veterinary prescription use of phenylbutazone injectable solution 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: John K. Harshman, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9808, e-mail: john.harshman@fda.gov.

SUPPLEMENTARY INFORMATION: Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215-3591, filed ANADA 200-371 for the use of Phenylbutazone 20% Injection by veterinary prescription for relief of inflammatory conditions associated with the musculoskeletal system in horses. Sparhawk Laboratories, Inc.'s, Phenylbutazone 20% Injection is approved as a generic copy of Schering-Plough Animal Health Corp.'s, BUTAZOLIDIN Injectable 20%, approved under NADA 11-575. The ANADA is approved as

cv0518

NFR1

of July 8, 2005, and the regulations in 21 CFR 522.1720 are amended to reflect the approval. The basis of approval is discussed in the freedom of information(FOI) summary.

In accordance with the FOI 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 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(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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

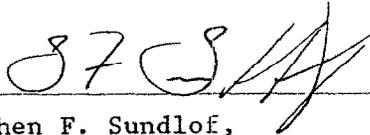
■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1720 [Amended]

■ 2. Section 522.1720 is amended in paragraph (b)(2) by removing “No. 000010” and by adding in its place “Nos. 000010 and 058005”.

Dated: 7/26/05
July 26, 2005.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

