

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

DMB

Display Date	<u>3-9-01</u>
Publication Date	<u>3-12-01</u>
Certifier	<u><i>[Signature]</i></u>

Oral Dosage Form New Animal Drugs; Phenylbutazone Tablets and Boluses

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 Phoenix Scientific, Inc. The supplemental NADA provides for oral use of a 200-milligram (mg) strength phenylbutazone tablet for relief of inflammatory conditions associated with the musculoskeletal system in dogs and horses.

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

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed a supplement to approved NADA 094-170 for Phenylbutazone Tablets, USP. The supplemental NADA provides for use of a 200-mg strength phenylbutazone tablet for relief of inflammatory conditions associated with the musculoskeletal system in dogs and horses. The supplemental NADA is approved as of January 12, 2001, and the regulations are amended in 21 CFR 520.1720a 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 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

cv00114

NADA 094-170

NFR-

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 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

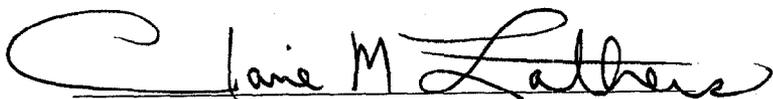
1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1720a [Amended]

2. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(2) by removing "No. 000010" and by adding in its place "Nos. 000010 and 059130"; and in paragraph (b)(3) by removing "015579, 059130" and by adding in its place "015579".

Dated: 2/26/01
February 26, 2001.



Claire M. Lathers,
Director, Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S