

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Phenylbutazone Powder

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 A & G Pharmaceuticals, Inc. The ANADA provides for the veterinary prescription use of phenylbutazone powder administered to horses in feed for the 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: A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527, filed ANADA 200-334 that provides for the veterinary prescription use of EQUIZONE 100 (phenylbutazone), a powder administered to horses in feed for the relief of inflammatory conditions associated with the musculoskeletal system. A & G Pharmaceuticals, Inc.'s, EQUIZONE 100 is approved as a generic copy of Phoenix Scientific, Inc.'s, Phenylbutazone Tablets, USP, approved under NADA 91-818. The ANADA is approved as of November 18, 2005, and the regulations are amended in 21

CFR part 520 by adding new § 520.1720e. The basis of approval is discussed in the freedom of information summary.

In addition, A & G Pharmaceuticals, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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 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.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for “A & G Pharmaceuticals, Inc.” and in the table in paragraph (c)(2) by numerically adding a new entry for “057699” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

| Firm name and address | Drug labeler code |
|--|-------------------|
| A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527. | 057699 |

(2) * * *

| Drug labeler code | Firm name and address |
|-------------------|---|
| 057699 | A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527 |

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. Section 520.1720e is added to read as follows:

§ 520.1720e Phenylbutazone powder.

(a) *Specifications.* Each 10 grams (g) of powder contains 1 g phenylbutazone.

(b) *Sponsor.* See No. 057699 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 1 to 2 g (1 to 2 level scoops, using the scoop provided) per 500 pounds of body weight on a small amount of palatable feed.

(2) *Indications for use.* For the relief of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations.* Do not exceed 4 g per animal daily. Administer at a relatively high dosage level for the first 48 hours, then reduce gradually to a maintenance dosage level with the lowest dosage maintained at the level capable of producing the desired clinical response. Do not use in horses intended for human consumption. Federal law prohibits the extralabel use of this product in female cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 11111111111

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

BILLING CODE 4160-01-S