

Date of Approval: July 8, 2005

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-371

Phenylbutazone 20% Injection
(phenylbutazone)

Horses

For relief of inflammatory conditions with the musculoskeletal system in
horses

Sponsored by:

Sparhawk Laboratories, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-371
- b. Sponsor: Sparhawk Laboratories, Inc.
12340 Santa Fe Trail Dr.
Lenexa, KS 66215
- Drug Labeler Code: 058005
- c. Established Name: Phenylbutazone
- d. Proprietary Name: Phenylbutazone 20% Injection
- e. Dosage Form: Sterile Injection
- f. How Supplied: 100 mL vials, 200 mg/mL
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Each mL contains 200 mg of phenylbutazone
- i. Route of Administration: Intravenous injection (not for subcutaneous or intramuscular use)
- j. Species/Class: Horses
- k. Recommended Dosage: 1 to 2 g per 1,000 lb body weight (5 to 10 mL/1000 lb) daily. Injection should be given slowly and with care.
- l. Pharmacological Category: Anti-inflammatory
- m. Indications: For relief of inflammatory conditions associated with the musculoskeletal system in horses.
- n. Pioneer Product: BUTAZOLIDIN Injectable 20%; phenylbutazone; NADA 011-575; Schering-Plough Animal Health Corp.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guidance, revised October 9, 2002).

Based on the formulation characteristics of the generic product Sparhawk Laboratories, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for Phenylbutazone 20% Solution. The generic product is administered as a sterile injection, contains similar active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product BUTAZOLIDIN Injectable 20%, the subject of Schering-Plough Animal Health Corp., NADA 011-575, was approved on December 15, 1958.

3. HUMAN SAFETY:

This drug is intended for use in horses, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: **“FOR HORSES ONLY”** and **“KEEP OUT OF REACH OF CHILDREN.”**

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Phenylbutazone 20% Injection, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Generic Labeling for ANADA 200-371:
Phenylbutazone 20% Injection
100 mL multidose bottle label and outsert

Pioneer Labeling for NADA 011-575:

100 mL multidose bottle label

100 mL bottle carton label

Package Insert

Re: Pioneer labeling for Cooper's Animal Health Inc.

This product is no longer being manufactured or marketed but is still a listed drug currently sponsored by Schering-Plough Animal Health Corp.