

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-177

B. Sponsor

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
P.O. Box 6457
St. Joseph, MO 64506-0457

C. Proprietary Name

Sulfadimethoxine

D. Established Name

sulfadimethoxine injection 40%

E. Pharmacological Category

Antibacterial

F. Dosage Form

Injection

G. Amount of Active Ingredient

Each mL contains 400 mg of Sulfadimethoxine

H. How Supplied

250 mL multiple vials

I. Dispensing Status

OTC

J. Dosage Regimen

25 mg/lb initial dose followed by 12.5 mg/lb for maintenance doses every 24 hours

K. Route of Administration

IV

L. Species/Class

Bovine

M. Indication

For treatment of bovine respiratory disease complex (shipping fever complex) and bacterial pneumonia associated with *Pasteurella* Spp. Sensitive to sulfadimethoxine; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.

N. Pioneer

Albon[®] Injection - 40% manufactured by Hoffman-La Roche (NADA 41-245)

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (53 FR 50460, December 15, 1988; first GADPTRA Policy Letter), an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). For certain dosage forms, the Agency grants a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; fifth GADPTRA Policy Letter). In lieu of in vivo bioequivalence testing, the bioequivalence of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver June 9, 1994 (photocopy attached) from conducting an in vivo bioequivalence study with Sulfadimethoxine Injection 40%. The generic and pioneer products are solutions with the same active and inactive ingredients in the same concentration.

III. HUMAN FOOD SAFETY**Tolerance**

The tolerances established for the pioneer product apply to the generic product. Tolerances are established for residues of sulfadimethoxine in uncooked edible tissues of cattle as follows: 0.1 part per million (negligible residue). In milk at 0.01 part per million (negligible residue) (21 CFR 556.640)

Withdrawal Time

When a waiver from the requirement of an in vivo bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for Sulfadimethoxine Injection 40% is established under 21 CFR 520.2220 (a)(2)(iii): 5 days for cattle: During treatment and for 60 hours (5 milkings) after the latest treatment for milk.

Regulatory Method for Residues

No new method required for this approval.

IV. USER SAFETY

Labeling contains adequate caution/warning statements.

V. AGENCY CONCLUSIONS

This is an Abbreviated New Animal Drug Application (ANADA) filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Bioequivalence for this generic animal drug, Sulfadimethoxine Injection 40%, was established by demonstration of chemical equivalence to the pioneer product, Hoffmann-La Roche's Albon® Injection 40% (NADA 041-245)

This generic product and the pioneer product have identical labeling indications for the 250 mL vial for use in cattle. The route and method of administration of the two drugs are identical. Both drugs are administered IV. The generic and pioneer products contain the same active and inactive ingredients in the same concentration.

Therefore, this ANADA satisfies the requirements of section 512 of the Act and demonstrates that Sulfadimethoxine Injection 40% is safe and effective for its labeled indications when used under its proposed conditions of use.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.