

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-038

B. Sponsor

Agri Laboratories Ltd
P.O. Box 3103
St. Joseph, MO 64503

C. Proprietary Name

Sulfadimethoxine Injection 40%

D. Established Name

sulfadimethoxine

E. Dosage Form

Injectable solution

F. Amount of Active Ingredient

each mL contains 400 mg sulfadimethoxine

G. How Supplied

250 mL vials

H. Dispensing Status

OTC

I. Dosage Regimen

25 mg/lb (55 mg/kg) for the initial dose, followed by 12.5 mg/lb (27.5 mg/kg) for maintenance doses every 24 hours

J. Route of Administration

Intravenous injection only

K. Species/Class

Cattle

L. Indication

Recommended in cattle for the 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*, sensitive to sulfadimethoxine; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*, sensitive to sulfadimethoxine.

M. Pioneer Product

ALBON (sulfadimethoxine) Injection 40% NADA 041-245 by Hoffmann-LaRoche, Inc.

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). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

Based upon the formulation characteristics of the generic product, Agri Laboratories, Ltd. was granted a waiver from conducting an *in vivo* bioequivalence study for sulfadimethoxine injection 40%. The generic and pioneer products are injectable solutions with the same active and inactive ingredients. The generic and pioneer products also contain the same concentration of active ingredient.

III. HUMAN FOOD SAFETY

Tolerance for the marker residue

The tolerance established for the pioneer product applies to the generic product.

A tolerance of 0.1 ppm (negligible residue) is established for sulfadimethoxine residues in the uncooked edible tissues of cattle under 21 CFR 556.640.

A tolerance of 0.01 ppm (negligible residue) is established for sulfadimethoxine residues in milk under 21 CFR 556.640.

Withdrawal Times:

When a waiver of the *in vivo* bioequivalence study is granted, the generic product withdrawal times are those previously assigned to the pioneer product.

Slaughter:

5 days in cattle

Milk Withholding:

Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food.

Regulatory Method:

The analytical method for the determination of sulfadimethoxine in tissues uses a thin layer-densitometric procedure. This method is found in the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 15th edition, 1990.

IV. AGENCY CONCLUSIONS

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that sulfadimethoxine injectable solution, when used under its proposed conditions of use, is safe and effective for its labeled indications.

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.