

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-165

B. Sponsor

Fermenta Animal Health Company
P. O. Box 338
15th & Oak Streets
Elwood, Kansas 66024

C. Proprietary Name

SDM Sulfadimethoxine 12.5% Oral Solution

D. Established Name

sulfadimethoxine 12.5% oral solution

E. Pioneer Product

Albon[®]/Agribon[®] 12.5% Oral Solution (NADA 31-205) (Pfizer)

F. Dosage Form

Oral solution

G. Composition

Each fluid ounce contains 3.75 g sulfadimethoxine solubilized with sodium hydroxide.

H. How Supplied

Net contents: 1 gallon (3.785 liters)

I. Dispensing Status

OTC

J. Dosage Regimen

Refer to labeling

K. Species/Class

Broiler and replacement chickens, meat producing turkeys, dairy calves and heifers, and beef cattle

L. Indication

Chickens: Coccidiosis, fowl cholera, and coryza.

Turkeys: Coccidiosis and fowl cholera.

Cattle: Shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

II. 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, (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 and conducts a tissue residue study to establish the withdrawal time for the generic product. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (61 FR 26182, May 24, 1996, Bioequivalence Guidance).

Based upon the formulation characteristics of the generic product, Fermenta Animal Health. was granted a waiver from conducting an *in vivo* bioequivalence study for sulfadimethoxine 12.5% oral solution. The generic and pioneer products are solutions which contain the same active and inactive ingredients

III. HUMAN FOOD SAFETY

Tolerance

The tolerances established for the pioneer drug product apply to the generic drug product. A tolerance of 0.1 ppm is established for the uncooked edible tissues of chickens, turkeys and cattle as per 21 CFR 556.640

Withdrawal Time

When a waiver of *in vivo* bioequivalence testing is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal times for sulfadimethoxine oral solution are 5 days for chickens and turkeys and 7 days for cattle.

Regulatory Method for Residues

The analytical method for detection of residue in tissue is the 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 submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that sulfadimethoxine 12.5% oral solution when used under the 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.