Approval Date: August 3, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-251

B. Sponsor

Med Pharmex, Inc.

C. Proprietary Name

Sulforal®

D. Established Name

Sulfadimethoxine

E. Dosage Form

Oral solution

F. Amount of Active Ingredient

3.75 gram sulfadimethoxine solubilized with sodium hydroxide

G. How Supplied

1 gallon (128 fl. oz.) bottle

H. Dispensing Status

OTC

I. Route of Administration

Oral in drinking water

J. Species/Class

Chicken, Turkeys, Dairy Calves, Dairy Heifers and Beef Cattle

K. Indication

Broiler and Replacement Chickens:
For the treatment of coccidiosis, fowl cholera and infectious coryza-concentration: 0.05% 1 fl. oz to 2 gallons of drinking water.

Meat-Producing Turkeys:
For the treatment of coccidiosis and fowl cholera-concentration: 0.025% 1 fl. oz to 4 gallons of drinking water.

Dairy Calves, Dairy Heifers and Beef Cattle:
For the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria and foot rot-dosage: 25 mg/lb first day followed by 12.5 mg/lb for 4 days (as drinking water or drench).

L. Reference Listed New Animal Drug

Pfizer's Albon® 12.5% Concentrated Solution (NADA 31-205)

M. Patents/Exclusivity

The drug is listed in the GREEN BOOK. There are no unexpired patents listed in the GREEN BOOK, and no exclusivity protection for Albon®.

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 applications. 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 1996).

Based on the formulation characteristics of the generic product, Med-Pharmex, Inc., was granted a waiver from the requirement on an *in vivo* bioequivalence study for the generic product Sulfadimethoxine 12.5% Oral Solution. The generic product is administered as an oral solution and contains the same active and inactive ingredients in the same concentration as the pioneer product.

III. HUMAN FOOD SAFETY

Tolerance
The tolerances (21 CFR 556.640) established for the pioneer product apply to the generic product. Tolerances are established for residues of sulfadimethoxine in uncooked edible tissues of chickens, turkeys, and cattle as follows: 0.1 part per million (negligible residue).

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 times for sulfadimethoxine 12.5% Oral Solution in medicated drinking water are established under:

- **21 CFR 520.2220a (e) (1) (iii):** Broiler and Replacement Chickens-5 days before slaughter.

- **21 CFR 520.2220 a(e) (2) (iii):** Meat-Producing Turkeys-5 days before slaughter.

- **21 CFR 520.2220 a(e) (3) (iii):** Dairy Calves, Dairy Heifers and Beef Cattle-7 days before slaughter.

Regulatory Method for Residues
The regulatory analytical method for detection of residues of the drug is a thin layer densitometric procedure. This method is found in the *Official Methods of Analysis of AOAC International*, 16th edition.

Human Safety Relative to Possession, Handling and Administration
Labeling contains adequate caution/warning statements.

IV. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of sections 512(n) of the Act and demonstrates that Sulforal® Oral Solution (3.75 gram sulfadimethoxine solubilized with sodium hydroxide) when used under its proposed conditions of use, is safe and effective for the 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.