Approval Date: July 28, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-238

B. Sponsor

Med-Pharmex, Inc.

C. Proprietary Name

Sulfasol® Soluble Powder

D. Established Name

Sulfadimethoxine

E. Dispensing Status

OTC

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 approval is based on a demonstration that the generic product is bioequivalent to the pioneer product.

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 (Fifth GADPTRA Policy Letter: 55 FR 24645, June 18, 1990; Bioequivalence Guidance: 61 FR 26182 - 26186, May 24, 1996).

Based upon the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for Sulfasol Soluble Powder. The generic and pioneer products contain the same active and inactive ingredients and are oral solutions.

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

chickens, turkeys, and 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 soluble powder is established under:

- 21 CFR 520.2220 a (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 Methods for Residues
Sulfadimethoxine: 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 is an Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Sulfadimethoxine Soluble Powder , were established by demonstration of chemical equivalence to the pioneer product, Pfizer's Albon® (NADA 046-285)

This generic product and the pioneer product have identical labeling indications for the gallon bottle for use in chickens, turkeys and cattle. The route and method of administration of the two drugs are identical. Both drugs are administered orally in the drinking water. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy implementing section 512(b)(2) of FFD&C Act, *in vivo* bioequivalency studies were neither necessary nor required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Sulfasol (Sulfadimethoxine Soluble Powder), 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.