Date of Approval: October 28, 2009

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-443

Sulfadimethoxine Soluble Powder (sulfadimethoxine)

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

For the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza in broiler and replacement chickens only; the treatment of coccidiosis and fowl cholera in meat-producing turkeys only; and the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine in dairy calves, dairy heifers and beef cattle

Sponsored by:

First Priority, Inc.

1. GENERAL INFORMATION:

a. ANADA Number:	ANADA 200-443
b. Sponsor:	First Priority, Inc. 1590 Todd Farm Dr. Elgin, IL 60123 Drug Labeler Code: 058829
c. Established Name:	Sulfadimethoxine
d. Proprietary Name:	Sulfadimethoxine Soluble Powder
e. Dosage Form:	Soluble Powder
f. How Supplied:	25 x 3.77 oz (107 g) pail and a 3.77 oz (107 g) pouch
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each 107 gram packet contains 3.34 oz (94.6 g) of sulfadimethoxine in the form of soluble sodium salt and disodium edetate.
i. Route of Administration:	Oral
j. Species/Class:	Broiler and replacement chickens, meat-producing turkeys, dairy calves, dairy heifers, and beef cattle
k. Recommended Dosage:	Chickens: 1.875 (0.05%) grams per gallon to prepare a drench or drinking water (contents of packet diluted to 50 gallons of water) Turkeys: 0.938 (0.025%) grams per gallon to prepare a drench or drinking water (contents of the packet diluted to 100 gallons of water). Dairy calves, dairy heifers and beef cattle: 1.18 to 2.36 (0.031 to 0.062%) grams per gallon to prepare a drench or drinking water. Administer 25 mg/lb the first day followed by 12.5 mg/lb/day for 4 consecutive days.
l. Pharmacological Category:	Antibacterial

m. Indications:	For Broiler and Replacement Chickens Only – Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza. For Meat-producing Turkeys Only – Use for the treatment of coccidiosis and fowl cholera. For Dairy Calves, Dairy Heifers, and Beef Cattle - Use for the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine, and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.
n. Pioneer Product:	ALBON Soluble Powder; sulfadimethoxine; NADA 046-285; Pfizer, Inc.

2. 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 (GAPTRA) of 1988, 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 and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, First Priority, Inc., was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product Sulfadimethoxine Soluble Powder. The generic product is administered as an oral soluble powder, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product ALBON (sulfadimethoxine) Soluble Powder, the subject of Pfizer, Inc., NADA 046-285, was approved on August 21, 1971.

3. HUMAN SAFETY:

- **Tolerances for Residues:**
  The tolerance established for the pioneer product applies to the generic product. A tolerance of 0.1 parts per billion (ppb) is established for negligible residues in the uncooked edible tissues of chickens, turkeys, cattle, ducks, salmonids, catfish, and chukar partridges and 0.01 ppb in milk under 21 CFR 556.640.

- **Withdrawal Times:**
  Because a waiver of the *in vivo* bioequivalence testing was granted, the withdrawal times are those previously assigned to the pioneer product.

  The withdrawal time for broiler and replacement chickens, and meat producing turkeys is 5 days before slaughter. The withdrawal period of 7 days before slaughter for dairy calves, dairy heifers, and beef cattle, only, has been established for Sulfadimethoxine Soluble Powder (21 CFR 520.2220a).

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

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Sulfadimethoxine Soluble Powder, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-443:
Pail Label
25 x 3.77 oz (107 g)
Pouch Label
3.77 oz (107 g)

Pioneer Labeling for NADA 046-285:
Pouch Label
3.77 oz (107 g)