Approval Date: November 14, 2005

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-376

SULFAMED-G Soluble Powder
(sodium sulfadimethoxine)

For treatment of coccidiosis or various bacterial diseases in chickens, turkeys, and cattle

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-376
b. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Road, Tallaght Dublin 24, Ireland Drug Labeler Code: 061623
US Agent:	Linda M. Duple Director, North American Regulatory Affairs Bimeda, Inc. A Division of Cross Vetpharm Group Ltd. 2836 Dolliver Park Ave. Lehigh, IA 50557
c. Established Name:	Sodium sulfadimethoxine
d. Proprietary Name:	SULFAMED-G Soluble Powder
e. Dosage Form:	Soluble powder
f. How Supplied:	107 g (3.77 oz) pouch 535 g (18.87 oz) pouch 25 lb (11.34 kg) pail
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	107 g (3.77 oz) pouch: each packet contains 3.34 oz (94.6 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edetate. 535 g (18.87 oz) pouch: each packet contains 16.8 oz (473 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edetate. 25 lb (11.34 kg) pail: 3 scoops contain 3.34 oz (94.6 g) Sulfadimethoxine in the form of the 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 cattle
k. Recommended Dosage:	Chickens: 1.875 (0.05 percent) grams per gallon of drinking water in automatic proportioners for six days. Turkeys: 0.938 (0.025 percent) grams per gallon of drinking water in automatic proportioners for six days. Cattle: 25 mg/lb first day followed by 12.5 mg/lb/day for 4 four days or 1.18 to 2.36 (0.031 to 0.062 percent) grams per gallon. Administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days.
l. Pharmacological Category:	Antimicrobial, anticoccidial
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 disease outbreaks of coccidiosis and fowl cholera. ***For Dairy Calves, Dairy Heifers, and Beef Cattle***: Use for the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.
n. Pioneer Product:	ALBON; sodium 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 (GADPTRA) 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 shows 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, Cross Vetpharm Group Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product SULFAMED-G (sodium sulfadimethoxine) Soluble Powder. The generic product is administered as an oral solution, contains the same active ingredients 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 (sodium sulfadimethoxine) Soluble Powder, the subject of Pfizer, Inc., NADA 046-285, was approved on June 17, 1992.

3. HUMAN SAFETY:

- **Tolerances for Residues:**
  The tolerance established for the pioneer product applies to the generic product. A tolerance 0.01 ppm is established for sulfadimethoxine residues in milk and uncooked edible tissues of chickens, turkeys and cattle under 21 CFR 556.640.

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

  The withdrawal times are 5 days for chickens and turkeys, and 7 days for cattle.

- **Regulatory Method for Residues:**
  The analytical method for 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. The method is available from the Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

4. 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 SULFAMED-G 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 200-376:
SULFAMED-G Soluble Powder
107 g (3.77 oz) pouch, front and back
107 g (3.77 oz) 25 packets label
535 g (18.87 oz) pouch, front and back
535 g (18.87 oz) 20 packets label
25 lb (11.34 kg) pail, front and back pouch

Pioneer Labeling for NADA 046-285:
ALBON Soluble Powder
107 g (3.77 oz) pouch, front and back