Approval Date: November 3, 2006

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-434

SMZ-MED 454 Soluble Powder
(sodium sulfamethazine)

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

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-434
b. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Rd. Tallaght, Dublin 24, Ireland Drug Labeler Code: 061623 U.S. Agent: Linda Duple Director, North American Regulatory Affairs 2836 Dolliver Park Ave. Lehigh, IA 50557
c. Proprietary Names:	SMZ-MED 454 Soluble Powder
d. Establishes Names:	Sodium sulfamethazine
e. Pharmacological Category:	Antibacterial
f. Dosage Form:	Soluble Powder
g. Amount of Active Ingredients:	100 % sodium sulfamethazine
h. How supplied:	453.5 g (1 lb.) pouch
i. How Dispensed:	OTC
j. Dosages:	Administer in drinking water to provide: Chickens 58 to 85 milligrams of sulfamethazine sodium per pound of body weight per day; turkeys 50 to 124 milligrams of sulfamethazine sodium per pound of body weight per day; depending upon the dosage, age, and class of chickens or turkeys, ambient temperature, and other factors. Administer to cattle and swine in drinking water, or as a drench, to provide 108 milligrams of sulfamethazine sodium per pound of body weight on the first day and 54 milligrams of sulfamethazine sodium per pound of body weight per day on the second, third, and fourth days of administration.

k. Route of Administration:	Oral
l. Species:	Beef and nonlactating dairy cattle, swine, chickens and turkeys
m. Indications:	For treatment and control of disease caused by organisms sensitive to sulfamethazine: Beef and nonlactating dairy cattle: Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella spp*.), colibacillosis (bacterial scours)(*Escherichia coli*), necrotic pododermatitis (foot rot)(*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum), acute mastitis (Streptococcus spp*.), and acute metritis (*Streptococcus spp*.). Swine: Treatment of porcine colibacillosis (bacterial scours) (*Escherichia coli*), and bacterial pneumonia (*Pasteurella spp*.). Chickens and turkeys. In chickens for control of infectious coryza (*Haemophilus gallinarum*), coccidiosis (*Eimeria tenella, Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*). In turkeys for control of coccidiosis (*Eimeria meleagrimitis*, *Eimeria adenoeides*).
n. Pioneer Product:	SULMET Soluble Powder, (sodium sulfamethazine); NADA 122-272; Fort Dodge Animal Health, A Division of Wyeth Holdings Corp.

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 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, Cross Vetpharm Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product SMZ-MED 454 (sodium sulfamethazine) Soluble Powder. The generic product is a soluble powder, containing a single active ingredient and no other ingredients, as the pioneer. The pioneer product, SULMET (sodium sulfamethazine) Soluble Powder, the subject of Fort Dodge Animal Health, A Division of Wyeth Holdings Corp., NADA 122-272, was approved on June 11, 1982.

3. HUMAN SAFETY:

- **Tolerances for Residues:**
  The tolerance established for the pioneer product applies to the generic product. A tolerance of 0.1 part per million is established for negligible residues of sulfamethazine in the uncooked edible tissues of chickens, turkeys, cattle, and swine under 21 CFR 556.670.

- **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 time of 10 days is established for cattle, chickens, and turkeys. Withdraw medication from swine 15 days prior to slaughter for food. Not for use in lactating dairy animals. Do not medicate chickens or turkeys producing eggs for human consumption (21 CFR 520.2261b).

- **Regulatory Method for Residues:**
  The regulatory method of detection for sulfamethazine residues is colorimetric. It is described in the USDA FSIS Analytical Chemistry Laboratory Guidebook-Residue Chemistry; Winter 1991, pp. 1-23 (Determinative method). The methods are on file at the Center for Veterinary Medicine, Food and Drug Administration, HFV-199, 7500 Standish Place, Rockville, Maryland 20855.

4. AGENCY CONCLUSIONS:

This original 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 SMZ-MED 454 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 200-434:
453.5 g (1 lb.) pouch label
20 x 453.5 (1 lb.) shipping carton label
Package Insert

Pioneer Labeling for NADA 122-272:
1 Lb (453.5 g) label