Date of Approval: July 29, 2004

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-364

SPECMED SCOUR-CHEK
(spectinomycin dihydrochloride pentahydrate)

Oral Solution for Use in Pigs Under Four (4) Weeks of Age

For treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-364
b. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24 Ireland Drug Labeler Code: 061623
US Agent:	Bimeda, Inc. A Division of Cross Vetpharm Group Ltd. Attention: Linda M. Duple Director, North American Regulatory Affairs 2836 Dolliver Park Ave. Lehigh, IA 50557
c. Established Names:	Spectinomycin dihydrochloride pentahydrate
d. Proprietary Name:	SPECMED SCOUR-CHEK
e. Dosage Form:	Solution
f. How Supplied:	240 mL and 1000 mL containers
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	50 mg of spectinomycin as spectinomycin dihydrochloride pentahydrate per mL
i. Route of Administration:	Oral
j. Species/Class:	Pigs under 4 weeks of age or weighing less than 15 lbs.
k. Recommended Dosage:	Pigs under 10 lbs. – 1 pump (1 mL) twice daily. Pigs over 10 lbs. – 2 pumps (2 mL) twice daily.
l. Pharmacological Category:	Antimicrobial
m. Indications:	For use in pigs under four (4) weeks of age for treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin.

n. Pioneer Product: SPECTAM SCOUR-HALT; spectinomycin dihydrochloride pentahydrate; NADA 033-157; Phoenix Scientific, 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 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 Guidance, revised 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 SPECMED SCOUR-CHEK (spectinomycin dihydrochloride pentahydrate). The generic product is administered as an oral solution, 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 SPECTAM SCOUR-HALT (spectinomycin dihydrochloride pentahydrate), the subject of Phoenix Scientific, Inc. NADA 033-157, was approved on August 21, 1970.

3. HUMAN SAFETY:

- **Tolerance for Residues:**

  The tolerances established for the pioneer product apply to the generic product. There are no tolerances listed for the pioneer product under 21 CFR 556.600.

- **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 21 days has been established for SPECMED SCOUR-CHEK, spectinomycin dihydrochloride pentahydrate, in pigs not over 15 lbs body weight or over 4 weeks of age (21 CFR 520.2122).

- **Regulatory Method for Residues:**

  The analytical method for detection of parent spectinomycin residues in tissues utilizes an HPLC ion exchange separation with post-column derivatization and fluorescence detection.

  This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed 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 SPECMED SCOUR-CHEK, 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 200-364:
SPECMED SCOUR-CHEK (spectinomycin dihydrochloride pentahydrate)
Container Label – 240 mL and 1000 mL
Carton Label – 240 mL

Pioneer Labeling for NADA 033-157:
SPECTAM SCOUR-HALT (spectinomycin dihydrochloride pentahydrate)
Container Label – 240 mL and 1000 mL
Carton Label – 240 mL