Date of Approval: September 13, 2005

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-374

TETRAMED 324 HCA
(tetracycline hydrochloride)

Water Soluble Powder

Swine, calves, and poultry

For use in the control and treatment of certain bacterial diseases in swine, calves, and poultry.

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION:

a. File Number: ANADA 200-374

b. Sponsor:

Cross Vetpharm Group Ltd.
Broomhill Rd.
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: Tetracycline hydrochloride

d. Proprietary Name: TETRAMED 324 HCA

e. Dosage Form: Soluble powder

f. How Supplied:

Packet – 141.7 g (5 oz.)
Packet – 1134 g (40 oz.)
Pail – 907.2 g (2 lb.)
Pail – 2.27 kg (5 lb.)
Pail – 11.34 kg (25 lb.)

g. How Dispensed: OTC

h. Amount of Active Ingredients: Each pound contains 324 g of tetracycline hydrochloride

i. Route of Administration: Oral

j. Species/Class: Swine, calves, and poultry

k. Recommended Dosage:

FOR SWINE AND CALVES
RECOMMENDED DOSAGE LEVEL: Use soluble powder in the drinking water at a drug level of tetracycline hydrochloride per gallon to provide 10 mg/lb of body weight per day in divided doses.

FOR CHICKENS
RECOMMENDED DOSAGE LEVEL: CRD and air sac disease: Use soluble powder in the drinking water at a drug level of 400-800 mg tetracycline hydrochloride per gallon. Infectious synovitis: Use soluble powder in drinking water at a drug level of 200-400 mg tetracycline hydrochloride per gallon.

FOR TURKEYS
RECOMMENDED DOSAGE LEVEL: Infectious synovitis: Use soluble powder in the drinking water at a drug level of 400 mg tetracycline hydrochloride per gallon. Bluecomb: Use soluble powder in the drinking water at a drug level of tetracycline hydrochloride per gallon to provide 25 mg/lb of body weight per day in divided doses.

l. Pharmacological Category: Antimicrobial

m. Indications: For use in the control and treatment of the following conditions in swine, calves, and poultry.

SWINE AND CALVES:
Use for the control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Actinobacillus pleuropneumoniae*, *Pasteurella* spp., and *Klebsiella* spp. sensitive to tetracycline hydrochloride.

CHICKENS:
Use for the control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli;* infectious synovitis caused by *Mycoplasma synoviae* sensitive to tetracycline hydrochloride.

TURKEYS:
Use for the control of infectious synovitis caused by *Mycoplasma synoviae* and bluecomb (transmissible enteritis, coronaviral enteritis) complicated by organisms susceptible to tetracycline hydrochloride.

n. Pioneer Product: TETRASURE 324; tetracycline hydrochloride; NADA 065-496; Boehringer Ingelheim Vetmedica, 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 the generic product TETRAMED 324 HCA (tetracycline hydrochloride). The generic product is administered as an oral solution, contains similar 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 TETRASURE 324 (tetracycline hydrochloride), the subject of Boehringer Ingelheim Vetmedica, Inc., NADA 065-496, was approved on December 5, 1984.

3. HUMAN SAFETY:

- **Tolerance for Residues:**
  The tolerances established for the pioneer product apply to the generic product. A tolerance of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney is established for the sum of tetracycline residues in the uncooked edible tissues of calves, swine, chickens and turkeys under 21 CFR 556.720. The acceptable daily intake for total residues of tetracycline is 25 micrograms per kilogram of body weight per day (21 CFR 556.720).

- **Withdrawal Times:**
  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product (21 CFR 520.2345d).

The withdrawal times are 5 days before slaughter for cattle; 4 days before slaughter for swine; and 4 days before slaughter for chickens and turkeys.

- **Regulatory Method for Residues:**
  The analytical method for detection of residues in tissues is the microbiological test using *Bacillus cereus* var. *mycoides* suspension. The method is published by the Food and Drug Administration, "*Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Methods, Reports, and Protocol*s" revised October 1968, reprinted 1974. 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 TETRAMED 324 HCA, 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 200-374:
TETRAMED 324 HCA (tetracycline hydrochloride)
Packet Label – (Front & Back), 141.7 g (5 oz.)
Case Label – 24 x 141.7 g (5 oz.)
Pail Label – 907.2 g (2 lb.)
Case Label – 6 x 907.2 g (2 lb.)
Pail Label – 2.27 kg (5 lb.)
Packet Label – (Front & Back), 1134 g (40 oz.)
Case Label – 10 x 1134 g (40 oz.)
Pail Label – 11.34 kg (25 lb.)

Pioneer Labeling for NADA 065-496:
TETRASURE 324 (tetracycline hydrochloride)
Packet Label – (Front & Back), 5 oz. (141.7 g)
Case Label – 50 x 5 oz. (141.7 g)
Pail Label – 2 lb. (907.2 g)