Date of Approval: March 14, 2014

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-468

GENTAMED-P for Poultry

Injection

Chickens and Turkeys

Chickens: GentaMed™-P for Poultry Injection is recommended for the prevention of early mortality in day-old chickens associated with *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* susceptible to gentamicin sulfate. Turkeys: As an aid in the prevention of early mortality of 1 to 3-day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.

Sponsored by:

Cross Vetpharm Group Ltd.

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-468

B. Sponsor

Cross Vetpharm Group Ltd.
Broomhill Rd., Tallaght, Dublin 24, Ireland

Drug Labeler Code: 061623

Bimeda, Inc.
Attention: Linda M. Duple
Director, North American Regulatory Affairs
2836 Dolliver Park Avenue
Lehigh, IA 50557

C. Proprietary Name

GENTAMED-P for Poultry

D. Established Name

gentamicin sulfate, USP

E. Pharmacological Category

Anti-microbial

F. Dosage Form

Injection

G. Amount of Active Ingredient

100 mg/mL

H. How Supplied

100 mL multi dose vials

I. Dispensing Status

OTC

J. Dosage Regimen

Chickens: 0.2 milligram of gentamicin per 0.2 milliliter dose

Turkeys: One (1) milligram of gentamicin per 0.2 milliliter dose

K. Route of Administration

Subcutaneously: in the neck

L. Species/Class

Chickens (day-old) and Turkeys (1 to 3-day-old)

M. Indication

Chickens: GentaMed™-P for Poultry Injection is recommended for the prevention of early mortality in day-old chickens associated with *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* susceptible to gentamicin sulfate. Turkeys: As an aid in the prevention of early mortality of 1 to 3-day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.

N. Reference Listed New Animal Drug

GARASOL Injection; gentamicin sulfate; NADA 101-862; Intervet, Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). 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 reference listed new animal drug (RLNAD), 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 demonstrating bioequivalence (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 to demonstrate bioequivalence for the generic product GENTAMED-P (gentamicin sulfate, USP) for Poultry Injection. The generic product is administered as an injectable solution that contains the same active ingredient and excipients in the same concentration and dosage form as the RLNAD. Furthermore this generic new animal drug contains no additional excipients or other changes in formulation from the RLNAD that may significantly affect the bioavailability of the active ingredient. The RLNAD is GARASOL (gentamicin sulfate) Injection, sponsored by Intervet, Inc. under NADA 101-862, and was approved for use in chickens and turkeys on March 28, 1996.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

The following are assigned to this product for chickens and turkeys:

A. Tolerances for Residues:

The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.1 part per million is established for negligible residues of gentamicin sulfate in the uncooked edible tissues of chickens and turkeys, under 21 CFR 556.300.

B. Withdrawal Periods:

Because a waiver from the requirement to demonstrate *in vivo* bioequivalence was granted, the withdrawal periods are those previously assigned to the RLNAD product.

A withdrawal period of 5 weeks has been established for gentamycin sulfate in chickens. A withdrawal period of 9 weeks has been established for gentamycin sulfate in turkeys.

C. Regulatory Method for Residues:

The validated regulatory method for the determination and confirmation of residues of gentamycin sulfate is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to GENTAMED-P for Poultry:

- NOT FOR USE IN HUMANS
- KEEP OUT OF REACH OF CHILDREN

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that GENTAMED-P for Poultry, when used according to the label, is safe and effective.