Date of Approval: December 14, 2011

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-494

GENTAMED
(gentamicin sulfate)

Soluble Powder

Swine

For the control and treatment of colibacillosis, in weanling swine, caused by strains of *Escherichia coli* sensitive to gentamicin and for the control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.

Sponsored by:
Cross Vetpharm Group Ltd.

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I. GENERAL INFORMATION:

A. File Number: ANADA 200-494

B. Sponsor: Cross VetPharm Group Ltd.
Broomhill Rd., Tallaght
Dublin 24, Ireland

Drug Labeler Code: 061623

U.S. Agent: Linda Duple
Bimeda Inc.
2836 Dolliver Park Ave.
Lehigh, IA 50557

C. Proprietary Name: GENTAMED

D. Established Name: gentamicin sulfate

E. Pharmacological Category: Antimicrobial

F. Dosage Form: Soluble powder

G. Amount of Active Ingredient: Each gram of gentamicin sulfate soluble powder contains gentamicin sulfate equivalent to 333.3 milligrams of gentamicin.
120 grams of gentamicin per 360 gram jar

H. How Supplied: 360 gram jar

I. How Dispensed: OTC

J. Dosages: **For control and treatment of colibacillosis**: 25 mg per gallon (1 scoop/240 gallons) drinking water, for three consecutive days. The concentration of the medication should be adjusted in extremely hot or cold weather to ensure a gentamicin dosage of approximately 0.5 mg/lb/day for 3 days.

For control and treatment of dysentery: 50 mg per gallon (1 scoop/120 gallons) for three consecutive days. The concentration of the medication should be adjusted in extremely hot or cold weather to ensure a gentamicin dosage of

	approximately 1.0 mg/lb/day for 3 days. If the condition recurs the medication may be repeated. (*Note*: the jar contains a scoop that provides approximately 18 g of product when level full.)
K. Route of Administration:	Oral (in drinking water)
L. Species/Class:	Swine
M. Indications:	For the control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for the control and treatment of swine dysentery associated with *Treponema hyodysenteriae.*
N. Reference listed new animal drug:	GARACIN Soluble Powder; gentamicin sulfate; NADA 133-836; 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 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 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 for an *in vivo* bioequivalence study for the generic product GENTAMED (gentamicin sulfate) soluble powder. The generic product is a soluble powder administered in drinking water, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The RLNAD is GARACIN (gentamicin sulfate) Soluble Powder, sponsored by Intervet, Inc. under NADA 133-836, and was approved for use in swine on July 24, 1984.

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 swine:

A. Tolerances for Residues: The tolerances established for the RLNAD apply to the generic product, under 21 CFR 556.300.

Tolerances are established for total residues of gentamicin in edible tissues of swine as follows: 0.1 part per million (ppm) in muscle, 0.3 ppm in liver, and 0.4 ppm in fat and kidney.

B. Withdrawal Times: Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product. Do not slaughter treated swine for food for at least 10 days following treatment.

C. Regulatory Method for Residues: The procedure for the determination of gentamicin in tissues is a microbiological determinative procedure, and an HPLC confirmatory procedure for gentamicin has been developed to assay gentamicin in kidney at 0.4 ppm. Since residues of gentamicin as the parent compound and total residues are equal, the marker (parent drug) residue concentration of 0.4 ppm in kidney corresponds to 0.4 ppm of total residue. The validated methods are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

The product labeling contains no specific information regarding safety to humans handling, administering, or exposed to GENTAMED.

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, when used according to the label, is safe and effective for the control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for the control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.