Date of Approval: May 23, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-519

FLORVIO 2.3% Concentrate Solution

florfenicol

Swine

For the treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis,* and *Streptococcus suis* in swine.

Sponsored by:

Novartis Animal Health US, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-519

B. Sponsor

Novartis Animal Health US, Inc.
3200 Northline Ave., suite 300
Greensboro, NC 27408

Drug Labeler Code: 058198

C. Proprietary Name

FLORVIO 2.3% Concentrate Solution

D. Established Name

Florfenicol

E. Pharmacological Category

Antimicrobial

F. Dosage Form:

Oral concentrate solution

G. Amount of Active Ingredient

23 mg florfenicol/mL

H. How Supplied

1 liter plastic bottle containing 0.54 liter solution
4 liter plastic bottle containing 2.17 liter solution

I. Dispensing Status

Rx

J. Dosage Regimen

400 mg per gallon of water (100 parts per million (ppm)) provided in the drinking water for 5 consecutive days.

K. Route of Administration

Oral. For use in swine drinking water only.

L. Species/Class

Swine

M. Indication

For the treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis* in swine.

N. Reference Listed New Animal Drug

NUFLOR 2.3% Concentrate Solution; florfenicol; NADA 141-206; 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, Novartis Animal Health US, Inc., was granted a waiver from the requirement to demonstrate bioequivalence for the generic product FLORVIO (florfenicol) 2.3% Concentrate Solution. The generic product, administered as an oral concentrate solution containing 23 mg florfenicol per mL reconstituted in drinking water to a concentration of 400 mg/gallon, 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 bioavailability of the active ingredient. The RLNAD is NUFLOR (florfenicol) 2.3% Concentrate Solution and was approved for use in swine on September 4, 2002.

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. A tolerance of 2.5 ppm is established for parent florfenicol (the marker residue) in

liver (the target tissue), and 0.2 ppm in the muscle, under 21 CFR 556.283. The acceptable daily intake (ADI) for total residues of florfenicol is 10 micrograms per kilogram of body weight per day.

B. Withdrawal Times:

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

A withdrawal period of 16 days has been established for florfenicol in swine.

C. Regulatory Method for Residues:

The validated regulatory method for the determination and confirmation of residues of florfenicol 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 FLORVIO 2.3% Concentrate Solution:

"For Use in Animals Only", "For Oral Use in Swine Drinking Water Only", "Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian", "NOT FOR HUMAN USE", "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 FLORVIO 2.3% Concentrate Solution, when used according to the label, is safe and effective.