Date of Approval: December 21, 2016

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-589

FLORCON

florfenicol

2.3% Concentrate Solution

Swine

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

Sponsored by:

Med-Pharmex, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-589

B. Sponsor

Med-Pharmex, Inc.
2727 Thompson Creek Rd.
Pomona, CA 91767-1861

Drug Labeler Code: 054925

C. Proprietary Name

FLORCON

D. Product Established Name

Florfenicol

E. Pharmacological Category

Antimicrobial

F. Dosage Form

2.3% oral concentrate solution

G. Amount of Active Ingredient

23 mg florfenicol/mL

H. How Supplied

One gallon plastic bottle with a 2.2 liter fill

I. Dispensing Status

Rx

J. Dosage Regimen

Dilute to 400 mg/gallon of water (100 ppm) and administer as the only source of drinking water for five (5) consecutive days.

K. Route of Administration

Oral. For use in swine drinking water only.

L. Species/Class

Swine

M. Indication(s)

FLORCON 2.3% Concentrate Solution is indicated 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®; (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 (GADPTRA) 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 (RLNAD)). 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 period 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, Med-Pharmex, Inc., was granted a waiver from the requirement to demonstrate bioequivalence for the generic product FLORCON (florfenicol) 2.3% concentrate solution. The generic drug product is a 2.3% concentrate solution, 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, sponsored by Intervet Inc., under NADA 141-206 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. Acceptable Daily Intake and Tolerances for Residues:

The acceptable daily intake (ADI) for total residues of florfenicol is 10 micrograms per kilogram of body weight per day. The tolerances established for the RLNAD

apply to the generic product. A tolerance of 2.5 ppm is established for florfenicol (the marker residue) in liver (the target tissue), and 0.2 ppm in muscle, under 21 CFR 556.283.

B. Withdrawal Period(s):

Because a waiver from the requirement to demonstrate bioequivalence was granted, the withdrawal periods 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 FLORCON:

"For Use in Animals Only", "For Oral Use in Swine Drinking Water Only", "Federal 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", and "This product contains material that can be irritating to skin and eyes. Avoid direct contact with skin, eyes and clothes. In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. Consult a physician if irritation persists. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information."

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 FLORCON, when used according to the label, is safe and effective.

Additionally, data demonstrate that residues in food products derived from species treated with FLORCON will not represent a public health concern when the product is used according to the label.