Date of Approval: July 9, 2015

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-582

LONCOR 300

Florfenicol

Injectable Solution

Beef and Non-lactating Dairy Cattle

For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacilosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*

For the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*

Sponsored by:

Orkeo USA Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-582

B. Sponsor

Orkeo USA, Inc.
77 Water Street
7th and 8th Floors
New York, NY 10005

Drug Labeler Code: 086050

C. Proprietary Name

LONCOR 300

D. Product Established Name

Florfenicol

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

300 mg/mL

H. How Supplied

100 mL, 250 mL, and 500 mL vials

I. Dispensing Status

Rx

J. Dosage Regimen

For treatment of bovine respiratory disease (BRD) and bovine interdigital phlegmon (foot rot): LONCOR 300 mg/mL Injectable Solution should be administered by intramuscular injection to cattle at a dose rate of 20 mg/kg body weight (3 mL/100 lbs). A second dose should be administered 48 hours later. Alternatively, LONCOR 300 mg/mL Injectable Solution can be administered by a single subcutaneous (SC) injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. The injection should be given only in the neck.

For control of respiratory disease in cattle at high-risk of developing BRD: LONCOR 300 mg/mL Injectable Solution should be administered by a single subcutaneous injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. The injection should be given only in the neck.

K. Route of Administration

Intramuscular, subcutaneous

L. Species/Class

Beef and non-lactating dairy cattle

M. Indications

LONCOR 300 is indicated for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*, and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteriodes melaninogenicus*. Also, it is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

N. Reference Listed New Animal Drug

NUFLOR Injectable Solution; florfenicol; NADA 141-063; 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, Orkeo USA Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product LONCOR 300 (florfenicol) 300 mg/mL injectable solution. The generic drug product is a 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) Injectable Solution, sponsored by Intervet, Inc. under NADA 141-063, and was approved for use in beef and non-lactating dairy cattle on May 31, 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 beef and non-lactating dairy cattle:

A. Acceptable Daily Intake and Tolerances for Residues:

The acceptable daily intake (ADI) for total residues of florfenicol is 10 micrograms per kilogram body weight per day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 3.7 parts per million (ppm) is established for florfenicol amine (the marker residue) in liver (the target tissue) and a tolerance of 0.3 ppm is established for florfenicol amine in muscle under 21 CFR 556.283.

B. Withdrawal Periods:

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 28 days has been established for florfenicol in beef and non-lactating dairy cattle when administered as an intramuscular (IM) injection. A withdrawal period of 38 days has been established for florfenicol in beef and non-lactating dairy cattle when administered as a subcutaneous (SC) injection.

C. Regulatory Method for Residues:

The validated regulatory method for the determination and confirmation of residues of florfenicol amine is described in the RLNAD FOI Summary (NADA 141-063, dated May 31, 1996) and 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 LONCOR 300:

WARNINGS: NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN. This product contains materials that can be irritating to skin and eyes. Avoid direct contact with skin, eyes, and clothing. 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. Accidental

injection of this product may cause local irritation. Consult a physician immediately. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. For customer service, adverse effects reporting, and/or a copy of the MSDS, call 1-800-422-9874.

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 LONCOR 300, when used according to the label, is safe and effective.

Additionally, data demonstrate that residues in food products derived from species treated with LONCOR 300 will not represent a public health concern when the product is used according to the label.