Date of Approval: January 9, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-828

nixiFLOR™

(florfenicol and flunixin meglumine)

Injectable solution

Beef and non-lactating dairy cattle

nixiFLOR™ is indicated for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle.

Sponsored by:

Parnell Technologies Pty. Ltd.

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-828

B. Sponsor

Parnell Technologies Pty. Ltd.
unit 4, 476 Gardeners Rd.
Alexandria, New South Wales 2015, Australia

Drug Labeler Code: 068504

C. Proprietary Name

nixiFLOR™

D. Drug Product Established Name

florfenicol and flunixin meglumine

E. Pharmacological Category

Antimicrobial and non-steroidal anti-inflammatory drug

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

300 mg florfenicol and 16.5 mg flunixin (as flunixin meglumine) per mL

H. How Supplied

100, 250, and 500 mL sterile, multiple-dose, glass vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

nixiFLOR™ should be administered once by subcutaneous injection at a dose rate of 40 mg florfenicol/kg body weight and 2.2 mg flunixin/kg body weight (6 mL/100 lb). Do not administer more than 10 mL at each site. The injection should be given only in the neck. Injection sites other than the neck have not been evaluated.

nixiFLOR™ Dosage Guide*	
ANIMAL WEIGHT (lbs)	**DOSAGE (mL)**
100	6.0
200	12.0

300	18.0
400	24.0
500	30.0
600	36.0
700	42.0
800	48.0
900	54.0
1000	60.0

*Do not administer more than 10 mL at each site.

K. Route of Administration

Subcutaneous injection

L. Species/Classes

Beef and non-lactating dairy cattle

M. Indications

nixiFLOR™ is indicated for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle.

N. Reference Listed New Animal Drug (RLNAD)

Resflor GOLD®; florfenicol and flunixin meglumine; NADA 141-299; Intervet, Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). 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. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Parnell Technologies Pty. Ltd., was granted a biowaiver for the generic product nixiFLOR™ (florfenicol and flunixin meglumine) injectable solution. The generic drug product is an injectable solution, contains the same active ingredients in the same concentrations and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Resflor GOLD® (florfenicol and flunixin meglumine) injectable solution sponsored by Intervet, Inc., under NADA 141-299, and was approved for use in beef and non-lactating dairy cattle on November 23, 2009.

III. HUMAN FOOD SAFETY

The tolerances for residues and withdrawal period established for the RLNAD apply to the generic product. 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 µg/kg of 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 0.3 ppm in muscle, under 21 CFR 556.283.

The ADI for total residues of flunixin is 0.72 µg/kg of body weight per day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 125 parts per billion (ppb) is established for flunixin free acid (the marker residue) in liver (the target tissue), and 25 ppb in muscle, under 21 CFR 556.286.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 38 days has been established for florfenicol and flunixin meglumine in beef and non-lactating dairy cattle.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of florfenicol and flunixin meglumine is on file at the Center for Veterinary Medicine, 5001 Campus Drive, College Park, MD 20740. To obtain a copy of the analytical method, please submit a Freedom of Information request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to nixiFLOR™:

WARNINGS: NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN. This product contains material 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 Safety Data Sheet (SDS) contains more detailed occupational safety information. For customer service, adverse effects reporting, and/or a copy of the SDS, contact Parnell at 1-800-887-2763.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that nixiFLOR™, when used according to the

label, is safe and effective for the conditions of use in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from beef and non-lactating dairy cattle treated with nixiFLOR™ will not represent a public health concern when the product is used according to the label.