Date of Approval: April 3, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-791

Flunine-S™

(flunixin meglumine injection)

Injectable solution

Swine

Flunine-S™ (flunixin meglumine injection) is indicated for the control of pyrexia associated with swine respiratory disease.

Sponsored by:

Cronus Pharma Specialities India Private Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-791

B. Sponsor

Cronus Pharma Specialities India Private Ltd.
Plot No.9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd.
Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy
Hyderabad, Telangana, 500108, India

Drug Labeler Code: 069043

C. Proprietary Name

Flunine-S™

D. Drug Product Established Name

flunixin meglumine injection

E. Pharmacological Category

Nonsteroidal anti-inflammatory drug

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

50 mg flunixin (equivalent to 83 mg flunixin meglumine) per mL

H. How Supplied

100 mL, 250 mL, and 500 mL multi-dose vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

2.2 mg/kg (1 mg/lb; 2 mL per 100 lbs) body weight given by a single intramuscular administration. The injection should be given only in the neck musculature with a maximum of 10 mL per site.

K. Route of Administration

Intramuscular injection

L. Species/Class

Swine

M. Indication

Flunine-S™ (flunixin meglumine injection) is indicated for the control of pyrexia associated with swine respiratory disease.

N. Reference Listed New Animal Drug (RLNAD)

Banamine®-S; flunixin meglumine injection; NADA 101-479; 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, Cronus Pharma Specialities India Private Ltd., was granted a biowaiver for the generic product Flunine-S™ (flunixin meglumine injection). The generic drug product is an injectable 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 Banamine®-S (flunixin meglumine injection), sponsored by Intervet, Inc., under NADA 101-479, and was approved for use in swine on November 1, 2005.

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 swine:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (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 30 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 12 days has been established for flunixin meglumine injection in swine.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of flunixin meglumine injection is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. 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 Flunine-S™:

The labeling does not contain user safety information.

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 Flunine-S™, 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 swine treated with Flunine-S™ will not represent a public health concern when the product is used according to the label.