Date of Approval: December 22, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-764

EnroPro™ 22.7

(enrofloxacin)

Injectable Solution

Dogs

EnroPro™ 22.7 (enrofloxacin) Injectable Solution is indicated for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

Sponsored by:

Cronus Pharma Specialities India Private Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-764

B. Sponsor

Cronus Pharma Specialities India Private Ltd.,
Sy No–99/1, M/s GMR Hyderabad Aviation SEZ Ltd.,
Mamidipalli Village, Shamshabad Mandal,
Ranga Reddy, Hyderabad, Telangana, 501218, India

Drug Labeler Code: 069043

C. Proprietary Name

EnroPro™ 22.7

D. Drug Product Established Name

enrofloxacin

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

22.7 mg/mL (2.27%)

H. How Supplied

20 mL and 50 mL vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

EnroPro™ 22.7 Injectable Solution may be used as the initial dose at 2.5 mg/kg. It should be administered intramuscularly (IM) as a single dose, followed by initiation of enrofloxacin tablet therapy.

EnroPro™ 22.7 Injectable Solution may be administered as follows:

Weight of Animal	**EnroPro™ 22.7 Injectable Solution* 2.5 mg/kg**
9.1 kg (20 lb)	1.00 mL
27.2 kg (60 lb)	3.00 mL

*The initial EnroPro™ 22.7 Injectable administration should be followed 12 hours later by initiation of enrofloxacin tablet therapy.

K. Route of Administration

Intramuscular injection

L. Species/Class

Dogs

M. Indication

EnroPro™ 22.7 (enrofloxacin) Injectable Solution is indicated for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

N. Reference Listed New Animal Drug (RLNAD)

Baytril®; enrofloxacin; NADA 140-913; Elanco US 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 EnroPro™ 22.7 (enrofloxacin) injectable solution. 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 Baytril® (enrofloxacin) injectable solution, 2.27%, sponsored by Elanco US Inc., under NADA 140-913, and was approved for use in dogs on May 4, 1990.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to EnroPro™ 22.7:

For use in animals only. Keep out of reach of children.

Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. In case of dermal contact, wash skin with soap and water. Consult a physician if irritation persists following ocular or dermal exposure. Individuals with a history of hypersensitivity to quinolones should avoid this product. In humans, there is a risk of user photosensitization within a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Cronus Pharma LLC at 1-844-227-6687 or 1-844-2-CRONUS. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

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 EnroPro™ 22.7, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.