

Date of Approval: August 2, 2021

# FREEDOM OF INFORMATION SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-708  
Enrofloxacin  
Injectable Solution  
Dogs

Enrofloxacin Injectable Solution is indicated for the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

Sponsored by:  
Felix Pharmaceuticals Pvt. Ltd.

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**I. GENERAL INFORMATION**

**A. File Number**

ANADA 200-708

**B. Sponsor**

Felix Pharmaceuticals Pvt. Ltd.  
25-28 North Wall Quay  
Dublin 1, Ireland

Drug Labeler Code: 086101

U.S. Agent Name and Address:  
Dr. James H. Schafer  
Schafer Veterinary Consultants, LLC  
800 Helena Court  
Fort Collins, CO 80524

**C. Proprietary Name**

Enrofloxacin

**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 vial

**I. Dispensing Status**

Prescription (Rx)

**J. Dosage Regimen**

Enrofloxacin 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. The initial enrofloxacin injectable administration should be followed 12 hours later by initiation of enrofloxacin tablet therapy.

**K. Route of Administration**

Intramuscular (IM) injection

**L. Species/Class**

Dogs

**M. Indication**

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 (GADPTA) 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 GADPTA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Felix Pharmaceuticals Pvt. Ltd., was granted a biowaiver for the generic product 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, 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 Enrofloxacin:

**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 Felix Pharmaceuticals Private Limited at 1-833-571-1525. 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 Enrofloxacin, when used according to the label, is safe and effective for the indications listed in Section I.M. above.