Date of Approval: May 8, 2014

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-513

ENROFLOX Injection for Dogs 2.27%

enrofloxacin

Injectable Solution

Dogs

For the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

Sponsored by:

Norbrook Laboratories, Ltd.

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-513

B. Sponsor

Norbrook Laboratories, Ltd.
Station Works
Newry BT35 6JP
Northern Ireland

Drug Labeler Code: 055529

U.S. Agent
S. Lee Whaley
Norbrook, Inc.
9733 Loiret Boulevard
Lenexa, KS 66219

C. Proprietary Name

ENROFLOX Injection for Dogs 2.27%

D. Established Name

enrofloxacin

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

22.7 mg/mL

H. How Supplied

20 mL and 100 mL vials

I. Dispensing Status

Rx

J. Dosage Regimen

Administer intramuscularly (IM) as a single injection at the rate of 1 mL/9.1 kg (20 lb) to provide 2.5 mg/kg (1.13 mg/lb). The injectable dose should be followed by oral tablet treatment in 12 hours.

K. Route of Administration

Intramuscular

L. Species/Class

Dogs

M. Indication

For the management of diseases in dogs associated with bacteria susceptible to enrofloxacin

N. Reference Listed New Animal Drug

BAYTRIL Antibacterial Injectable Solution; enrofloxacin; NADA 140-913; Bayer HealthCare LLC, Animal Health Division

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 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). 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 reference listed new animal drug (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 time 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, Norbrook Laboratories, Ltd. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product ENROFLOX (enrofloxacin) Injection for Dogs 2.27%. The generic product is administered intramuscularly as 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) Antibacterial Injectable Solution, and was approved for use in dogs on May 4, 1990.

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:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs, which are not food producing animals.

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 ENROFLOX Injection for Dogs 2.27%:

> 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 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 risk of user photosensitization within a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight. For customer service, to obtain Material Safety Data Sheet (MSDS) or to report adverse reactions call Norbrook at 1-866-591-5777.

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 ENROFLOX Injection for Dogs 2.27%, when used according to the label, is safe and effective.