Date of Approval: February 28, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-495

ENROFLOX 100

(enrofloxacin)

Injectable Solution

Beef and Non-Lactating Dairy Cattle

Swine

For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolitica*, *Pasturella multocida* and *Histophilus somni* in beef and non-lactating dairy cattle (multiple-day therapy).

For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis* and *Streptococcus suis*.

Sponsored by:

Norbrook Laboratories, Ltd.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-495

B. Sponsor

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

Drug Labeler Code: 055529

US representative:
Norbrook, Inc.
9733 Loiret Boulevard
Lenexa, KS 66219

C. Proprietary Name

ENROFLOX 100

D. Established Name

Enrofloxacin

E. Pharmacological Category

Antimicrobial

F. Dosage Form:

Injectable solution

G. Amount of Active Ingredient

100 mg/mL

H. How Supplied

100 and 250 mL bottles

I. Dispensing Status

Rx

J. Dosage Regimen

Cattle: 2.5 – 5.0 mg/kg of body weight (1.1 – 2.3 mL/100 lb). Treatment should be repeated at 24-hour intervals for three days. Additional treatments may be given on Days 4 and 5 to animals that have shown clinical improvement but not total recovery.

Swine: 7.5 mg/kg of body weight (3.4 mL/100 lb) once.

K. Route of Administration

Subcutaneous injection

L. Species/Class

Cattle (beef and non-lactating dairy) and swine

M. Indications

Cattle: For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolitica*, *Pasturella multocida* and *Histophilus somni* in beef and non-lactating dairy cattle (multiple-day therapy).

Swine: For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis* and *Streptococcus suis*.

N. Reference Listed New Animal Drug

BAYTRIL 100; (enrofloxacin); NADA 141-068; 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 an *in vivo* bioequivalence study. (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 *in vivo* bioequivalence study for the generic product ENROFLOX 100 (enrofloxacin) injectable solution. The generic product is administered as 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, BAYTRIL 100 (enrofloxacin) injectable solution, sponsored by Bayer HealthCare LLC, Animal Health Division, under NADA 141-068, was originally approved for use in cattle on July 24, 1998, and was approved for use in swine on March 14, 2008.

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:

Because a waiver from the requirement to demonstrate *in vivo* bioequivalence was granted, the tolerances for residues and the withdrawal times previously established for the RLNAD apply to the generic product.

A. Tolerances for Residues:

A tolerance of 0.1 part per million (ppm) is established for desethylene ciprofloxacin residues (the marker residue) in the uncooked edible tissues of the cattle liver (the target tissue), and 0.5 ppm enrofloxacin (the marker residue) in the swine liver (the target tissue), under 21 CFR 556.226. The acceptable daily intake (ADI) for total residues of enrofloxacin is three micrograms per kilogram of body weight per day.

B. Withdrawal Times:

Cattle: Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. A withdrawal period has not been established for this product in preruminating calves.

Swine: Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

C. Regulatory Method for Residues:

The validated regulatory analytical methods for desethylene ciprofloxacin residues (the marker residue) in cattle liver and enrofloxacin (the marker residue) in swine liver are on file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to ENROFLOX 100:

"For use in animals only. Keep out of the 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 exposures. 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. For customer service, to obtain a copy of the 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 100, when used according to the label, is safe and effective.