Date of Approval: July 28, 2015

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-495

ENROFLOX 100

Enrofloxacin injectable solution

Beef and non-lactating dairy cattle

This supplement provides for the addition of new indications, "Single-Dose Therapy: ENROFLOX 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*"

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

U.S. Representative:
S. Lee Whaley, M.S.
Norbrook, Inc.
9401 Indian Creek Parkway, Suite 680
Overland Park, KS 66210

C. Proprietary Name

ENROFLOX 100

D. Product Established Name

enrofloxacin injectable solution

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

Single-Dose Therapy (BRD Treatment): Administer, by subcutaneous injection, a single dose of 7.5 - 12.5 mg/kg of body weight (3.4 - 5.7 mL/100 lb).

Single-Dose Therapy (BRD Control): Administer, by subcutaneous injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lb).

K. Route of Administration

Subcutaneous injection

L. Species/Class

Beef and non-lactating dairy cattle

M. Indications

Cattle - Single-Dose Therapy: ENROFLOX 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of BRD in beef and non- lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*.

N. Reference Listed New Animal Drug

BAYTRIL 100 Injectable Solution; enrofloxacin; NADA 141-068; Baytril Healthcare LLC, Animal Health Division.

O. Effect of Supplement

This supplement provides for the addition of new indications, "Single-Dose Therapy: ENROFLOX 100 is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of BRD in beef and non- lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*."

II. BIOEQUIVALENCE:

This supplemental ANADA does not require re-evaluation of bioequivalence.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this supplemental approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this supplemental approval.

V. HUMAN FOOD SAFETY:

The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues:

The acceptable daily intake (ADI) for total residues of enrofloxacin is 3 micrograms per kilogram of body weight per day. The tolerances established for

the RLNAD apply to the generic product. A tolerance of 0.1 part per million is established for desethylene ciprofloxacin (the marker residue) in liver (the target tissue) under 21 CFR 556.226.

B. Withdrawal Period(s):

Because a waiver from the requirement to demonstrate bioequivalence was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 28 days has been established for enrofloxacin in cattle. A withdrawal period has not been established for this product in preruminating calves.

C. Regulatory Method for Residues:

The validated regulatory method for the determination and confirmation of residues of enrofloxacin is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

CVM did not require user safety studies for this supplemental approval.

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

"**Not for use in humans. 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.