Date of Approval: July 6, 2018

# FREEDOM OF INFORMATION SUMMARY

## SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-495

Enroflox® 100

enrofloxacin

Injectable Solution

Swine

The effect of the supplement provides for the addition of the use of the drug via intramuscular injection in swine, the addition of two pathogens, *Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae,* to the swine respiratory disease (SRD) treatment and control indications and the addition of indications for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

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 Agent:
Dr. Bill Zollers
Norbrook, Inc.
9401 Indian Creek Parkway
Suite 680
Overland Park, Kansas 66210

### C. Proprietary Name

Enroflox® 100

### D. Product Established Name

enrofloxacin

### E. Pharmacological Category

Antimicrobial

### F. Dosage Form

Injectable solution

### G. Amount of Active Ingredient

Each mL contains 100 mg of enrofloxacin

### H. How Supplied

100 mL, 250 mL and 500 mL vials

### I. Dispensing Status

Rx

### J. Dosage Regimen

Swine:

Colibacillosis: Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lb). For the

control of colibacillosis, administration should be initiated within the first 60 days post-weaning when clinical signs are present in at least 2% of the animals in the group. If no improvement is noted within 48 hours, the diagnosis should be reevaluated.

Swine respiratory disease (SRD): Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lb).

**K. Route of Administration**

Intramuscular and subcutaneous injection

**L. Species/Class**

Swine

**M. Indications**

For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, *Streptococcus suis*, *Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae*. For the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

**N. Reference Listed New Animal Drug**

Baytril® 100; enrofloxacin; NADA 141-068; Bayer HealthCare LLC, Animal Health Division

**O. Effect of Supplement**

This supplement provides for the addition of the use of the drug via intramuscular injection in swine, the addition of two pathogens, *Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae*, to the swine respiratory disease (SRD) treatment and control indications and the addition of indications for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

## 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 (GADPTRA) 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 (RLNAD)). 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 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 period for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the

requirement of performing 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 perform an *in* vivo bioequivalence study for the generic product Enroflox® 100 (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® 100 (enrofloxacin) injectable solution, sponsored by Bayer HealthCare LLC, Animal Health Division, under NADA 141-068 and, was approved for use in swine on March 14, 2008.

## 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:

CVM did not require human food safety studies for this supplemental approval.

The following are assigned to this product for swine:

### A. Acceptable Daily Intake and Tolerances for Residues:

The acceptable daily intake (ADI) for total residues of enrofloxacin is three micrograms per kilogram of body weight per day as they appear in 21 CFR 556.226. The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.5 part per million (ppm) is established for enrofloxacin (the marker residue) in the swine liver (the target tissue), under 21 CFR 556.226.

### B. Withdrawal Times:

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

### C. Analytical Method for Residues:

The validated regulatory analytical methods for analysis of residues of enrofloxacin (the marker residue) in swine liver are on file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, please submit a Freedom of Information Summary request to:
https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

## 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 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.

## 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.

Additionally, data demonstrate that residues in food products derived from species treated with Enroflox® 100 will not represent a public health concern when the product is used according to the label.