

Date of Approval: December 6, 2010

## FREEDOM OF INFORMATION (FOI) SUMMARY

### SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-026

PENNOX 343

(oxytetracycline hydrochloride)

For use in chickens, turkeys, finfish, swine, calves, beef cattle, non-lactating dairy cattle, sheep, and honey bees.

This supplement provides for the addition of two new species (finfish and honey bees) and their corresponding indications. Finfish are indicated for the marking of skeletal tissues in finfish fry and fingerlings, and honey bees are indicated for control of American Foulbrood caused by *Paenibacillus larvae* and for use in European Foulbrood caused by *Streptococcus pluton*.

Sponsored by:  
Pennfield Oil Co.

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. File Number: ANADA 200-026
- b. Sponsor: Pennfield Oil Co.  
14040 Industrial Rd.  
Omaha, NE 68144
- Drug Labeler Code: 048164
- c. Established Names: Oxytetracycline hydrochloride
- d. Proprietary Names: PENNOX 343
- e. Dosage Form: Soluble powder
- f. How Supplied: 23.9 oz packet (677.6 g) and 35.9 lb (16.3 kg) shipping carton as 24 x 23.9 oz packets. A previously approved 4.78 oz size packet is no longer marketed and is not subject to this approval.
- g. How Dispensed: OTC
- h. Amount of Active Ingredient: Each 23.9 oz packet contains 512 grams of oxytetracycline hydrochloride.
- i. Route of Administration: Oral use in honey bees.
- Immersion for treatment of finfish fry and fingerlings.
- j. Species/Class: Finfish fry and fingerlings and honey bees.
- For a full list of previously approved species see FOI Summary dated March 13, 1997.
- k. Recommended Dosage: **Dosage information is unchanged in all other labeled species. For more information see Freedom of Information (FOI) Summary dated March 13, 1997.**

**The following information has been added to the labeling:**

**FINFISH–**

Immerse in 200-700 milligrams of oxytetracycline hydrochloride (buffered)/L of water for 2-6 hours.

**HONEY BEES –**

200 milligrams of oxytetracycline hydrochloride/colony.

Administer in 3 applications of 1:1 sugar syrup (equal parts of sugar and water weight to weight) or 3 dustings at 4- to 5- day intervals. Apply dust on the outer parts or ends of the frames.

l. Pharmacological Category:

Antimicrobial

m. Indications:

**Indication information is unchanged in all other labeled species. For more information see FOI Summary dated March 13, 1997.**

**The following information has been added to the labeling:**

**FINFISH–**

For the marking of skeletal tissues in finfish fry and fingerlings.

**HONEY BEES –**

For the control of American foulbrood caused by *Paenibacillus larvae*.

For use in European Foulbrood caused by *Streptococcus pluton*.

n. Pioneer Products:

TERRAMYCIN-343; oxytetracycline hydrochloride; NADA 008-622; Pfizer, Inc.

o. Effect of Supplement

This supplement provides for the addition of new species (finfish and honey bees) and their corresponding indications to all labeling components.

**2. TARGET ANIMAL SAFETY AND EFFECTIVENESS:**

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 (pioneer product). 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 pioneer, 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, Pennfield Oil Co. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product PENNOX 343 (oxytetracycline hydrochloride) soluble powder. The generic product is administered as a soluble powder and by immersion, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product TERRAMYCIN-343 (oxytetracycline hydrochloride) soluble powder, the subject of Pfizer, Inc., NADA 008-622, was approved on September 17, 1952.

### **3. HUMAN SAFETY:**

- a. Human Warnings are provided on the product label as follows: **“Keep out of the reach of children. Not for human use.”**
- b. The following are assigned to this product for honey bees and finfish fry and fingerlings:
  - **Tolerances for Residues:**

The tolerances established for the reference listed new animal drug apply to the generic product. A tolerance of 6 parts per million (ppm) is established for residues (the marker residue) in the uncooked edible tissues of the liver, 2 ppm in the muscle, 12 ppm in fat and kidney, and 0.3 ppm in milk under 21 CFR 556.500. The acceptable daily intake (ADI) for total tetracycline residues (chlortetracycline, oxytetracycline, and tetracycline) is 25 micrograms per kilogram of body weight per day.
  - **Withdrawal Time:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times established for the pioneer product is also assigned to the generic product. For this reason, withdrawals have been established for PENNOX 343; oxytetracycline in honeybees (21 CFR 520.1660d) and finfish fry and fingerlings (21 CFR 529.1660). In honey bees the drug should be fed early in the spring or fall and consumed by the bees before main honey flow begins, to avoid contamination of the production honey.

Remove the drug at least 6 weeks prior to main honey flow. In finfish fry and fingerlings an additional withdrawal time beyond the grow-out period is not needed.

- **Regulatory Method for Residues:**

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Bacillus cereus var mycoides* (ATCC 11778). The method is found in Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols, Revised October 1968, Reprinted December 1974, Nation Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204. The method is on file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

#### **4. AGENCY CONCLUSIONS:**

This ANADA filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that PENNOX 343, when used under its proposed conditions of use, is safe and effective for its labeled indications.

#### **5. ATTACHMENTS:**

Generic Labeling for ANADA 200-026

23.9 oz (677.6 g) packet

35.9 lb (16.3 kg) (24 x 23.9 oz packets) shipping carton

Pioneer Labeling for NADA 008-622

9.55 oz (270.7 g) packet