Date approval letter:Feb. 5, 1999

SUPPLEMENTAL FREEDOM OF INFORMATION SUMMARY

Oxytetracycline hydrochloride

PennField Oil Company
14040 Industrial Road
Omaha, Nebraska 68144

SUPPLEMENTAL FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION **ANADA 200-026**

ANADA/GENERIC SPONSOR--
PennField Oil Company
14040 Industrial Road
Omaha, Nebraska 68144

a. Established Name: Oxytetracycline hydrochloride

b. Trade Name/Proprietary Name: Pennox 343

c. Dosage Form: Soluble Powder for drinking water

d. How Supplied: 4.78 oz packets and 23.9 oz packets (new)

e. How Dispensed: OTC

f. Amount of Active Ingredients: Each packet contains oxytetracycline hydrochloride equivalent to 102.4 gram or 512 grams

g. Species: Chickens, Turkeys, Cattle, Swine, Sheep

h. Labeled Dosage and Indications: (Refer to attached labeling for additional details on mixing instructions)
Turkeys: For the control and treatment of hexamitiasis caused by *Hexamita meleagridis;* infectious synovitis caused by *Mycoplasma synoviae;* growing turkeys-complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

i. Effect of the Supplements: Revised withdrawal period (0-day) in turkeys & additional package size of 23.9 oz.

j. Pioneer Product "Listed" Product: Terramycin® Soluble Powder, NADA 8-622

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

No further effectiveness or safety data were required.

3. HUMAN FOOD SAFETY

A. Tolerance

The tolerances established for the pioneer product apply to the generic product. Tolerances are established for the sum of residues in tissues of cattle, beef calves, dairy calves, swine, chickens, turkeys as follows:
(a) 2 ppm in muscle
(b) 6 ppm in liver
(c) 12 ppm in fat and kidney

B. Study to Establish a Withdrawal Time

Palatability and Residue Depletion study-Oxytetracycline in turkeys.

Study design: Thirty-two turkeys were used in the study. Four birds (two males and two females) were assigned to each of six treatment groups. Turkeys in the treatment groups were feed medicated drinking water containing oxytetracycline HCl to provide 25 mg/lb body weight. Treatment continued for 14 days. Eight animals served as untreated controls. Animals were slaughtered at 1, 3, 5, 7, 9, and 12 hours withdrawal. At slaughter samples of liver, muscle and skin/fat were collected for analysis using the official regulatory assay. Residue values are summarized in Table 1.

Table 1: Mean tissue residue data summary

Withdrawal (hours)	Liver	Muscle	Skin/Fat
Control	-	-	-
1	0.78±0.14	0.37±0.10	0.77±0.62
3	0.73±0.20	0.38±0.09	0.51±0.20
5	0.37±0.08	0.31±0.08	0.33±0.10
7	0.43±0.14	0.33±0.03	0.38±0.06
9	0.47±0.16	0.30±0.04	0.41±0.17
12	0.26	<0.25	0.53±0.19

C. Calculating the Withdrawal Time

Using the Agency's statistical tolerance limit algorithm to evaluate the 99th percentile with 95% confidence and the revised tetracycline tolerances stated in section "A", a zero day withdrawal is calculated for the use of oxytetracycline soluble powder in turkeys. All of the residue values in all of the tissues at all of the sampling times are less than their respective revised tolerances.

Regulatory Method:

The analytical method for the determination of oxytetracycline hydrochloride in tissues uses a microbiological assay procedure. This method is found in the Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols, revised October 1968, reprinted December 1974, National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204.

4. AGENCY CONCLUSIONS

This supplemental ANADA submitted 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 the labeled indications.

Under the Center's supplemental approval policy, (21 CFR 514.106(b)(1)(iv), the approval of the addition of a new package size is considered a Category I change; therefore, this action did not require a reevaluation of the safety and effectiveness data in the parent application. However, the approval of the revised withdrawal time for turkeys is considered a Category II change under the approval policy 21 CFR 514.106(b)(2)(x). This approval did cause a reevaluation of the human food safety data in the parent application and the revised withdrawal period was based on the revised tolerances for oxytetracycline; 2 ppm in muscle, 6 ppm in liver and 12 ppm in fat and kidney.

LABELING:

4.78 oz and 23.9 oz packets