

HFA 305 DMB

FEB -5 1999

Date approval letter \_\_\_\_\_

**SUPPLEMENTAL FREEDOM OF INFORMATION SUMMARY**

Oxytetracycline hydrochloride

PennField Oil Company  
14040 Industrial Road  
Omaha, Nebraska 68144

ANADA-200-026

FOIS-1

**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<sup>®</sup> 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 99<sup>th</sup> 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, 5 ppm in liver and 12 ppm in fat and kidney.

**LABELING:**

4.78 oz and 23.9 oz packets

**INDICATIONS AND DIRECTIONS FOR USE**

For the control of the following poultry diseases caused by organisms susceptible to oxytetracycline: Add the following amount to two gallons of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

<b>CHICKENS</b>	Infectious synovitis caused by <i>Mycoplasma synoviae</i>	DOSAGE	PACKS / 2 GALLONS STOCK SOLUTION
	Chronic respiratory disease (CRD) and air-sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i>	200-400 mg / gal	1/2-1
	Fowl cholera caused by <i>Pasteurella multocida</i>	400-800 mg / gal	1-2
<b>TURKEYS</b>	Hexamitiasis caused by <i>Hexamita meleagridis</i>	400-800 mg / gal	1-2
	Infectious synovitis caused by <i>Mycoplasma synoviae</i>	200-400 mg / gal	1/2-1
	Growing Turkeys - Complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis)	400 mg / gal 25 mg / lb body weight daily	1 varies with age & water consumption (1 pack will treat 4096 pounds of turkeys)

Medicate continuously at the first clinical signs of disease and continue for 7 to 14 consecutive days. If improvement is not noted with 24 to 48 hours, consult a veterinarian or a diagnostic laboratory to determine diagnosis and advice on dosage.

**WARNING:** Do not administer to swine, cattle or sheep within 5 days of slaughter. Zero day withdrawal in chickens and turkeys. Do not administer to chickens or turkeys producing eggs for human consumption. **RECOMMENDED STORAGE:** STORE BELOW 77 F (25 C) Livestock Drug-Not For Human Use **KEEP OUT OF REACH OF CHILDREN**

Distributed by: PennField Animal Health, Omaha, NE 68144

TAKE TIME



OBSERVE DIRECTIONS

CUT HERE TO OPEN

# PENMOX 343

..... OXYTETRACYCLINE HCl

## SOLUBLE POWDER

A broad-spectrum antibiotic for control and treatment of specific diseases in poultry, cattle, swine and sheep.

Each packet contains 102.4 grams of oxytetracycline HCl and will make:

- 512 gallons (1938 L) containing 200 mg oxytetracycline HCl per gallon
- 256 gallons (969 L) containing 400 mg oxytetracycline HCl per gallon
- 128 gallons (484 L) containing 800 mg oxytetracycline HCl per gallon

Distributed by

**Net Contents: 4.78 OZ**  
ANADA 200-026; Approved by FDA

**PennField**  
ANIMAL HEALTH  
14040 Industrial Road Omaha, NE 68144

**For the control and treatment of the following diseases caused by organisms susceptible to oxytetracycline.**

**SWINE**

Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*  
Bacterial pneumonia caused by *Pasteurella multocida*  
For Breeding Swine: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*

**CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE**

Bacterial enteritis caused by *Escherichia coli*  
Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*

**SHEEP**

Bacterial enteritis caused by *Escherichia coli*  
Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*  
This packet will treat 10,240 pounds of swine, cattle or sheep at 10 mg/pound. Do not mix this product with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers.

**CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 14 consecutive days in chickens and turkeys or 5 consecutive days in cattle, swine or sheep. Prepare fresh solutions every 24 hours.

**DOSAGE**

Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.

Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.

Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.

**Special Note:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate and the environmental temperature and humidity, each of which affects water consumption.

FOR USE IN DRINKING WATER ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS

**INDICATIONS AND DIRECTIONS FOR USE**

For the control of the following poultry diseases caused by organisms susceptible to oxytetracycline: Add the following amount to ten gallons of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

<b>CHICKENS</b>	Infectious synovitis caused by <i>Mycoplasma synoviae</i>	200-400 mg / gal	1/2-1
	Chronic respiratory disease (CRD) and air-sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i>	400-800 mg / gal	1-2
	Fowl cholera caused by <i>Pasteurella multocida</i>	400-800 mg / gal	1-2
<b>TURKEYS</b>	Hexamitiasis caused by <i>Hexamita meleagridis</i>	200-400 mg / gal	1/2-1
	Infectious synovitis caused by <i>Mycoplasma synoviae</i>	400 mg / gal	1
	Growing Turkeys - Complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis)	25 mg / lb body weight daily	varies with age & water consumption (1 pack will treat 20,480 pounds of turkeys)

DOSAGE	PACKS / 10 GALLONS STOCK SOLUTION
200-400 mg / gal	1/2-1
400-800 mg / gal	1-2
400-800 mg / gal	1-2
200-400 mg / gal	1/2-1
400 mg / gal	1
25 mg / lb body weight daily	varies with age & water consumption (1 pack will treat 20,480 pounds of turkeys)

Medicate continuously at the first clinical signs of disease and continue for 7 to 14 consecutive days. If improvement is not noted with 24 to 48 hours, consult a veterinarian or a diagnostic laboratory to determine diagnosis and advice on dosage.

**WARNING:** Do not administer to swine, cattle or sheep within 5 days of slaughter. Zero day withdrawal in chickens and turkeys. Do not administer to chickens or turkeys producing eggs for human consumption. **RECOMMENDED STORAGE:** STORE BELOW 77 F (25°C) Livestock Drug-Not For Human Use **KEEP OUT OF REACH OF CHILDREN**

Distributed by: PennField Animal Health, Omaha, NE 68144

TAKE TIME



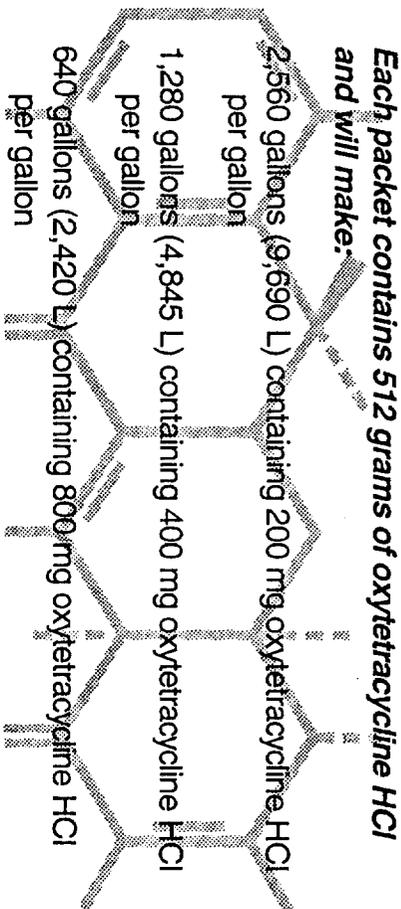
CUT HERE TO OPEN

# PENMOX 343

..... OXYTETRACYCLINE HCl

## SOLUBLE POWDER

A broad-spectrum antibiotic for control and treatment of specific diseases in poultry, cattle, swine and sheep.



Distributed by

**PennField**  
ANIMAL HEALTH  
14040 Industrial Road Omaha, NE 68144

**Net Contents: 23.9 OZ**  
ANADA 200-026; Approved by FDA

**For the control and treatment of the following diseases caused by organisms susceptible to oxytetracycline.**

**SWINE**

Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*  
Bacterial pneumonia caused by *Pasteurella multocida*  
For Breeding Swine: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*

**CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE**

Bacterial enteritis caused by *Escherichia coli*  
Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*

**SHEEP**

Bacterial enteritis caused by *Escherichia coli*  
Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*  
This packet will treat 51,200 pounds of swine, cattle or sheep at 10 mg/pound. Do not mix this product with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers.

**CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 14 consecutive days in chickens and turkeys or 5 consecutive days in cattle, swine or sheep. Prepare fresh solutions every 24 hours.

**DOSAGE**

Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.

Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.

Administer in the drinking water at a level of 10 mg oxytetracycline HCl per pound of body weight daily. Administer up to 5 days.

**Special Note:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate and the environmental temperature and humidity, each of which affects water consumption.

FOR USE IN DRINKING WATER ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS