HFA-305

DATE OF APPROVAL LETTER: APR 10 2002

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-026

PENNOX™ 343 (oxytetracycline HCl)

"revision of the withdrawal period for swine"

Sponsored by PennField Oil Company

ANADA 200-026 F015

I. GENERAL INFORMATION:

ANADA: 200-026

Sponsor: PennField Oil Company
14040 Industrial Road
Omaha, Nebraska 68144

Generic Name: Oxytetracycline HCl

Trade Name: PENNOX™ 343 SOLUBLE POWDER

Marketing Status: OTC

Effect of the Supplement: Revision of the withdrawal period for swine.

II. DRUG EFFECTIVENESS AND TARGET ANIMAL SAFETY:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 10, 2000).

Based upon the formulation characteristics of the generic product, PENNOX™ 343 was granted a waiver on December 19, 1995, from conducting an *in vivo* bioequivalence study and approved on March 13, 1997. The generic and pioneer products contain the same active and inactive ingredients and are soluble powders.

III. HUMAN FOOD SAFETY:

A. TOLERANCES

Tolerances are established in 21 CFR 556.500 for the sum of residues in tissues of swine and turkeys as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney. The acceptable daily intake (ADI) for total oxytetracycline residues is 25 micrograms per kilogram of body weight per day.

B. WITHDRAWAL TIME:

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for pioneer oxytetracycline soluble powders (Pfizer, Inc.'s TERRAMYCIN® 343) is established under CFR 520.1660d. Pfizer, Inc. received approval on April 25, 2001, for a zero day withdrawal time for swine. No new data were required for the reduced withdrawal time in swine for this supplemental approval for this generic product.

C. REGULATORY METHODS

The regulatory method for determination of oxytetracycline in tissues is a microbiological assay procedure using *Bacillus cereus* var. *mycoides* (ATCC 11778) suspension and is found in the FDA publication "Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols" revised October 1968, reprinted December 1974.

IV. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) to demonstrate that PENNOX™ 343 (oxytetracycline HCl), is safe and effective for use in swine for the approved indications, when administered in water at the approved dose.

V. APPROVED PRODUCT LABELING (attached)

A. Pioneer Facsimile label – TERRAMYCIN® 343

24.8 Lb (11.3 kg), 4.78 oz (135.5 g)

9.55 oz (270.7 g), and 4.5 Lb (2041.2 g)

B. Generic Facsimile labels – PENNOX™ 343

4.78 oz (135.5 g)and 23.9 oz (512 g)

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are any problems sending a fax call (301) 827-6567.

cc:
Courtesy Copy for the Sponsor
HFV-199 Orig. Anada 200026-C-0039
HFV-2 (Special Mailing List)
HFV-12 (FOI Staff)
HFV-102 (GADQC Reserve Copy)
HFV-102 (GREEN BOOK)
HFV-120 (P. Ryan)
HFA-305 (Dockets Management Branch)
HFR-SW350 (KAN-DO)

ec: CVM Records\ONADE\\A200026\C0039FOI.SUM

INDICATIONS AND DIRECTIONS FOR USE

For the control of the following poultry diseases caused by organisms susceptible to oxytetracycline. Add the following amount to 2 gal of stock solution when proportioner is set to meter at the rate of 1 oz/gal.

	DOSAGE	PACKS/2 GAL OF STOCK SOLUTION
CHICKENS		
Infectious synovitis caused by *Mycoplasma synoviae*	200–400 mg/gal	5–10
Chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*	400–800 mg/gal	10–20
Fowl cholera caused by *Pasteurella multocida*	400–800 mg/gal	10–20
TURKEYS		
Hexamitiasis caused by *Hexamita meleagridis*	200–400 mg/gal	5–10
Infectious synovitis caused by *Mycoplasma synoviae*	400 mg/gal	10
For growing turkeys—Complicating bacterial organisms associated with blucomb (transmissible enteritis, coronaviral enteritis)	25 mg/lb of body weight daily	Varies with age & water consumption (1 packet will treat 400 lb of turkeys)

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

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

	DOSAGE
SWINE Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* Bacterial pneumonia caused by *Pasteurella multocida* For breeding swine—Leptospirosis (reducing the incidence of abortion and shedding of leptospira) caused by *Leptospira pomona*	Administer in the drinking water at a level of 10 mg of oxytetracycline HCl per lb of body weight daily. Administer up to 14 days.
CALVES, BEEF CATTLE AND NONLACTATING DAIRY CATTLE Bacterial enteritis caused by *Escherichia coli* Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*	Administer in the drinking water at a level of 10 mg of oxytetracycline HCl per lb of body weight daily. Administer up to 14 days.
SHEEP Bacterial enteritis caused by *Escherichia coli* Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*	Administer in the drinking water at a level of 10 mg of oxytetracycline HCl per lb of body weight daily. Administer up to 14 days.

This packet will treat 1000 lb of swine, cattle or sheep at 10 mg/lb.

HONEY BEES For control of American Foulbrood caused by *Bacillus larvae*	200 mg/colony The drug is administered in 3 applications of sugar syrup or 3 dustings at 4- to 5-day intervals. 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 production honey.

Remove at least 8 weeks before main honey flow.

0 87219 02490 4

62 x 4163

Terramycin®

(oxytetracycline HCl)

Soluble Powder

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

Each packet contains 10 grams of oxytetracycline HCl.

For oral use only

Net Contents: 24.8 lb (11.3 kg)
(62 x 6.4 oz unit packages)

NADA #8-622, Approved by FDA

Pfizer

CAUTION: Use as sole source of oxytetracycline. Prepare fresh solutions every 24 hours.
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.

WARNING: Do not administer to turkeys, cattle or sheep within 5 days of slaughter. Zero-day slaughter withdrawal in swine. Do not administer to chickens or turkeys producing eggs for human consumption. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers.

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

Store Below 25°C (77°F)
For Animal Use Only
Keep Out of Reach of Children
Restricted Drug (California)—Use Only As Directed
Not for Human Use

TAKE TIME
OBSERVE LABEL DIRECTIONS

Pfizer Animal Health
Distributed by:
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

892
03-2358-35-X1
Made in USA

10 3/4" (W) with 1/2" Tab x 4 1/2" (H)

PMS 116 | PMS 485 | Black

03-2358-35-X1 Draft #1 2/23/99

TO OPEN CUT HERE

5632

Terramycin-343®

(oxytetracycline HCl)

Soluble Powder

A broad-spectrum

antibiotic

for control and treatment of specific diseases in poultry, cattle, swine, sheep, and bees.

This 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

For oral use only

NADA #8-622, Approved by FDA

Net Weight: 4.78 oz (135.5 g)

Pfizer

0 87219 02398 3

INDICATIONS AND DIRECTIONS FOR USE
For the control of the following poultry diseases caused by organisms susceptible to oxytetracycline. Add the following amount to 2 gallons of stock solution when proportioner is set to meter at the rate of 1 ounce per gallon.

		DOSAGE	PACKS/2 GALLONS STOCK SOLUTION
CHICKENS	Infectious synovitis caused by *Mycoplasma synoviae*	200–400 mg/gal	1/2–1
	Chronic respiratory disease (CRD) and infectious coryza caused by *Mycoplasma gallisepticum* and *E. coli*	400–800 mg/gal	1–2
	Fowl cholera caused by *Pasteurella multocida*	400–800 mg/gal	1–2
TURKEYS	Hexamitiasis caused by *Hexamita meleagridis*	200–400 mg/gal	1/2–1
	Infectious synovitis caused by *Mycoplasma synoviae*	400 mg/gal	1
	Growing Turkeys – Control of mortality associated with bluecomb transmissible enteritis	25 mg/kg body weight/day	(Males with age & water consumption (1 packet will treat 4096 lb of turkeys)

Medicate continuously after exposure is confirmed or suspected. Consult a veterinarian for diagnostic laboratory support and recommendations on dosage. If improvement is not noted within 24-48 hours, consult a poultry

WARNING: To prevent injection site reactions in young chickens or turkeys, do not administer by injection. Do not administer to chickens or turkeys within 5 days of slaughter or 24 hours after the last egg production. Do not administer to laying hens producing eggs for human consumption. Do not administer with milk or milk replacer. Administer 1 hour before or 2 hours after feeding milk or milk replacer.

RECOMMENDED STORAGE: STORE BELOW 25°C (77°F)
FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN
Restricted Drug(s) (California): Non-food animals only. Not to be used in lactating dairy cattle.

Pfizer Animal Health
Division of Pfizer Inc.
New York, NY 10017

INSTRUCTIONS INSIDE

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

SWINE
Bacterial enteritis – scours and salmonellosis caused by *Salmonella choleraesuis*
Bacterial pneumonia caused by *Pasteurella multocida*
For Breeding Swine – control of nonspecific scours and shedding of leptospires associated with scours

DOSAGE
Administer the medicated water at a level of 10 mg oxytetracycline HCl per kg body weight daily. Administer up to 14 days.

CALVES – BEEF CATTLE AND NONLACTATING DAIRY CATTLE
Bacterial pneumonia caused by *Pasteurella multocida*
Bacterial pneumonia complicating shipping fever complex caused by *Pasteurella haemolytica*

Administer the medicated water at a level of 10 mg oxytetracycline HCl per kg body weight daily. Administer up to 14 days.

SHEEP
Bacterial enteritis
Bacterial pneumonia

Administer the medicated water at a level of 10 mg oxytetracycline HCl per kg body weight daily. Administer up to 14 days.

HONEY BEES
For control of American foulbrood disease caused by *Bacillus larvae* in colonies of honey bees. Add 200 mg of sugar syrup per 200 mg of oxytetracycline HCl. The syrup should be fed early in the morning when brood begins to hatch. Consult your veterinarian for dosage information.

CAUTION: Use as directed.
Special Notes: Do not feed to lactating dairy cattle or to laying hens producing eggs for human consumption. Do not feed continuously for more than 14 days.

892 (11-2002-SX)

TO OPEN CUT HERE

5633

Terramycin-343

(oxytetracycline HCl)

Soluble Powder

A broad-spectrum

antibiotic

for control and treatment of specific diseases in poultry, cattle, swine, sheep, and bees.

This packet contains 204.8 grams of oxytetracycline HCl and will make:

1024 gallons (3876 L) containing
200 mg oxytetracycline HCl per gallon

512 gallons (1938 L) containing
400 mg oxytetracycline HCl per gallon

256 gallons (969 L) containing
800 mg oxytetracycline HCl per gallon

For oral use only

NADA #8-622, Approved by FDA

Net Weight: 9.55 oz (270.7 g)

Pfizer

0 87219 02399 0

000005

5637

Terramycin-343®

(oxytetracycline HCl)

Soluble Powder

A broad-spectrum antibiotic

For control and treatment of specific diseases in poultry, cattle, swine, sheep, and bees.

This tub contains 1543.5 grams of oxytetracycline HCl and will make:

7,718 gal (29,215 L) containing 200 mg of oxytetracycline HCl per gal

3,859 gal (14,608 L) containing 400 mg of oxytetracycline HCl per gal

1,930 gal (7,306 L) containing 800 mg of oxytetracycline HCl per gal

For oral use only

Net Weight: 4.5 lb (2041.2 g)

NADA #8-622, Approved by FDA

INDICATIONS AND DIRECTIONS FOR USE

For the control of the following poultry diseases caused by organisms susceptible to oxytetracycline: Add 1 tub of soluble powder to the amounts of water listed below to make a stock solution for use in a proportioner set to meter at the rate of 1 ounce per gallon.

		DOSAGE	GAL OF STOCK SOLUTION PER TUB
CHICKENS	Infectious synovitis caused by *Mycoplasma synoviae*	200–400 mg/gal	60–30
	Chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*	400–800 mg/gal	30–15
	Fowl cholera caused by *Pasteurella multocida*	400–800 mg/gal	30–15
	Hexamitiasis caused by *Hexamita meleagridis*	200–400 mg/gal	60–30
TURKEYS	Infectious synovitis caused by *Mycoplasma synoviae*	400 mg/gal	30
	Growing Turkeys—Complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis)	25 mg/lb body weight daily	Varies with age & water consumption (1 tub will treat 61,740 lb of turkeys)

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

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

		DOSAGE
SWINE	Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per lb of body weight daily. Administer up to 14 days.
	Bacterial pneumonia caused by *Pasteurella multocida*	
	For Breeding Swine: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per lb of body weight daily. Administer up to 14 days.
CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE	Bacterial enteritis caused by *Escherichia coli*	Administer in the drinking water at a level of 10 mg oxytetracycline HCl per lb of body weight daily. Administer up to 14 days.
	Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*	
SHEEP	Bacterial enteritis caused by *Escherichia coli*	This tub will treat 154,350 lb of swine, cattle or sheep at 10 mg/lb.
	Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*	
HONEY BEES	For control of American Foulbrood caused by *Bacillus larvae*	200 mg/colony The drug is administered in 3 applications of sugar syrup or 3 dustings at 4- to 5- day intervals. 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 production honey. Remove at least 6 weeks prior to main honey flow.

CAUTION: Use as sole source of oxytetracycline. Prepare fresh solutions every 24 hours.

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.

WARNINGS: Do not administer to turkeys, cattle, or sheep within 5 days of slaughter. Zero-day slaughter withdrawal in swine. Do not administer to chickens or turkeys producing eggs for human consumption. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers.

Store Below 25°C (77°F)
For Animal Use Only
Keep Out of Reach of Children
Restricted Drug(s) (California)—
Not for Human Use
Use Only as Directed

Distributed by
Animal Health
Exton, PA 19341, USA
Div of Pfizer Inc
NY, NY 10017

992 05-9402-35-X2
Made in USA

11" (W) x 4 3/4" (H)

Pennox 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

Net Contents: 4.78 oz

ANADA 200-026; Approved by FDA

Distributed by

PennField® ANIMAL HEALTH™

14040 Industrial Road Omaha, NE 68144

#F343-1 01/02

CUT HERE TO OPEN

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.

		DOSAGE	PACKS / 2 GALLONS STOCK SOLUTION
CHICKENS	Infectious synovitis caused by *Mycoplasma synoviae*	200-400 mg / gal	1/2–1
	Chronic respiratory disease (CRD) and air-sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*	400-800 mg / gal	1–2
	Fowl cholera caused by *Pasteurella multocida*	400-800 mg / gal	1–2
TURKEYS	Hexamitiasis caused by *Hexamita meleagridis*	200-400 mg / gal	1/2–1
	Infectious synovitis caused by *Mycoplasma synoviae*	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 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 cattle or sheep within 5 days of slaughter. Zero day withdrawal in chickens, turkeys and swine. Do not administer to chickens or turkeys producing eggs for human consumption. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers.

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 TO OBSERVE DIRECTIONS

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*

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.

CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE

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

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

SHEEP

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

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

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.

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

Pennox™ 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 512 grams of oxytetracycline HCl and will make:

2,560 gallons (9,690 L) containing 200 mg oxytetracycline HCl per gallon

1,280 gallons (4,845 L) containing 400 mg oxytetracycline HCl per gallon

640 gallons (2,420 L) containing 800 mg oxytetracycline HCl per gallon

Net Contents: 23.9 oz

ANADA 200-026 APPROVED BY FDA

Distributed by

PennField® ANIMAL HEALTH™

14040 Industrial Road Omaha, NE 68144

#F343-2 01/02

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

	DOSAGE	STOCK SOLUTION
SWINE		
Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*	200–400 mg / gal	1/2–1
Bacterial pneumonia caused by *Pasteurella multocida*	400–800 mg / gal	1–2
For Breeding Swine: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*	400–800 mg / gal	1–2
CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE		
Bacterial enteritis caused by *Escherichia coli*	200–400 mg / gal	1/2–1
Bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*	400 mg / gal	1
SHEEP		
Bacterial enteritis caused by *Escherichia coli*	25 mg / lb body weight daily	varies with age & water consumption (1 pack will treat 20,480 pounds of turkeys)
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.

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

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.

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.

CHICKENS	Infectious synovitis caused by *Mycoplasma synoviae*
	Chronic respiratory disease (CRD) and air-sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*
	Fowl cholera caused by *Pasteurella multocida*
TURKEYS	Hexamitiasis caused by *Hexamita meleagridis*
	Infectious synovitis caused by *Mycoplasma synoviae*
	Growing Turkeys – Complicating bacterial organisms associated with blackcomb (transmissible enteritis, coronavirus enteritis)

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 cattle or sheep within 5 days of slaughter. Zero day withdrawal in chickens, turkeys and swine. Do not administer to chickens or turkeys producing eggs for human consumption. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. 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 HE