

Approval Date: NOV 12 2003

**FREEDOM OF INFORMATION SUMMARY**  
**SUPPLEMENTAL ABBREVIATED NEW ANIMAL**  
**DRUG APPLICATION (ANADA)**

**ANADA 200-247**

**OXYTETRACYCLINE HCL SOLUBLE POWDER – 343**  
**(oxytetracycline HCl)**

**Indications for use: For control and treatment of specific diseases in  
poultry, cattle, sheep, swine and honeybees.**

**Sponsored by:**

**Phoenix Scientific, Inc.**  
**3915 South 48<sup>th</sup> St. Terrace**  
**St. Joseph, MO 64503**

FREEDOM OF INFORMATION SUMMARY

1. **General Information:**

- a. File Number: ANADA 200-247
- b. Sponsor: Phoenix Scientific, Inc.  
3915 South 48<sup>th</sup> St. Terrace  
St. Joseph, MO 64503  
  
Drug Labeler Code: 059130
- c. Established Names: Oxytetracycline HCl
- d. Proprietary Name: OXYTETRACYCLINE HCL SOLUBLE  
POWDER-343
- e. Dosage Form: Soluble powder
- f. How Supplied: 4.78 oz (135.5 g) & 9.6 oz (272.2 g)
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each packet contains 102.4 or 204.8 grams of  
oxytetracycline HCl
- i. Route of Administration: Oral
- j. Species/Class: Poultry, cattle, sheep, swine, and honeybees
- k. Recommended Dosage:  
  
SWINE-10mg/lb/day, up to 14 days  
  
CALVES, Beef cattle and non-lactating dairy  
cattle- 10 mg/lb/day, up to 14 days  
  
SHEEP- 10 mg/lb/day, up to 14 days  
  
HONEYBEES- 200 mg/colony, administered in 3  
applications of sugar syrup or 3 dustings at 4- to 5-  
day intervals in early spring or fall.

CHICKENS-

Infectious synovitis caused by *Mycoplasma synoviae* - 200-400 mg/gal

Chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *E.coli* - 400-800 mg/gal

Fowl cholera caused by *Pasteurella multocida* - 400-800 mg/gal

TURKEYS-

Hexamitiasis caused by *Hexamita meleagridis* - 200-400 mg/gal

Infectious synovitis caused by *Mycoplasma synoviae* - 400 mg/gal

Growing turkeys- complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) - 25 mg/lb body weight daily

For chickens and turkeys medicate continuously at the first clinical signs and continue for 7-14 consecutive days.

l. Pharmacological Category:

Antibacterial

m. Indications:

OXYTETRACYCLINE HCL SOLUBLE POWDER - 343 is indicated for a variety of bacterial infections in cattle, sheep, swine, chickens, turkeys, and honeybees associated with organisms susceptible to oxytetracycline. CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE: Control and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*.

SHEEP: Control and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*.

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

CHICKENS: Control of infectious synovitis caused by *Mycoplasma synoviae*, chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*, and fowl cholera caused by *Pasteurella multocida*.

TURKEYS: Control of hexamitiasis caused by *Hexamita meleagridis* and infectious synovitis caused by *Mycoplasma synoviae*. Growing turkeys-complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

HONEYBEES: Control and treatment of American and European foulbrood caused by *Bacillus larvae*.

n. Pioneer Product:

TERRAMYCIN-343 Soluble Powder,  
(oxytetracycline HCl); NADA-8-622, Pfizer, Inc.

o. Effect of Supplement:

This submission for OXYTETRACYCLINE HCL SOLUBLE POWDER - 343 is a supplement to the original ANADA 200-247 providing for: (a) a zero- day slaughter withdrawal period for swine; the pioneer sponsor was approved on April 25, 2001, and did not qualify for marketing exclusivity for the zero-day withdrawal period for swine (b) additional pouch size, 4.78 ounce (135.5 g) (c) claim for the treatment and control of foulbrood in honeybees.

## 2. TARGETANIMAL SAFETYAND DRUG 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) 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 shows 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, Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product OXYTETRACYCLINE HCL SOLUBLE POWDER - 343. The generic product is administered as an oral solution, 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 ingredients. The pioneer product, TERRAMYCIN-343 Soluble Powder (oxytetracycline HC1), sponsored by Pfizer, Inc., NADA 8-622, was approved on September 18, 1952.

### 3. HUMAN SAFETY:

- **Tolerance**

Tolerances are established in 21 CFR 556.500 for the sum of residues of the tetracyclines, including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk, beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows: 2 parts per million (ppm) in muscle, 6 ppm in liver, 12 ppm in fat and kidney, and 0.3 ppm in milk. The acceptable daily intake (ADI) for total oxytetracycline is 25 micrograms per kilogram of body weight per day.

- **Withdrawal Times**

Because a waiver of *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal time for swine is zero-day. This withdrawal period is codified at §520.1660d (d)(1)(iii)(C).

- **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 as published by the Food and Drug Administration, "Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Method, Reports, and Protocols," revised October 1968, reprinted December 1974.

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 OXYTETRACYCLINE HCL SOLUBLE POWDER - 343 (oxytetracycline HCl), when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. *ATTACHMENTS:*

Facsimile generic labeling (ANADA 200-247) and currently approved pioneer labeling (NADA 8-622) are attached as indicated below:

Foil Pouch Label (Pioneer)-TERRAMYCIN-343 Soluble Powder  
(9.55oz)

Foil Pouch Label (Generic)-OXYTETRACYCLINE HCL SOLUBLE POWDER - 343  
(4.78 oz & 9.6 oz)

NDC 59130-704-78

# **OXYTETRACYCLINE HCl SOLUBLE POWDER-343**

A broad spectrum  
**ANTIBIOTIC**

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

**This packet contains 102.4 grams of oxytetracycline HCl**

This packet will make:

512 gallons (1,938 L) containing 200 mg oxytetracycline HCl per gallon

256 gallons (969 L) containing 400 mg oxytetracycline HCl per gallon

128 gallons (484.5 L) containing 800 mg oxytetracycline HCl per gallon

**For oral use only in poultry, cattle, sheep, swine and bees.**

**FOR ANIMAL USE ONLY**

**KEEP OUT OF REACH OF CHILDREN**

**NET WEIGHT: 135.5 g (4.78 oz)**

ANADA 200-247, APPROVED BY FDA

**AmTech**®  
Group, Inc.

200-247

F0151

### 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.

CHICKENS	DOSAGE	PACKETS/2 GALLONS STOCK SOLUTION
Infectious synovitis caused by <i>Mycoplasma synoviae</i>	200-400 mg/gal	1/4-1/2
Chronic respiratory disease (CRD) and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i>	400-800 mg/gal	1/2-1
Fowl cholera caused by <i>Pasteurella multocida</i>	400-800 mg/gal	1/2-1

### TURKEYS

Hexamitiasis caused by <i>Hexamita meleagridis</i>	200-400 mg/gal	1/4-1/2
Infectious synovitis caused by <i>Mycoplasma synoviae</i>	400 mg/gal	1/2

Growing Turkeys—Complicating bacterial organisms associated with bluecomb (transmissible enteritis, body weight daily consumption (1 packet will treat 8,192 pounds of turkeys.)  
coronaviral enteritis)

Medicate continuously at the first clinical signs of disease and continue for 7 to 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:

### 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 14 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 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 oxytetracycline HCl per pound of body weight daily. Administer up to 14 days.

This packet will treat 20,480 pounds of swine, cattle or sheep at 10 mg/pound.

### HONEY BEES

American and European Foulbrood caused by *Bacillus larvae* susceptible to oxytetracycline.

200 mg/colony  
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.

**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.

A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

RECOMMENDED STORAGE: STORE BELOW 77°F (25°C)

FOR USE IN DRINKING WATER ONLY

NOT FOR USE IN LIQUID FEED SUPPLEMENTS

FOR ANIMAL USE ONLY. KEEP OUT OF REACH OF CHILDREN

Restricted Drug(s) (California). Not For Human Use. Use Only As Directed.

Manufactured by  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

800507  
Rev. 9-02

Lot No.

Exp. Date



NDC 59130-704-27

# OXYTETRACYCLINE HCl SOLUBLE POWDER-343

A broad spectrum  
**ANTIBIOTIC**

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

**This packet contains 204.8 grams of oxytetracycline HCl**

This packet will make:

1,024 gallons (3,876 L) containing 200 mg oxytetracycline HCl per gallon

512 gallons (1,938 L) containing 400 mg oxytetracycline HCl per gallon

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

**For oral use only in poultry, cattle, sheep, swine and bees.**

**FOR ANIMAL USE ONLY**

**KEEP OUT OF REACH OF CHILDREN**

**NET WEIGHT: 272.2 g (9.6 oz)**

**ANADA 200-247, APPROVED BY FDA**

**AmTech**<sup>®</sup>  
Group, Inc.

1797 BK

23444 amtech 3/30/00 133-2/00

**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>DOSAGE</b>	<b>PACKETS/2 GALLONS STOCK SOLUTION</b>
<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 packet will treat 4,096 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 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:

**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 14 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 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 oxytetracycline HCl per pound of body weight daily. Administer up to 14 days.

This packet will treat 10,240 pounds of swine, cattle or sheep at 10 mg/pound.

**HONEY BEES**

American and European Foulbrood caused by *Bacillus larvae* susceptible to oxytetracycline.

200 mg/colony  
 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.

**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. A withdrawal period has not been established for this product in prenatating calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.



Manufactured by  
 Phoenix Scientific, Inc.  
 St. Joseph, MO 64503

800507  
 Iss. 8-02

**RECOMMENDED STORAGE: STORE BELOW 77°F (25°C)**  
**FOR USE IN DRINKING WATER ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS**  
**FOR ANIMAL USE ONLY. KEEP OUT OF REACH OF CHILDREN**  
 Restricted Drug(s) (California). Not For Human Use. Use Only As Directed.



Lot No.  
 Exp. Date

TO OPEN CUT HERE

5633

# Terramycin-343<sup>®</sup>

(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)**



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 leptospiral) 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*

**HONEY BEES**

For control of American Foulbrood caused by *Bacillus larvae*

**DOUSAGE**

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

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

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

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, and to offset the effect of water consumption.

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Flat: 11 1/2" (W) x 8 1/8" (H)  
 Finished Packet: 5 3/4" (W) x 9" (H)

PMS 116

PMS 485

Black

01-4536-35-X1 Draft #1 2/23/99

**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
<b>CHICKENS</b> Infectious synovitis caused by <i>Mycoplasma synoviae</i>	200-400 mg/gal	1/4-1/2
Chronic respiratory disease (CRD) and/or sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i>	400-800 mg/gal	1/2-1
Fowl cholera caused by <i>Pasteurella multocida</i>	400-800 mg/gal	1/2-1
<b>TURKEYS</b> Hexamitiasis caused by <i>Hexamita meleagridis</i>	200-400 mg/gal	1/4-1/2
Infectious synovitis caused by <i>Mycoplasma synoviae</i>	400 mg/gal	1/2
Growing Turkeys—Complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis)	25 mg/lb body weight daily	Varies with age & water consumption (1 packet will treat 8192 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.

**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.

**RECOMMENDED STORAGE:** STORE BELOW 25°C (77°F)

**FOR ANIMAL USE ONLY**  
 KEEP OUT OF REACH OF CHILDREN

Registered Brand (California) May Exp Human Use. Use Only As Directed.



Distributed by

**Animal Health**  
 Exton, PA 19341, USA  
 Div. of Pfizer Inc.

TAKE TIME



**OBSERVE LABEL DIRECTIONS**