Approval Date: November 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 48th 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 48th 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. TARGET ANIMAL SAFETY AND 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 HCl), 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)-OXYTETRACYLINE HCL SOLUBLE POWDER – 343
(4.78 oz & 9.6 oz)