Date of approval ltr.: Feb. 10, 1999

FREEDOM OF INFORMATION SUMMARY

ANADA200-247

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64506-0457

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION **ANADA 200-247**

ANADA/GENERIC SPONSOR-- Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64506-0457

a. Established Name: oxytetracycline hydrochloride

b. Trade Name/Proprietary Name: OXYTETRACYCLINE HCL SOLUBLE POWDER-343

c. Dosage Form: Soluble Powder for drinking water

d. How Supplied: 9.6 oz foil pouches, 2 and 5 pound buckets

e. How Dispensed: OTC

f. Amount of Active Ingredients: Each pound contains oxytetracycline hydrochloride equivalent to 343 gram oxytetracycline hydrochloride

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

h. Labeled Dosage and Indications: (Refer to attached labeling for additional details on mixing instructions)

CHICKENS- INDICATIONS	DOSAGE
Control of infectious synovitis caused by *Mycoplasma synoviae*	200-400 mg/gal
Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*	400-800 mg/gal
Control of fowl cholera caused by *Pasteurella multocida*	400-800 mg/gal

TURKEYS - INDICATIONS	DOSAGE
Control of Hexamitiasis caused by *Hexamita meleagridis*	200-400 mg/gal
Control of infectious synovitis caused by *Mycoplasma synoviae*	400 mg/gal
Growing Turkeys- Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis)	25 mg/lb b.wt.

SWINE - INDICATIONS	DOSAGE
FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE: Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, susceptible to oxytetracycline. Bacterial pneumonia caused by *Pasteurella multocida*, susceptible to oxytetracycline.	10 mg/lb body weight
FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of Leptospira) caused by *Leptospira pomon*a, susceptible to oxytetracycline.	10 mg/lb body weight

CATTLE - INDICATIONS	DOSAGE
FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE: Bacterial enteritis caused by *Escherichia coli* susceptible to oxytetracycline. Bacterial pneumonia	10 mg/lb body weight

(shipping fever) caused by *Pasteurella multocida*, susceptible to oxytetracycline.	
SHEEP - INDICATIONS	DOSAGE
FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES: Bacterial enteritis caused by *Escherichia coli* susceptible to oxytetracycline. Bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*, susceptible to oxytetracycline.	10 mg/lb body weight

General Directions

Mix fresh solutions daily. Use as sole source of oxytetracycline. Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. 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. Administer up to 14 days in swine, cattle, and sheep, and 7 to 14 days for chickens and turkeys.

i. Pioneer Product "Listed" Product: Terramycin® Soluble Powder, NADA 008-622

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, (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. Ordinarily the ANADA sponsor shows that the generic product is bioequivalent to the pioneer and conducts a

tissue residue study to establish the withdrawal time for the generic product. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (61 FR 26182, May 24, 1996, Bioequivalency Guideline).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc.

was granted a waiver from conducting an *in vivo* bioequivalence study for OXYTETRACYCLINE HCL SOLUBLE POWDER-343. The generic and pioneer products are water soluble powders with the same active ingredients and no differences in the inactive ingredients which would affect absorption of the active ingredients.

3. HUMAN FOOD SAFETY

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

Withdrawal Time:

On April 18, 1997, a waiver from the requirement of an *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

For oxytetracycline hydrochloride, [21 CFR 520.1660d], do not administer to turkeys, swine, cattle, or sheep within 5 days of slaughter. Do not administer to chickens or turkeys producing eggs for human consumption.

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 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, when used under its proposed conditions of use, is safe and effective for the labeled indications.

Attachments: The following **generic** labeling and currently approved **pioneer** labeling are attached.

Generic Labeling	1. Facsimile package labeling for generic product
Pioneer Labeling	2. Pioneer package labeling for Terramycin® Soluble Powder