

## FREEDOM OF INFORMATION SUMMARY

### I. GENERAL INFORMATION

#### A. File Number

ANADA 200-146

#### B. Sponsor

Phoenix Scientific, Inc.

#### C. Proprietary Name

OXYTETRACYCLINE HCL SOLUBLE POWDER

#### D. Established Name

oxytetracycline hydrochloride

#### E. Dosage Form

Soluble Powder for drinking water

#### F. Amount of Active Ingredient

Each gram contains oxytetracycline hydrochloride equivalent to 55 mg oxytetracycline hydrochloride

#### G. How Supplied

OXYTETRACYCLINE HCL SOLUBLE POWDER 50 grams of OTC HCl is supplied in 907.2 grams (2 lb) of product in a bucket container

#### H. Dispensing Status

OTC

#### I. Dosage Regimen and Indications

##### CHICKENS - INDICATIONS

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

##### TURKEYS- INDICATIONS

- Control of Hexamitiasis caused by *Hexamita meleagridis*

DOSAGE: 200-400 mg/gal

- Control of infectious synovitis caused by *Mycoplasma synoviae*  
DOSAGE: 400 mg/gal
- Growing turkeys: Control of body weight complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis)  
DOSAGE: 25 mg/lb

### **SWINE - INDICATIONS**

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.  
DOSAGE: 10 mg/lb body weight
- FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*, susceptible to oxytetracycline.  
DOSAGE: 10 mg/lb body weight

### **CATTLE - INDICATIONS**

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 (shipping fever) caused by *Pasteurella multocida*, susceptible to oxytetracycline.  
DOSAGE: 10 mg/lb body weight

### **SHEEP - INDICATIONS**

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.  
DOSAGE: 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.

### **J. Species/Class**

Chickens, Turkeys, Cattle, Swine, Sheep

**K. Reference Listed New Animal Drug**

Terramycin® Soluble Powder, NADA 008-622

**L. Date of Approval**

December 7, 1995

**II. TARGET ANIMAL SAFETY AND 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. A tissue residue study to establish the withdrawal time for the generic product is also required. 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, April 1990.)

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. 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.

**III. HUMAN FOOD SAFETY**

**Tolerance**

The tolerances established for the pioneer product apply to the generic product. Tolerances of 3 ppm in uncooked kidney and 1 ppm in uncooked muscle, liver, fat, and skin are established for residues of oxytetracycline in chickens and turkeys under 21 CFR 556.500(a). A tolerance of 0.1 ppm in uncooked edible tissues is established for residues of oxytetracycline in swine [21 CFR 556.500(b)], cattle, beef calves, nonlactating dairy cattle [21 CFR 556.500(c)], and sheep [21 CFR 556.500(e)].

**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.

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.

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

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.