

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-068

B. Sponsor

Phoenix Pharmaceutical, Inc.
4621 Easton Rd.
St. Joseph, MO 64506-0457

C. Proprietary Name

OXYTETRACYCLINE Hydrochloride Injection

D. Established Name

Oxytetracycline Hydrochloride

E. Pharmacological Category

Antibiotic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

100 mg Oxytetracycline HCl per mL of solution

H. How Supplied

OXYTETRACYCLINE HCL SOLUTION 500 mL bottle

I. Dispensing Status

OTC

J. Dosage Regimen

3-5 mg/lb body weight per day for a maximum of 4 consecutive days, administer only intravenously

K. Route of Administration

Dermal, immersion, injection, oral, topical, etc.

L. Species/Class

Beef cattle, beef calves, non-lactating dairy cattle, and dairy calves

M. Indication

OXYTETRACYCLINE HCL INJECTABLE SOLUTION is for treatment of:

- *Pasteurella* spp. -- Bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.
- *Escherichia coli* -- Bacterial enteritis (scours)
- *Spherophorous necrophorus* -- Necrotic pododermatitis (foot rot), calf diphtheria
- *Actinobacillus lignierseii* -- Wooden tongue
- Wound infection, acute metritis, traumatic injury -- caused by oxytetracycline susceptible strains of streptococcal and staphylococcal bacteria

N. Reference Listed New Animal Drug

Fermenta's MEDAMYCIN ®-100, NADA 108-963.

O. Date of Approval

July 31, 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. If bioequivalence is demonstrated through a clinical end-point study, then 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 Pharmaceutical, Inc., was granted a waiver from conducting an *in vivo* bioequivalence study for OXYTETRACYCLINE HYDROCHLORIDE. The generic and pioneer products contain the same active and inactive ingredients and are injectable solutions.

III. HUMAN FOOD SAFETY

Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.1 ppm is established for the uncooked edible tissues of beef cattle, beef calves, non-lactating dairy cattle, and dairy calves (21CFR556.500(c)).

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 oxytetracycline HCl injectable solution is established under 21 CFR 522.1662a: 22 days for cattle. Not for use in lactating dairy cattle.

Regulatory Method for Residues

The analytical method for the detection of residues of oxytetracycline is a microbiological test using *Bacillus cereus* var. *mycoides*. This method may be found in *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, DC 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 hydrochloride when used under the proposed conditions of use, is safe and effective for its 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.