

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-146

B. Sponsor

Phoenix Scientific, Inc.
3915 South 48th St. Terrace
P.O. Box 6457
St. Joseph, Missouri 64506-0457

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 is supplied in 907.2 gram (2 Lb.) buckets or 125 grams is supplied in 2.26 Kg (5 Lb.) buckets.

H. Dispensing Status

OTC

I. Dosage Regimen and Indications

See indications in labeling

J. Species/Class

Chickens, Turkeys, Cattle, Swine, and Sheep

K. Effect of Supplement

This supplemental application provides for the addition of the 2.26 kg (5 lb) bucket with a scoop. The scoop has also been added to the 907.2 g (2 lb) bucket. Revised

labeling provides the statement warning against use in calves to be processed for veal and female dairy cattle 20 months of age or older.

L. Reference Listed New Animal Drug

Terramycin® Soluble Powder, NADA 008-622

II. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

See original approval ANADA 200-146, (Federal Register, January 30, 1996, vol 61, No. 20:2914- 2915)

III. HUMAN FOOD SAFETY

See original approval ANADA 200-146, (Federal Register, January 30, 1996, vol 61, No. 20:2914- 2915)

IV. AGENCY CONCLUSIONS

This ANADA submitted under 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.