

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-193

B. Sponsor

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

C. Proprietary Name

Clindamycin hydrochloride oral liquid

D. Established Name

clindamycin hydrochloride, USP

E. Pioneer Product

Upjohn's Antirobe Aquadrops (NADA 135-940)

II. 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).

For certain dosage forms, the agency grants a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990: fifth GADPTRA Policy Letter). In lieu of *in vivo* bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on December 8, 1995, from conducting an *in vivo* bioequivalence study with Clindamycin Hydrochloride Oral Liquid. The generic and pioneer products are solutions with the same active and inactive ingredients.

III. HUMAN FOOD SAFETY

The product is labeled for use in dogs only, not a food producing animal. Therefore, no human food safety information is required.

Human Safety Relative to Possession, Handling and Administration

Labeling contains adequate caution/warning statements.

IV. AGENCY CONCLUSIONS

This is an abbreviated ew animal drug application (ANADA) filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic (FFD&C) Act.

Bioequivalence of this generic animal drug, Clindamycin Hydrochloride Oral Liquid (25 mg/mL), to the pioneer product, Upjohn's Antirobe Aquadrops (NADA 135-940), was established by demonstration of chemical equivalence.

This generic product and the pioneer product have identical labeling indications for the 20mL (0.68 fl oz.) vial for use in dogs. The route and method of administration of the two drugs are identical. Both drugs are administered orally. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy implementing section 512(b)(2) of FFD&C Act, *in vivo* bioequivalency studies were not required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Clindamycin Hydrochloride Oral Liquid is safe and effective for its labeled indications when used under its proposed conditions of use.

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.