Approval letter dated: Dec 27 2000

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

ANADA 200-193

Clindamycin Hydrochloride Oral Liquid

For the therapy of wounds, abscesses,
dental infections in dogs and cats, and osteomyelitis in dogs.

Sponsored by:

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503-0457

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number:	200-193
Original Approval Date:	August 1, 1997
Sponsor:	Phoenix Scientific, Inc. 3915 South 48th Street Terrace P. O. Box 8039 St. Joseph, MO 64506-0457
Generic Name:	Clindamycin Hydrochloride, USP
Trade Name:	Clindamycin Hydrochloride Oral Liquid
Dosage Form:	Oral Solution
How Supplied:	30 mL bottles
How Dispensed:	Rx
Amount of Active Ingredients:	Each ml contains 25 mg of Clindamycin (base)
Route of Administration:	Oral
Species:	Canine and feline (new)
Labeled Dosage/Indications for Use:	Canine: For therapy of wounds, abscesses, and dental infections, orally administer 2.5 mg/lb (1 mL/10lbs) body weight every 12 hours. For therapy of osteomyelitis orally administer 5.0 mg/lb (2 mL/10 lbs) body weight every 12 hours. Feline: For therapy of wounds, abscesses, and dental infections, orally administer 5.0 to 10.0 mg/lb body weight every 24 hours for a maximum of 14 days (11 to 22 mg/kg body weight per day).
Effect of Supplement	The supplement provides for the addition of feline claims to the previous approved label for use in canine only.
Pioneer Product/"Listed Product	Pharmacia & Upjohn Co. Antirobe Aquadrops®, NADA 135-940

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). Phoenix Scientific, Inc. is supplementing their ANADA for the addition of feline claims.

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 product was approved on August 1, 1997, for use in dogs only.

The three-year exclusivity period for the feline claims granted to the pioneer product ended on October 7, 1999. Phoenix Scientific is supplementing their approved generic product for the addition of the feline claims. No new data was required for the addition of the feline claims.

3. HUMAN FOOD SAFETY

The product is labeled for use in dogs and cats, which are not food producing animals. Therefore, no human food safety information is required.

4. AGENCY CONCLUSION:

This is a Supplemental Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic (FFD&C) Act. The Supplement provides for the addition of feline claims to the previously approved canine claims. The exclusivity period granted to the pioneer for feline claims ended on October 7, 1999.

Bioequivalence of this generic animal drug, Clindamycin Hydrochloride Oral Liquid (25 mg/mL), to the pioneer product, Pharmacia & Upjohn's Antirobe Aquadrops® (NADA 135-940), was established by demonstration of chemical equivalence. The original generic animal drug was approved on August 1, 1997 for use in dogs only.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)(v)(vii)), this is a Category II change providing for the addition of new therapeutic claims in feline. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Attachment:

Generic and pioneer labeling facsimile