Date of Approval: June 14, 2002

FREEDOM OF INFORMATION SUMMARY

ANADA 200-298

Clindamycin Hydrochloride Capsules

(Dogs only)

Sponsored by:

Phoenix Scientific, Inc.
3915 S. 48th St. Terrace
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA:	200-298
Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th St. Terrace St. Joseph, MO 64503
Generic Name:	Clindamycin Hydrochloride Capsules
Trade Name:	Clindamycin Hydrochloride Capsules
Dosage Form:	Capsules
How Supplied:	100, 200 & 600 count bottles
How Dispensed:	Rx
Amount of Active Ingredients:	25, 75 & 150 mg per capsule.
Route of Administration:	Oral
Species:	Dogs
Pharmacological Category:	Antibacterial
Dosage:	Wounds, abscesses, and dental infections: 2.5 milligrams per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 milligrams per pound of body weight every 12 hours for a minimum of 28 days.
Labeled Indications for Use:	Use as an antibiotic for the treatment of soft tissue infections, dental infections, and osteomyelitis.
Pioneer Product/ Listed Product:	Antirobe® Capsules NADA 120-161 (Pharmacia & Upjohn)

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). 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 is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. 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, October, 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific Inc. was granted a waiver on June 30, 1998, from conducting an *in vivo* bioequivalence study for Clindamycin Hydrochloride Capsules. The generic and pioneer products are immediate release solid dosage forms (capsules) that contain the same active and inactive ingredients in the same concentrations .

3. HUMAN SAFETY:

Clindamycin Hydrochloride Capsule is intended for use only in dogs.

Human Warnings are provided on the product label as follows:

"For Animal use only."

"Keep Out of Reach of Children."

Human Safety Relative to Possession, Handling, and Administration: Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal Food, Drug, and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the Act and demonstrates that Clindamycin Hydrochloride Capsules, when used under the proposed conditions of use, are safe and effective for the labeled indications.

5. LABELING:

Attachments: **Pioneer Labeling:**

1 common package Insert for Clindamycin HCl capsules & drops
25 mg, 75 mg and 150 mg bottle labels

Generic Labeling:

25 mg bottle label and package insert
75 mg bottle label and package insert
150 mg bottle label and package insert

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.