Approval Date: April 21, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-298

Clindamycin Hydrochloride Capsules
(clindamycin HCl)

Expands the dosage range and revises the indications section in dogs.

Sponsored by:

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

FREEDOM OF INFORMATION SUMMARY

1. General Information:

a. File Number:	ANADA 200-298
b. Sponsor:	Phoenix Scientific, Inc. 3915 South 48th St. Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Names:	Clindamycin hydrochloride capsules
d. Proprietary Name:	Clindamycin Hydrochloride Capsules
e. Dosage Form:	Capsules
f. How Supplied:	100, 200, & 600 count bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each capsule contains 25, 75, 150, 300 mg clindamycin hydrochloride
i. Route of Administration:	Oral
j. Species/Class:	Dogs
k. Recommended Dosage:	Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound of body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb of body weight every 12 hours for a minimum of 28 days.
l. Pharmacological Category:	Antibacterial
m. Indications:	Clindamycin Hydrochloride Capsules are indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

	For the treatment of skin infections (wounds and abscesses) due to coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius)*, deep wounds and abscesses due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum,* and *Clostridium perfringes*, dental infections due to *S. aureus, B. fragilis, P. melaninogenicus, F. nerophorum,* and *C. perfringens,* and osteomyelitis due to *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens.*
n. Pioneer Product:	ANTIROBE CAPSULES;Clindamycin HCl; NADA 120-161; Pharmacia & Upjohn Company
o. Effect of Supplements:	The supplements provide for an expanded dosage range for dogs and an additional capsule size, 300 mg. The pioneer sponsor, Pharmacia & Upjohn Co., received approval of these additional claims with no exclusivity periods as seen in the FEDERAL REGISTER on August 27, 2002.

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 (GADPTRA) 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 and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Clindamycin Hydrochloride Capsules. The generic product is administered as an oral capsule, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredients. The pioneer product, ANTIROBE (clindamycin HCl), sponsored by Pharmacia & Upjohn Co., NADA 120-161, was approved on June 6, 1984.

3. HUMAN SAFETY:

This new animal drug is to be labeled for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

4. AGENCY CONCLUSIONS:

This supplemental 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 Clindamycin Hydrochloride Capsules (clindamycin HCl), when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling (ANADA 200-298) and currently approved pioneer labeling (NADA 120-161) are attached as indicated below:

Label (Pioneer)-ANTIROBE CAPSULES, insert and box

Label (generic)-Clindamycin Hydrochloride Capsules, insert, box, & bottle