Approval Date: April 21, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-193

CLINDAMYCIN HYDROCHLORIDE
ORAL LIQUID
(clindamycin hydrochloride)

Indications for use: Expands the dosage range and revises the indications section in dogs and cats.

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 200-193
b. Sponsor:	Phoenix Scientific, Inc. 3915 South 48th St. Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Names:	Clindamycin hydrochloride oral liquid
d. Proprietary Name:	Clindamycin Hydrochloride Oral Liquid
e. Dosage Form:	Oral Solution
f. How Supplied:	20 mL (0.68 fl oz) multiple dose vials
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each mL contains clindamycin hydrochloride equivalent to clindamycin 25 mg.
i. Route of Administration:	Oral
j. Species/Class:	Dogs and cats
k. Recommended Dosage:	Dogs: 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. Cats: Wounds, abscesses, and dental infections; 5.0 to 15.0 mg//lb body weight every 24 hours for a maximum of 14 days.
l. Pharmacological Category:	Antibacterial
m. Indications:	Clindamycin Hydrochloride Oral Liquid is indicated for the treatment of infections caused by

susceptible strains of the designated microorganisms in the specific conditions listed below:
Dogs: For the treatment of skin infections (wounds and abscess) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphyloccus intermedius)*, deep wounds and abscess due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum,* and *Clostridium perfringens,* dental infections due to *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens,* and osteomyelitis due to *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens.*

Cats: For the treatment of skin infections (wounds and abscess) due to *Staphylococcus aureus, S. intermedius, Streptococcus* spp.*,* deep wounds and abscesses due to *Clostridium perfringens* and *Bacteroides fragilis,* and dental infections due to *S. aureus, S. intermedius, Streptococcus* spp.*, C. perfringens,* and *B. fragilis.*

n. Pioneer Product: ANTIROBE AQUADROPS; Clindamycin Hydrochloride; NADA 135-940; Pharmacia & Upjohn

o. Effect of Supplement: The supplement provides for approval of a dose range and revised indications for use of Clindamycin Hydrochloride Oral Liquid in dogs and cats which was approved for the pioneer product under NADA 135-940 (67 FR 54954, Aug. 27, 2002) with no exclusivity period. The expanded range was changed from a point dose of 2.5 mg/lb. in dogs to an expanded range of 2.5 to 15 mg/lb. The change in cats was from a range of 5.0 to 10.0 mg/lb. to a range of 5.0 to 15.0 mg/lb. The revised indications provides for a change in the words ‘soft tissues infections’ to ‘skin infections’ for dogs and cats.

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) of 1988, 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 Oral Liquid. The generic product is administered as an oral solution, 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 AQUADROPS (clindamycin hydrochloride), sponsored by Pharmacia & Upjohn Co., NADA 135-940, was approved on May 23, 1985.

3. HUMAN SAFETY:

This drug is intended for use in dogs and cats, 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 supplemental ANADA.

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 Oral Liquid (clindamycin hydrochloride), when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Pioneer Labeling for NADA 135-940:
ANTIROBE AQUADROPS-Insert

Generic Labeling for ANADA 200-193:
Clindamycin Hydrochloride Oral Liquid-bottle label, insert, clipboard carton