Approval Date: March 19, 2007

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-398

Clindamycin Hydrochloride Oral Drops
(clindamycin hydrochloride)

Indications: For the treatment of infected wounds, abscesses, and dental infections in dogs and cats, and the treatment of osteomyelitis in dogs.

Sponsored by:

First Priority, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a.	File Number:	ANADA 200-398
b.	Sponsor:	First Priority, Inc. 1585 Todd Farm Drive Elgin, IL 60123 Drug Labeler Code: 058829
c.	Established Name:	Clindamycin hydrochloride
d.	Proprietary Name:	Clindamycin Hydrochloride Oral Drops
e.	Dosage Form:	Liquid
f.	How Supplied:	20 mL filled in 30 mL bottles (25 mg/mL)
g.	How Dispensed:	Rx
h.	Amount of Active Ingredients:	Each mL contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.
i.	Route of Administration:	Oral
j.	Species/Class:	Dogs and cats
k.	Recommended Dosage:	Dogs: For therapy of wounds, abscesses, and dental infections, orally administer 2.5 to 15.0 mg/lb (1-6 mL/10 lbs) body weight every 12 hours. For therapy of osteomyelitis orally administer 5.0 to 15.0 mg/lb (2-6 mL/10 lbs) body weight every 12 hours. Cats: For therapy of wounds, abscesses, and dental infections, orally administer 1-3 mL/5lbs body weight once every 24 hours depending on the severity of the condition.
l.	Pharmacological Category:	Antimicrobial

m. Indications:	Clindamycin Hydrochloride Oral Drops (for use in dogs and cats) is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below: Dogs: **Skin infections (wounds and abscesses)** due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphyloccus intermedius*). **Deep wounds and abscesses** due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum,* and *Clostridium perfringens*. **Dental infections** due to *S. auerus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens*. **Osteomyelitis** due to *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens*. Cats: **Skin infections (wounds and abscesses)** due to *Staphylococcus aureus, Staphylococcus intermedius* and *Streptococcus* spp. **Deep wounds and infections** due to *Clostridium perfringens* and *Bacteroides fragilis*. **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 Co., a Division of Pfizer, Inc.

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 is required to show 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, First Priority, Inc., was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Clindamycin Hydrochloride Oral Drops. The generic product is an oral solution, contains the same active ingredients 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 ingredient. The pioneer product, ANTIROBE AQUADROPS (clindamycin hydrochloride), the subject of Pharmacia & Upjohn Company, a Division of Pfizer, Inc., under 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 ANADA.

4. AGENCY CONCLUSIONS:

This 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 product Clindamycin Hydrochloride Oral Drops, 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 follows:

<u>Generic Labeling for ANADA 200-398:</u>
Clindamycin Hydrochloride Oral Drops – Container Label; Box Label; Package Insert

<u>Pioneer Labeling for NADA 135-940:</u>
ANTIRODE AQUDROPS- Container Label; Box Label; Package Insert