FREEDOM OF INFORMATION SUMMARY

ANTIROBE AQUADROPS Liquid
(clindamycin hydrochloride)

Supplemental NADA 135-940
Pharmacia & Upjohn Co.

Addition of a Dose Range for Dogs
Expansion of the Dose Range for Cats
Addition of Recent MIC Data

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1. GENERAL INFORMATION

a.	*File Number:*	NADA 135-940
b.	*Sponsor:*	Pharmacia & Upjohn Co. 7000 Portage Road Kalamazoo, MI 49001-0199 Drug Labeler Code: 000009
c.	*Established Name:*	clindamycin hydrochloride
d.	*Proprietary Name:*	ANTIROBE AQUADROPS Liquid
e.	*Dosage Form:*	liquid
f.	*How Supplied:*	The product is available as 20 mL filled in 30 mL bottles (25 mg/mL) supplied in packers containing 12 cartoned bottles and calibrated dosing droppers.
g.	*How Dispensed:*	Prescription (Rx) – US Federal law restricts this drug to use by, or on the order of, a licensed veterinarian.
h.	*Amount of Active Ingredients:*	Each mL contains 25 mg of clindamycin hydrochloride.
i.	*Route of Administration:*	oral
j.	*Species/Class:*	dogs and cats
k.	*Recommended Dosage:*	The drug is administered at a dose range of 2.5-15 mg/lb every 12 hours for skin infections (wounds and abscesses), deep wounds and abscesses, and dental infections in dogs for a maximum of 28 days. The drug is also administered at a dose range of 5.0-15 mg/lb

every 12 hours for osteomyelitis in dogs for a minimum of 28 days. In cats, the dose range is 5-15 mg/lb every 24 hours for a maximum of 14 days.

l. *Pharmacological Category:* antibiotic

m. *Indications:* ANTIROBE AQUADROPS Liquid (brand of clindamycin hydrochloride) 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 *Staphylococcus intermedius*).
Deep wounds and abscesses due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.
Dental infections due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.
Osteomyelitis due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens.*

CATS:

Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*).
Deep wounds and abscesses due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.
Dental infections due to *Staphylococcus*

aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum and *Clostridium perfringens*.

n. *Effect of Supplement:*

The supplement provides for the use of clindamycin hydrochloride (ANTIROBE AQUADROPS Liquid) in dogs at a dose range of 2.5-15 mg/lb body weight every 12 hours for skin infections (wounds and abscesses), deep wounds and abscesses, and dental infections. It also provides for a dose range in dogs of 5-15 mg/lb every 12 hours for osteomyelitis. In addition, this supplement provides for an expanded dose range of 5-15 mg/lb every 24 hours in cats. This supplement also provides for the addition of recent MIC data derived from a survey of U.S. diagnostic laboratories.

2. EFFECTIVENESS

Please refer to the Freedom of Information (FOI) Summaries for ANTIROBE Capsules (clindamycin hydrochloride), NADA 120-161, dated June 6, 1984 and November 16, 1989 and for ANTIROBE AQUADROPS Liquid (clindamycin hydrochloride), NADA 135-940, dated May 23, 1985 and October 7, 1996. This approval does not affect this section of these summaries, however, a review of this data supports the lower ends of the two dose ranges of 2.5-15 mg/lb and 5-15mg/lb body weight every 12 hours in dogs. It also supports the lower end of the dosage range of 5-15 mg/lb in cats.

3. TARGET ANIMAL SAFETY

Please refer to the Freedom of Information (FOI) Summaries for ANTIROBE Capsules (clindamycin hydrochloride), NADA 120-161, dated June 6, 1984 and for ANTIROBE AQUADROPS Liquid (clindamycin hydrochloride), NADA 135-940, dated October 7, 1996. This approval does not affect this section of these summaries, however, a review of this data supports the upper end of the two dose ranges of 2.5-15 mg/lb and 5-15 mg/lb body weight every 12 hours in dogs for up to a maximum of 28 days. It also supports the upper end of the dose range of 5-15 mg/lb in cats for up to a maximum of 14 days.

4. 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 NADA.

Human Warnings are provided on the product label as follows: "WARNING: Keep out of reach of children. Not for human use."

5. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR 514 of the implementing regulations. The data demonstrates that ANTIROBE AQUADROPS Liquid (clindamycin hydrochloride), when administered to dogs and cats, is safe and effective when used under labeled conditions.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is judged to be critical in the diagnosis of bacterial infections in animals, treatment of these conditions, and monitoring for possible adverse effects of the drug.

Under the Center's supplemental approval policy 21 CFR 514.106(b)(2), this is a Category II change.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for non-food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for the approval and conducted or sponsored by the applicant.

6. APPROVED PRODUCT LABELING

Facsimile Labeling is attached as indicated below:

Package insert

Bottle Label

Box Label