Date of Approval: August 26, 2002

FREEDOM OF INFORMATION SUMMARY

Original ANADA 200-291

Clindamycin Hydrochloride Liquid

(Dogs and cats)

Sponsored by:

Delmarva Laboratories, Inc.
Suite 106
1500 Huguenot Road
Midlothian, VA 23113

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA:	200-291
Sponsor:	Delmarva Laboratories, Inc. Suite 106 1500 Huguenot Road Midlothian, VA 23113
Generic Name:	Clindamycin Hydrochloride Liquid
Trade Name:	Clinsol®
Dosage Form:	Liquid
How Supplied:	20 mL bottles
How Dispensed:	Rx
Amount of Active Ingredients:	25 mg/mL clindamycin HCL
Route of Administration:	Oral
Species:	Dogs and cats
Pharmacological Category:	Antibacterial
Labeled Dosage & Indications for Use:	**Dogs**: Aerobic bacteria: Clinsol (clindamycin hydrochloride) Liquid is indicated for the treatment of soft tissue infections (wounds and abscesses), dental infections and osteomyelitis caused by susceptible strains of *Staphylococcus aureus.* Anaerobic bacteria**:** Clinsol (clindamycin hydrochloride) Liquid is indicated for the treatment of soft tissue infections (deep wounds and abscesses), dental infections and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis, Bacteroides*

melaninogenicus, Fusobacterium necrophorum and *Clostridium perfringens.*

Cats: Aerobic bacteria: Clinsol (clindamycin hydrochloride) Liquid is indicated for the treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Staphylococcus aureus, Staphylococcus intermedius* and *Streptococcus spp.*.
Anaerobic bacteria**:** Clinsol (clindamycin hydrochloride) Liquid is indicated for the treatment of soft tissue infections (deep wounds and abscesses), dental infections caused by or associated with susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis.*

Dosage Schedule:

Dogs: 2.5 mg/lb body weight every 12 hours for a maximum of 28 days for the treatment of canine infected wounds, abscesses and dental infections.
5.0 mg/lb body weight every 12 hours for a maxmum of 28 days for the treatment of osteomyelitis.

Cats: 5.0 to 10.0 mg/lb body weight once every 24 hours for a maximum of 14 days depending on severity of the condition.

Pioneer Product/ Listed Product:	Antirobe® Liquid NADA 135-940 (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. ANADAs 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, Delmarva Laboratories, Inc. was granted a waiver on May 16, 1997, from conducting an *in vivo* bioequivalence study for Clinsol®. The generic and pioneer products are solutions that contain the same active and inactive ingredients in the same concentrations .

3. HUMAN SAFETY:

Clinsol® is intended for use only 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.

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 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 Clinsol®, when used under the proposed conditions of use, is safe and effective for the labeled indications.

The Three-year Exclusivity period for the feline claims granted to the pioneer ended on October 7, 1999. No new data was required for addition of the feline claims.

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:

20 mL bottle label, carton, 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.