Approval Date: June 6, 2002

CLINTABS®

Clindamycin Hydrochloride tablets

FREEDOM OF INFORMATION SUMMARY

ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-316

CLINTABS® (Clindamycin hydrochloride) 25 mg, 75 mg, and 150 mg tablets

For treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyeltis caused by susceptible gram positive and gram negative bacteria.

Sponsored by:

Delmarva Laboratories, Inc.

FREEDOM OF INFORMATION SUMMARY - CLINTABS®

1. General Information

ANADA Number: 200-316

Sponsor: Delmarva Laboratories, Incorporated
1500 Huguenot Road
Suite 106
Midlothian, VA 23113
Labeler Code: 059079

Generic Name: Clindamycin Hydrochloride 25 mg, 75 mg, and 150 mg tablets

Trade name: Clintabs®

Dosage form: 25 mg, 75 mg, and 150 mg tablets.

How Supplied: 25 mg tablets supplied in bottles of 600.
75 mg tablets supplied in bottles of 200.
150 mg tablets in bottles of 100.

How Dispensed: Rx

Amount of Active Ingredients: Each tablet contains clindamycin hydrochloride equivalent to 25 mg, 75 mg, or 150 mg clindamycin, respectively.

Route of Administration: Oral

Species: Canine

Recommended Dosage: For therapy of wounds, abscesses, and dental infections, orally administer 2.5 mg/lb body weight every 12 hours for a 28 day maximum. For therapy of osteomyelitis, orally administer 5.0 mg/lb body weight every 12 hours for a 28 day minimum.

Pharmacological Category: Antibotic

Indications for Use:

Dogs: Aerobic bacteria: Clintabs® (clindamycin hydrochloride) tablets are indicated for the treatment of soft tissue infections (wounds and abscesses), dental infections and osteomyelitis caused by susceptible strains of *Staphylococcus aureus.*

Anaerobic bacteria: Clintabs® (clindamycin hydrochloride) tablets are 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*.

Pioneer Product: Antirobe® Capsules, clindamycin hydrochloride, NADA 120-161, Pharmacia and Upjohn.

2. Target Animal Safety and Effectiveness

This Drug is the subject of the Generic Animal Drug and Patent Term Restoration Act of 1988 and is submitted as an Abbreviated New Animal Drug Application (ANADA). A Suitability petition (Sp 98P00580/CP) dated July 16, 1998, was submitted by the Sponsor requesting approval for a generic tablet form of clindamycin hydrochloride which was subject of the pioneer drug, Antrobe® Capsules, NADA#120-161, Pharmacia & Upjohn, the only approved solid oral dosage form. The Suitability Petition was approved by the Center for Veterinary Medicine, Food and Drug Administration on October 30, 1998.

A bioequivalence study comparing the bioavailability of the test article, Clintabs® (clindamycin hydrochloride) 150 mg tablets, to that of the reference article, Antirobe® (clindamycin hydrochloride) 150 mg Capsules, was conducted in dogs at Covance Laboratories, Vienna, Virginia. The investigation was conducted as a two periods, two sequences, and two-treatment crossover design employing twenty-four purebred Beagle dogs (12 males, 12 females). All animals were fasted from 12 hours prior to until 4 hours subsequent to dosing. On treatment Day 1, 12 dogs (6 males, 6 females) were orally administered one 150 mg Clintabs® tablet and 12 dogs (6 males, 6 females) were orally administered one 150 mg Antirobe® Capsule. On treatment day 15 the 2 groups of 12 dogs were orally administered the opposite drug from treatment Day 1. After drug administration, Days 1 and 15, blood was taken from each dog prior to dosing (0 hour) and at 0.6, 0.75, 1.0, 1.25, 1.5, 2.0, 4.0, 8.0, 12.0, 18.0, 24.0, 26.0, 36.0 and 48.0 hours relative to dosing. The serum was harvested, stored frozen, and subsequently analyzed for clindamycin concentration using a validated HPLC procedure.

The results of the *in-vivo* bioequivalence trial were as follows (Table 1):

Table 1: Pivotal bioavailability metrics, Clintabs vs Antirobe in dogs

Parameter	Antirobe geom. mean	Cintabs geom. mean	Clin/Anti	Diff LS means	SE diff	Lower CI	Upper CI
AUC 0-LOQ (µg*hr/mL)	22.77	24.32	1.07	0.0659	0.0556	0.97	1.17
CMAX (µg*mL)	5.55	5.5	1.0	0.00273	0.03238	0.95	1.06

3. Human Safety: Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this ANADA. The drug is to be labeled for use in dogs only, which are non-food animals.

Human Safety Considerations Other than Food Safety:

The labeling includes the following statement: "Warning -- Not for human use.

4. Agency Conclusions:

The data submitted in support of this original Abbreviated New Animal Drug Application (ANADA) filed under section 512 (b) satisfies the requirements of section 512 (n) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 514 of the implementing regulations. The data demonstrates that Clintabs® (clindamycin hydrochloride) is safe and effective when used under labeled conditions.

The innovator product, Anitrobe® requires a Veterinarians prescription.

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.

Based upon the results of the *in-vivo* bioequivalence study, it is concluded that Delmarva's Clintabs® (150 mg clindamycin tablets) are bioequivalent to Antirobe® 150 mg clindamycin capsules. When used under its proposed conditions of use, it is safe and effective for its labeled indications.

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

   Pioneer: (25 mg capsule, 75 mg capsule, 150 mg capsule, and package insert.)
   Generic: (25 mg tablet, 75 mg tablet, 150 mg tablet, and package insert.)