Date of Approval: November 22, 2006

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-120

CLOMICALM Tablets

Clomipramine hydrochloride
Tablet
Dogs

The effect of the supplement is the addition of a 5 mg tablet size.

Sponsored by:

Novartis Animal Health US, Inc.

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I. GENERAL INFORMATION:

A. File Number:	NADA 141-120
B. Sponsor:	Novartis Animal Health US, Inc. 3200 Northline Ave. suite 300 Greensboro, NC 27408 Drug Labeler Code: 058198
C. Proprietary Name(s):	CLOMICALM Tablets
D. Established Name(s):	Clomipramine hydrochloride
E. Pharmacological Category:	Tricyclic antidepressant
F. Dosage Form(s):	Tablet
G. Amount of Active Ingredient(s):	Tablets are scored and available in 4 strengths: 5 mg, 20 mg, 40 mg, and 80 mg
H. How Supplied:	Color-coded bottles of 30 tablets
I. How Dispensed:	Rx
J. Dosage(s):	The recommended daily dose of CLOMICALM Tablets is 2 to 4 mg/kg/day (0.9 - 1.8 mg/lb/day). It can be administered as a single daily dose or divided twice daily based on patient response and/or tolerance of side effects.
K. Route(s) of Administration:	Oral
L. Species/Class(es):	Dogs
M. Indication(s):	To be used as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.
N. Effect(s) of Supplement:	This supplement provides for the addition of a 5 mg tablet size.

II. EFFECTIVENESS:

A. Dosage Characterization:

This supplemental approval does not change the previously approved dosage range. The FOI Summary for the original approval of NADA 141-120 dated December 10, 1998 contains dosage characterization information for dogs at the approved label dose.

B. Substantial Evidence:

CVM did not require new effectiveness studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-120 dated December 10, 1998 contains a summary of studies that demonstrate effectiveness of the drug for dogs.

III. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-120 dated December 10, 1998 contains a summary of target animal safety studies for dogs.

IV. HUMAN FOOD SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this NADA.

V. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to CLOMICALM Tablets:

Human Warnings are provided on the product label as follows: "**Not for use in humans. Keep out of reach of children. In case of accidental ingestion seek medical attention immediately. In children, accidental ingestion should be regarded as serious. There is no specific antidote for clomipramine. Overdose in humans causes anticholinergic effects including effects on the central nervous (e.g., convulsions) and cardiovascular (e.g., arrhythmia, tachycardia) systems. People with known hypersensitivity to clomipramine should administer the product with caution**."

VI. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514. The data demonstrate that CLOMICALM Tablets, when used according to the label, are safe and effective as

part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

A. Marketing Status:

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose separation anxiety and monitor the safe use of the product.

B. Exclusivity:

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

C. Supplemental Applications:

This supplemental NADA did not require a reevaluation of the safety or effectiveness data in the original NADA (21 CFR §514.106(b)(2).

D. Patent Information:

The sponsor did not submit any patent information with this application.

VII. ATTACHMENTS:

Facsimile Labeling:
5 mg Bottle label
5 mg Carton label
Veterinary insert
Client insert