Date of Approval: June 13, 2007

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-203

DERAMAXX Chewable Tablets

Deracoxib Chewable Tablets
Dogs

The effect of the supplement is the addition of a 75 mg tablet size.

Sponsored by:

Novartis Animal Health US, Inc.

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I. GENERAL INFORMATION:

A. File Number:	NADA 141-203
B. Sponsor:	Novartis Animal Health US, Inc. 3200 Northline Ave. suite 300 Greensboro, NC 27408 Drug Labeler Code: 058198
C. Proprietary Name(s):	DERAMAXX Tablets
D. Established Name(s):	deracoxib
E. Pharmacological Category:	Non-steroidal anti-inflammatory
F. Dosage Form(s):	Tablet
G. Amount of Active Ingredient(s):	Tablets are scored and available in 3 strengths: 25 mg, 75 mg, and 100 mg
H. How Supplied:	Round, brownish, half-scored tablets in 7, 30, and 90 count bottles
I. How Dispensed:	Rx
J. Dosage(s):	The daily dose of DERAMAXX tablets for the control of pain and inflammation associated with osteoarthritis in dogs is 0.45-0.91 mg/lb/day (1-2 mg/kg/day) as a single daily dose, as needed. The dose for postoperative orthopedic pain is 1.4-1.8 mg/lb/day (3-4 mg/kg/day) as a single daily dose, as needed, not to exceed 7 days of administration. Tablets are scored and dosage should be calculated in half-tablet increments.
K. Route(s) of Administration:	Oral
L. Species/Class(es):	Dogs
M. Indication(s):	For the control of pain and inflammation associated with osteoarthritis in dogs, and for the control of postoperative pain and inflammation

associated with orthopedic surgery in dogs ≥ 4 lbs (1.8 kg).

N. Effect(s) of Supplement: This supplement provides for the addition of a 75 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 141-203 dated August 21, 2002, for the postoperative pain indication and the FOI Summary for the supplemental approval dated February 11, 2003 for the osteoarthritis indication contain the dosage characterization information for dogs at the approved label doses.

B. Substantial Evidence:

CVM did not require effectiveness studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-203 dated August 21, 2002, for the postoperative pain indication and the FOI Summary for the supplemental approval dated February 11, 2003 for the osteoarthritis indication contain a summary of studies that demonstrate the 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 141-203 dated August 21, 2002 for the postoperative pain indication contain 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 DERAMAXX Chewable Tablets:

"Not for use in humans. Keep this and all medication out of reach of children. Consult a physician in case of accidental ingestion by humans."

The following items were examined to ensure human user safety: the Material Safety Data Sheets (MSDS) for deracoxib, the FOI Summaries for DERAMAXX (NADA 141-203), and the Drug Experience Reports submitted to FDA regarding this NADA.

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 DERAMAXX Chewable Tablets, when used according to the label, are safe and effective for the control of pain and inflammation associated with osteoarthritis in dogs, and for control of postoperative orthopedic pain in dogs.

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 and treat osteoarthritis and postoperative pain 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:

DERAMAXX Chewable Tablets are under the following U.S. patent numbers:

U.S. Patent Number	Date of Expiration
5,521,207	November 30, 2013
5,756,529	September 29, 2015
5,892,053	May 25, 2015
5,910,597	May 25, 2015

VII. ATTACHMENTS:

Facsimile Labeling:
75 mg bottle label
Veterinary insert
Client insert