Date of Approval: July 27, 2006

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-366

NOVOX CAPLETS
(carprofen)

Effect of Supplement: For the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs

Sponsored by:

IMPAX Laboratories, Inc.

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1. GENERAL INFORMATION:

a. File Number:	ANADA 200-366
b. Sponsor:	IMPAX Laboratories, Inc. 30831 Huntwood Ave. Hayward, CA 94544 Drug Labeler Code: 000115
c. Established Name:	Carprofen
d. Proprietary Name:	NOVOX Caplets
e. Dosage Form:	Scored caplet
f. How Supplied:	25 mg caplets: Bottles of 60, 100, and 180 75 mg and 100 mg caplets: Bottles of 60 and 180
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	25 mg, 75 mg, or 100 mg carprofen per caplet
i. Route of Administration:	Oral
j. Species/Class:	Canine
k. Recommended Dosage:	For the relief of pain and inflammation associated with osteoarthritis, the total daily dose may be administered as 2 mg/lb (4.4 mg/kg) of body weight once daily or divided and administered as a 1 mg/lb (2.2 mg/kg) of body weight twice daily. For the control of postoperative pain, carprofen may be administered 2 hours prior to the procedure. NOVOX Caplets are scored and dosage should be calculated in half-caplet increments.
l. Pharmacological Category:	Non-steroidal anti-inflammatory drug (NSAID)
m. Indications:	For the relief of pain and inflammation associated with osteoarthritis in dogs and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

n. Effect of Supplement: This supplement provides for the addition of the claim for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs. The exclusivity period protecting this claim for the pioneer product expired July 08, 2005.

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 (GADPTRA) of 1988, 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 and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

The sponsor demonstrated *in vivo* bioequivalence via a blood-level bioequivalence study of the 25 mg generic and pioneer carprofen caplets to support the safety and efficacy of the generic product. Refer to the original Freedom of Information (FOI) Summary dated April 27, 2005, for more details.

3. HUMAN 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, 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: “Keep out of reach of children. Not for human use. Consult a physician in cases of accidental ingestion by humans.”

4. AGENCY CONCLUSIONS:

This ANADA filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that NOVOX Caplets, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

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

Generic labeling for ANADA 200-366: Package labeling; Package insert; Client information sheet

Pioneer labeling for NADA 140-053: Package labeling; Package insert; Client information sheet