Approval Date: May 8, 2003

FREEDOM OF INFORMATION SUMMARY

EtoGesic® (etodolac) Tablets

Supplemental NADA 141-108

Fort Dodge Animal Health

Allows for the addition of a 500 mg tablet

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	NADA 141-108
b. Sponsor:	Fort Dodge Animal Health P.O. Box 1339 Fort Dodge, Iowa 50501 Drug Labeler Code: 053501
c. Established Name:	Etodolac
d. Proprietary Name:	EtoGesic® Tablets
e. Dosage Form:	Tablet
f. How Supplied:	Each tablet size is scored and is available in bottles of 7, 30, and 90 tablets.
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	150 mg, 300 mg, and 500 mg etodolac.
i. Route of Administration:	Oral
j. Species/Class:	Canine
k. Recommended Dosage:	10 to 15 mg/kg body weight (4.5 to 6.8 mg/lb) given orally once daily.
l. Pharmacological Category:	Non-steroidal anti-inflammatory drug
m. Indications:	For the management of pain and inflammation associated with osteoarthritis in dogs.
n. Effect of Supplement**:**	This supplement allows for the addition of a 500 mg tablet.

2. ***EFFECTIVENESS:***

The approval of the larger size tablet containing 500 mg etodolac does not require new effectiveness data, as the minimum dose remains the same as currently approved. The approval is based on the manufacturing information on containers/closures,

labeling, dissolution and stability of the new larger size tablets. Refer to the FOI Summary for the original approval dated July 22, 1998.

3. *TARGET ANIMAL SAFETY:*

The approval of the larger size tablet containing 500 mg etodolac does not require new target animal safety data, as the maximum dose remains the same as currently approved. The approval is based on the manufacturing information on containers/closures, labeling, dissolution and stability of the new larger size tablets. Refer to the FOI Summary for the original approval dated July 22, 1998.

4. *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 supplemental NADA.

Human warnings are provided on the product label as follows: "Keep out of reach of children" and "Not for human use."

5. AGENCY CONCLUSIONS:

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrates that EtoGesic® Tablets, when administered orally, are safe and effective for the management of pain and inflammation associated with osteoarthritis in dogs.

This supplement is a Category II change under the Center's supplemental approval policy, 21 CFR 514.106(b)(2)(ii). The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

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

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

a. Bottle labels for 7, 30, and 90 count bottles.
b. Package insert