Approval Date: February 10, 2003

# FREEDOM OF INFORMATION SUMMARY

## NADA 141-007

Drontal® Plus Tablets
(Praziquantel/pyrantel pamoate/febantel)

1) For the removal of Tapeworms (*Dipylidium caninum, Taenia pisiformis, Echinococcus granulosus*, and removal and control of *Echinococcus multilocularis)*.

2) For the removal of Hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), Ascarids (*Toxocara canis*, *Toxascaris leonina*) and Whipworms (*Trichuris vulpis*) in dogs.

Sponsored by:
Bayer Corporation Agricultural Division
Animal Health
P.O. Box 390
Shawnee Mission Kansas 66202

**FREEDOM OF INFORMATION SUMMARY**

## *1. GENERAL INFORMATION:*

a. File Number: NADA 141-007

b. Sponsor: Bayer Corporation
Agricultural Division
Animal Health
P.O. Box 390
Shawnee Mission Kansas 66202
Drug Labeler Code: 000859

c. Established Name: Praziquantel, pyrantel pamoate, febantel

d. Proprietary Name: Drontal® Plus Tablets

e. Dosage Form: Tablet

f. How Supplied: Each tablet size is available in bottles of 50 tablets (puppies and small dogs, medium sized dogs) or 30 tablets (large dogs).

| | |
|---|---|
| Code 08713130-176099 | 50 tablets/bottle (Puppies and Small Dogs) |
| Code 08713149-177099 | 50 tablets/bottle (Medium Sized Dogs) |
| Code 08724639 | 30 tablets/bottle (Large Dogs) |

g. How Dispensed: Rx

h. Amount of Active Ingredients: The currently approved tablet sizes contain 22.7 mg, 22.7 mg and 113.4 mg (Puppies and Small Dogs) and 68.0 mg, 68.0 mg, 340.2 mg (Medium Sized Dogs) each of praziquantel, pyrantel base as pyrantel pamoate, and febantel respectively. The proposed new tablet (Large Dogs) contains 136.0 mg praziquantel, 136.0 mg pyrantel base as pyrantel pamoate and 680.4 mg febantel.

i. Route of Administration: Oral

j. Species/Class: Canine

k. Recommended Dosage:
The large size tablet size is administered as specified in the following table as a single oral treatment.

| Body Weight (lbs.) | Number of Tablets |
|---|---|
| 45-60 | 1.0 |
| 61-90 | 1.5 |
| 91-120 | 2.0 |

Tablets may be given directly by mouth or offered in a small amount of food. Fasting is neither necessary nor recommended prior to or after treatment.

l. Pharmacological Category: Anthelmintic

m. Indications: Drontal® Plus Tablets are indicated for the removal of Tapeworms (*Dipylidium caninum, Taenia pisiformis, Echinococcus granulosus*, and removal and control of *Echinococcus multilocularis)*. Drontal® Plus Tablets are also indicated for the removal of Hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), Ascarids (*Toxocara canis*, *Toxascaris leonina*) and Whipworms (*Trichuris vulpis*) in dogs.

n. Effect of Supplement**:** This supplement amends the NADA to provide for a larger tablet containing 136.0 mg praziquantel, 136.0 mg pyrantel base as pyrantel pamoate and 680.4 mg febantel and the associated label changes.

## 2. *EFFECTIVENESS:*

The approval of the larger size tablet containing praziquantel (136.0 mg), pyrantel base (136.0 mg) as pyrantel pamoate, and febantel (680.4 mg) tablet 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.

## 3. *TARGET ANIMAL SAFETY:*

The approval of the larger size tablet containing praziquantel (136.0 mg), pyrantel base (136.0 mg) as pyrantel pamoate, and febantel (680.4 mg) tablet 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.

## 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 NADA.

Human warnings are provided on the product label as follows: "Keep out of reach of children."

## *5. 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 of the implementing regulations. The data demonstrates that Drontal® Plus tablets, when administered orally, are safe and effective for the removal of tapeworms (*Dipylidium caninum, Taenia pisiformis, Echinococcus granulosus*, and removal and control of *Echinococcus multilocularis)*, the removal of hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), ascarids (*Toxocara canis*, *Toxascaris leonina*) and whipworms (*Trichuris vulpis*) in dogs.

This supplement is a Category II change under the Center's supplemental approval policy, 21 CFR 514.106(b)(2). 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.

Drontal® Plus Tablets are under the following U. S. patent numbers:

| U.S. Patent Number | Date of Expiration |
|---|---|
| 5,036,069 | July 30, 2008 |

## *6. ATTACHMENTS:*

Facsimile Labeling is attached as indicated below:

a. Bottle label for large, medium and small dog sizes.
b. Case label for large, medium and small dog sizes.
c. Package insert for large, medium and small dog sizes.