Date of Approval: May 27, 2009

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-292

FELIMAZOLE Coated Tablets

methimazole

cats

Sponsored by:

Dechra, Ltd.

TABLE OF CONTENTS

I. GENERAL INFORMATION....1

II. EFFECTIVENESS....2

A. DOSAGE CHARACTERIZATION....2
B. SUBSTANTIAL EVIDENCE....4

III. TARGET ANIMAL SAFETY....9

A. GLP MARGIN OF SAFETY STUDY....9

IV. HUMAN FOOD SAFETY....12

V. USER SAFETY....12

VI. AGENCY CONCLUSIONS....13

A. MARKETING STATUS....13
B. EXCLUSIVITY....13
C. PATENT INFORMATION....13

VII. ATTACHMENTS....13

I. GENERAL INFORMATION

A. File Number: NADA 141-292

B. Sponsor:

Dechra, Ltd.
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Stoke-on-Trent
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United Kingdom

Drug Labeler Code: 043264

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7015 College Boulevard, Suite 525
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C. Proprietary Name(s): FELIMAZOLE Coated Tablets

D. Established Name(s): Methimazole

E. Pharmacological Category: Antithyroid

F. Dosage Form(s): Coated tablet

G. Amount of Active Ingredient(s): 2.5 mg and 5 mg

H. How Supplied: 100 count bottles

I. How Dispensed: Rx

J. Dosage(s): The starting dose is 2.5 mg administered every 12 hours. Following three weeks of treatment, the dose should be titrated to effect based on individual serum total T4 (TT4) levels and clinical response. Dose adjustments should be made in 2.5 mg increments. The maximum total dosage is 20 mg per day divided, not to exceed 10 mg as a single administration.

K. Route(s) of Administration: Oral

L. Species/Class(es): Cats

M. Indication(s): FELIMAZOLE (methimazole) Coated Tablets are indicated for the treatment of hyperthyroidism in cats.

II. EFFECTIVENESS

A. Dosage Characterization

The starting dose of FELIMAZOLE Coated Tablets is 2.5 mg administered every 12 hours. Following three weeks of treatment, the dose should be titrated to effect based on individual serum total thyroxine (TT4) levels and clinical response. Dosing is based on the results from three studies conducted in client-owned cats and a published report in the scientific literature.

In a study of 26 client-owned cats newly diagnosed with hyperthyroidism, methimazole tablets were administered at a dose of 10 to 15 mg per day (in two or three divided doses). Cats with serum TT4 levels > 5.1 mcg/dL and clinical signs of hyperthyroidism were enrolled. Following 3 weeks of treatment, the dose was titrated to effect based on individual TT4 values. Nineteen cats completed the 3 week phase of the study. At the end of 3 weeks, 4/19 cats (21%) demonstrated effectiveness using the success criteria defined as a return to normal TT4 concentrations and an improvement in disease severity based on clinical signs (see Table 1).

Table 1. Effectiveness Evaluation Using TT4 and Disease Severity Scores

N=19 cats		Clinical Condition			
		Improved	Unchanged	Worse	Total
TT4 level	Normal	4 (21%)	2 (11%)	-	6 (32%)
	Low	10 (53%)	2 (11%)	-	12 (63%)
	High	1 (5%)	-	-	1 (5%)
Total		15	4	0	19

Eleven cats (41%) completed the study to 20 weeks. Eight cats were withdrawn for treatment-related adverse reactions and three cats died of adverse reactions associated with methimazole treatment. The majority of adverse reactions reported included lethargy, vomiting, anorexia, diarrhea, self-induced excoriations, and alopecia. Several adverse reactions were severe in nature. One cat was withdrawn from the study after reports of lethargy, vomiting, and facial excoriations. Marked thrombocytopenia was reported in two cats. Two cats collapsed and died within 12 days of beginning treatment at a dose of 5 mg twice daily. Both cats had lethargy, vomiting, anorexia, and a large volume of dark bloody stool prior to death. Pallor was reported in one of the cats. Necropsies were not performed, however based on clinical signs and normal pretreatment bloodwork, bleeding diathesis secondary to treatment could not be ruled out as a cause of death. A third cat died suddenly after 5 weeks of treatment following a dose increase to 5 mg three times daily at 3 weeks.

Adverse reactions prompted a reduction of the starting study dose to 5 mg once daily. Forty cats were enrolled following the dose reduction to 5 mg once daily. Of these, 25 cats (62.5%) completed the study to 20 weeks. Six cats were withdrawn for

treatment-related adverse reactions. Eight cats were withdrawn and one cat died for reasons unrelated to treatment. Of the 25 cats completing the 20-week study, 96% (24/25 cats) had no clinical signs or only mild signs of hyperthyroidism, however 21% of these cats had elevated TT4 levels (TT4 above 5.1 mcg/dL). Adverse reactions included vomiting, lymphopenia, and thrombocytopenia.

In another study of 71 client-owned cats newly diagnosed with hyperthyroidism, a starting dose of FELIMAZOLE Coated Tablets at 2.5 mg twice daily was shown to be effective with fewer adverse reactions. Cats with serum TT4 levels > 5.1 mcg/dL and clinical signs of hyperthyroidism were enrolled. Effectiveness was assessed at 3, 6, 10, 15, and 20 weeks, where the clinical endpoint for success was a reduction in serum TT4 levels to the normal range and a reduction in disease severity based on clinical signs (see Table 2). Fifty-eight cats completed the 20-week study.

Table 2. Percent of Cats with Normal TT4 Values and Reduced Disease Severity

Visit	# Cats with normal TT4 / # Cats tested for TT4	% Cats with Normal TT4	% Cats with Reduced Disease Severity
Initial	0/71	0	-
3 weeks	54/68	79.4	66.1
6 weeks	47/61	77.1	81.1
10 weeks	46/62	74.2	83.9
15 weeks	45/57	79.0	81.8
20 weeks	42/58	72.4	87.5

At the end of the 20-week study the mean total daily dose was 2.5 mg twice daily (see Table 3).

Table 3. FELIMAZOLE Coated Tablet dosing at Week 20 of Field Study

Dose at 20 weeks	Number of Cats (%) n=58
2.5 mg twice daily	34 (59%)
2.5 mg once daily	12 (21%)
2.5 mg three times daily	4 (7%)
2.5 mg daily, then twice daily every other day	2 (4%)
Other dose	6 (11%)

Vomiting, anorexia, lethargy, and diarrhea were the most frequently reported adverse reactions associated with methimazole treatment. One cat developed cholangiohepatitis, jaundice and anemia; the anemia resolved when treatment was discontinued. One cat developed pallor, anorexia, dehydration, bleeding diathesis, jaundice, and a regenerative anemia, and died in spite of supportive medical care. A

third cat developed anemia after 4 weeks of treatment. Renal disease was unmasked in one cat after 3 weeks of treatment.

The findings from these clinical studies are supported by published scientific literature, where a methimazole dose of 2.5 mg twice daily provided greater effectiveness than 5 mg once daily for reduction of serum TT4 within 2 to 4 weeks.[1]

B. Substantial Evidence

1. Field Study

a. A Multi-center Clinical Study of Methimazole Tablets for the Treatment of Naturally Occurring Feline Hyperthyroidism
Report No. EC/METH2005/PROTO(FDA001)

b. Investigators:

Colleen Currigan, DVM Chicago, IL	David Lukof, DVM Harleysville, PA
Deborah Edwards, DVM, ABVP Largo, FL	Elizabeth Rowlands, DVM Houston, TX
Samuel L. Geller, DVM Quakertown, PA	Doug Santen, DVM Denver, CO
Alice J. Johns, DVM, ABVP Indianapolis, IN	Roger Sifferman, DVM Springfield, MO
Matt Leara, DVM Oceanside, CA	Elaine Wexler-Mitchell, DVM, ABVP Orange, CA

c. Study Design:
1) Objective: This study assessed the field safety and effectiveness of FELIMAZOLE Coated Tablets administered for the treatment of hyperthyroidism in client-owned cats under clinical conditions.

2) Study Animals: Client-owned cats newly diagnosed with hyperthyroidism were enrolled in the study. Diagnosis of hyperthyroidism was based on laboratory testing demonstrating a TT4 of > 5.4 mcg/dL.

3) Treatment Groups: This was an open label study with historical control and all subjects were assigned to the FELIMAZOLE Coated Tablet group.

[1] Trepanier, L.A. et al. 2003. Efficacy and safety of once versus twice daily administration of methimazole in cats with hyperthyroidism. *JAVMA* 222:954-958.

Based on the natural history of hyperthyroidism, the disease was expected to continue to progress without spontaneous recovery.

4) Drug Administration: The starting dose was 2.5 mg twice daily. After 3 weeks, the dose was titrated to effect, if necessary, according to the TT4. Dose adjustments were made by increments of 2.5 mg.

5) Measurements and Observations: There were four planned visits. Enrollment, testing and initiation of dosing were performed during the first two visits. Subsequent visits were at 21 and 42 days after starting FELIMAZOLE Coated Tablets. At each visit, clinical signs were assessed and laboratory tests (TT4, hematology and biochemical profile) were conducted. At the Day 21 and 42 visits, the clinical investigator assessed whether each cat was improved, no change, or worse compared to baseline. Antinuclear antibodies (ANA) titers were evaluated pre-treatment and on Day 42. Owners completed daily dosing diaries including comments on any abnormalities observed in their cat during the study period.

6) Statistical Methods: The primary variable for effectiveness was treatment success or failure for each cat, evaluated at Day 42. Each cat was considered a treatment success if, on Day 42, it was clinically assessed by the investigator as improved relative to pre-treatment and its TT4 concentration was normal (TT4 $\leq$ 4.0 mcg/dL). A secondary variable for effectiveness at Day 21 was defined as a clinical assessment of improved or no change, and TT4 $\leq$ 4.0 mcg/dL. The percentage of cats successfully treated at Day 42 as defined above was calculated. The lower bound of the one-sided 95% confidence interval for treatment success was calculated. The percentage of cats that met these success criteria at Day 21 was summarized similarly.

Continuous outcome variables measured more than once were evaluated using methods appropriate for repeated measures. The statistical model included time as the only fixed effect, and clinic as a random effect. Categorical outcomes were dichotomized, and percentages and 95% confidence intervals were calculated.

d. Results: There were 113 cats (55 castrated males, 57 spayed females, and one intact female) of various breeds were enrolled in the study. Ages ranged from 7 to 20 years and body weights ranged from 4 to 20 pounds. One hundred and five cats were included in the effectiveness evaluation at Day 42. Eight cats were considered non-evaluable: three were removed due to owner non-compliance, three due to death unrelated to treatment, one due to inadequate TT4 elevation at baseline, and one due to unmasking of pre-existing renal disease.

Of the 105 evaluable cases, 64 (61%) were considered treatment successes. The lower bound of the one-sided 95% confidence interval was estimated as 53.1% (see Table 4). Table 5 contains summary effectiveness statistics.

Table 4: Evaluation of treatment success

Time of Assessment	Treatment Outcome[1]	N[2]	Percent Success	Lower Bound of the One-Sided 95% Confidence Interval
Day 21	TT4 concentration ≤ 4.0 mcg/dL and clinically assessed as no change or improved	110	65.4	58.0
Day 42	TT4 concentration ≤ 4.0 mcg/dL and clinically assessed as improved	105	61.0	53.1

[1] The primary outcome of treatment success is based on the Day 42 assessment.
[2] Number of clinically valid cases included in the assessment of treatment success. Five cases that were clinically valid at Day 21 were no longer evaluable by Day 42.

Table 5: Effectiveness variables: Summary statistics

Time of Assessment	Outcome	N[1]	Frequency	Percent
Day 21	TT4 ≤ 4.0 mcg/dL	110	65	59.1
	Clinically assessed as improved or no change	110	106	96.4
Day 42	TT4 ≤ 4.0 mcg/dL	105[2]	65	61.9
	Clinically assessed as improved	105[2]	92	87.6

[1] Number of clinically valid cases included in the assessment of treatment success. Five cases that were clinically valid at Day 21 were no longer evaluable by Day 42.
[2] At the Day 42 assessment, three cats were terminated early and classified as treatment failures. They are assumed to have failed both the TT4 and clinical criteria for treatment success.

The incidence of clinical signs associated with hyperthyroidism (e.g. vomiting, changes in activity level, bowel habits, and appetite) reported by cat owners decreased as the study progressed. Owners reported 69 of 105 (65.7%) cats had a lower incidence of clinical signs of hyperthyroidism, 21% had no change, and 13.3% had a higher incidence at the Day 42 visit compared to the baseline period.

Over the course of the study, heart rate and respiratory rate decreased, and body weight increased. By Day 42, fewer cats had palpable thyroid glands. The decrease in TT4 concentration was significant from the pre-enrollment visit to the Day 42 visit ($p < 0.0001$). Prior to treatment, many cats had elevated liver enzymes due to the pathophysiology of hyperthyroidism. By Day 42, means for alkaline phosphatase (ALP), alanine aminotransferase (ALT) and aspartate aminotransferase (AST) were decreased.

ANA titers were <1:40 for all 107 cats sampled at the pre-enrollment visit. Out of 95 cats with ANA titer data at Day 42, 92 (96.8%) remained at <1:40, one cat (1.1%) increased to 1:80, and two cats (2.1%) increased to 1:160. Hematocrit and counts for lymphocytes, monocytes, neutrophils, red blood cells, and white blood cells were lower at Day 42 compared to the baseline visit. Means remained within or near normal ranges for the testing laboratory.

e. Adverse Reactions: Three cats were withdrawn early from the study due to treatment related adverse reactions. One of these cats was withdrawn with unmasked renal disease and two cats were withdrawn due to the development of skin lesions related to treatment with FELIMAZOLE Coated Tablets. The most common adverse reactions observed included change in food consumption (increase or decrease), lethargy, vomiting, diarrhea/loose stool, skin lesions (including excoriations), and abnormal vocalization.

f. Conclusions: FELIMAZOLE Coated Tablets were effective in lowering TT4 concentration and improving clinical signs in cats with hyperthyroidism.

2. Field Study - Extended Use

a. Extended Use of Methimazole Tablets in the Long-Term Treatment of Naturally Occurring Feline Hyperthyroidism
Report No. EC/METH2005/PROTO(FDA002)

b. Investigators:

Deborah Edwards, DVM, ABVP Largo, FL	Elizabeth Rowlands, DVM Houston, TX
Samuel L. Geller, DVM Quakertown, PA	Doug Santen, DVM Denver, CO
Matt Leara, DVM Oceanside, CA	Roger Sifferman, DVM Springfield, MO
David Lukof, DVM Harleysville, PA	Elaine Wexler-Mitchell, DVM, ABVP Orange, CA

c. Study Design:

1) Objective: This study was conducted to collect additional safety and effectiveness information about FELIMAZOLE Coated Tablets in the target population.

2) Study Animals: Enrolled cats had successfully completed the preceding study (EC/METH2005/PROTO(FDA001)). Enrollment was not restricted by breed, age, weight or gender. There were 101 cats (48 castrated males, 52 spayed females, 1 intact female) of various breeds enrolled into the study. Ages ranged from 7 to 20 years and body weights ranged from 4.8 to 20.3 pounds.

3) Treatment Groups: This was an open label study, with all animals enrolled in the FELIMAZOLE Coated Tablet test group. Each cat acted as its own control.

4) Drug Administration: Treatment continued without interruption from Day 42 ± 4 of the previous study EC/METH2005/PROTO(FDA001), and was adjusted as necessary based on TT4 levels and clinical response every three months ± 14 days. Guidelines for dose adjustments were less stringent than in the short-term study, to allow flexibility for the Investigator to achieve a balance between the cat's TT4 levels and overall clinical condition.

5) Measurements and Observations: At each quarterly visit, clinical signs were assessed and TT4, hematology and biochemical profile were obtained. ANA titers were evaluated every 6 months. Results were compiled as a composite investigator score of improved, worse, or no change in clinical signs. Owners completed diaries documenting any abnormalities observed in their cat during the study period. Effectiveness variables were TT4 concentration and investigator improvement score. Safety variables were hematology and biochemistry test results, and the onset of new abnormal clinical signs or adverse reactions.

d. Results: The study was terminated by amendment after each cat had at least two quarterly examinations. The number of cats for each visit ranged from 89 cats (first quarterly visit) to 15 cats (fifth quarterly visit). At each of the first four quarterly visits, mean TT4 concentrations were within or near the normal laboratory reference range (0.8 – 4.0 mcg/dL). Investigators categorized 80.9% of cats as improved or stable at the first quarterly visit, and 75.8% as improved or stable at the fourth quarterly visit (33 cats), relative to their baseline assessment. At the fifth quarterly visit the mean TT4 was 6.90 mcg/dL and 60.0% of the cats were categorized by the investigators as improved or stable relative to their baseline assessment.

Serum chemistry and hematology results were consistent with the trends noted during the main effectiveness study. The mean ALT was above the reference range at the first two quarterly visits, but within the normal reference range through the next two quarterly visits. Mean lymphocyte counts decreased consistently during the study period, to slightly below the reference range (1200-8000 cells/mcL) at the fourth quarterly visit.

Sixteen cats experienced elevated ANA titers at one or more points during long-term therapy with FELIMAZOLE Coated Tablets, but the significance was not determined.

e. Adverse Reactions: Eighteen cats died or were euthanized during the study, four of which may have been related to FELIMAZOLE Coated Tablets due to the unmasking/ acceleration of chronic renal failure.

The most common adverse reactions reported (lethargy and anorexia) were similar to those observed in Study EC/METH2005/PROTO(FDA001). Additional adverse reactions reported more frequently in the long-term study were: depression/withdrawn behavior, weight loss, haircoat abnormalities, increased blood urea nitrogen (BUN), weakness, agitation and diarrhea. Most of these were transient and mild.

f. Conclusions: Long term treatment with FELIMAZOLE Coated Tablets was effective in lowering TT4 concentration and improving clinical signs in cats with hyperthyroidism.

III. TARGET ANIMAL SAFETY

A. GLP Margin of Safety Study

1. Methimazole tolerance study in cats, Study No. ANV005:

a. Investigators: VA Ross, B.Sc.
Cambridgeshire, England

b. Study Design:
1) Objective: To evaluate the tolerance to repeated oral administration of methimazole to cats over a three month period.

2) Study Animals: 24 domestic (British) cross bred cats (12 males and 12 females) aged 3 to 7 months and weighing 1.7 to 2.5 kilograms. There were 6 cats per treatment group.

3) Treatment Groups: The initial recommended 1X dose is 2.5 mg/animal twice daily. The cats in this study were given 2X, 4X, and 6X this dose, as shown in Table 6 below.

Table 6. Dosage Groups

Dosage group	Dose
0 mg twice daily	0X
10 mg (5 mg twice daily)	2X
20 mg (10 mg twice daily)	4X
30 mg (15 mg twice daily)	6X

At week 9, two cats in the 30 mg group were taken off the drug and allowed to recover for the remainder of the study.

4) Drug Administration: FELIMAZOLE Coated Tablets, 5 mg, (final market formulation) or a control (empty gelatin capsule) were administered orally to fasted cats twice daily for 12 weeks.

5) Measurements and Observations: Clinical observations, body weight, food consumption, hematology (weeks 2 and 9), serum biochemistry (weeks 2 and 9), coagulation profile (weeks 2 and 9), urinalysis (weeks 2 and 9), ELISA screening test for presence of antinuclear antibodies (week 9), bone marrow exam, gross and histological pathology exams.

6) Statistical Analysis: For hematology and clinical chemistry variables, body weight, and other variables observed at several time points during the study, a repeated measures analysis of variance was used to test for possible differences due to treatment effects and its interaction with gender and/or time. Pre-treatment values were included as covariates. For variables assessed only at the end of the study, such as organ weights, the analysis of variance was used to test for differences due to treatment effects and its interaction with gender, if applicable. For the analysis of organ weights, total body weight was used as a covariate. Follow-up mean comparisons between each treated group and control using linear contrasts were performed as necessary.

c. Results:

Mortality: Four cats in the 30 mg group were euthanized because of intolerance to the drug. Two of these cats developed immune mediated anemia with thrombocytopenia on days 34 and 58. Another had a nonspecific illness with anorexia, lymphadenopathy and mild anemia. She continued to deteriorate and was sacrificed on day 55, a week after stopping the drug. A fourth cat in the 30 mg group was euthanized after several days of anorexia when the decision was made to discontinue dosing in this group.

Clinical observations: Treatment related clinical signs were observed in all treated groups and included lethargy, anorexia, vomiting, and loose stool. Facial excoriations were seen in the 20 and 30 mg groups.

Body Weight: The 10 and 20 mg groups had higher mean body weights (2.62 and 2.65 kilogram) compared to the control group (2.48 kilogram) ($p < 0.10$).

Food consumption: Food consumption was reduced in all treated groups from week 4 onwards with a dose-related trend evident. The 30 mg cats that were allowed to recover ate normally within a few days of stopping the drug.

Urinalysis: No clinically significant findings were seen.

Bone marrow examinations: There were no treatment-related effects of methimazole administration.

Hematology: There were few treatment related changes in hematology. There was a reduction in white blood cells ($p <0.10$) and lymphocytes ($p <0.10$) at week two in all treated groups compared to the control group. The mean values stayed within the reference range and the animals showed no clinical changes. Two cats in the 30 mg group developed immune mediated anemia with thrombocytopenia.

Coagulation profile: No changes were seen in prothrombin time and activated partial thromboplastin time.

Serum chemistry: There were few treatment related changes in serum chemistry. Creatinine was elevated in all treatment groups compared to the control ($p <0.10$) at week 9. Blood urea nitrogen was elevated in the 10 mg and 20 mg groups compared to the control ($p <0.10$) at week 9. Magnesium was elevated in all treatment groups compared to the control ($p <0.10$) at week 9. Globulin values were elevated in the 20 mg and 30 mg groups compared to the control ($p <0.10$) at week 9. These values stayed within the reference range and the animals showed no clinical signs associated with the changes.

Antinuclear antibodies: There was a dose dependent increase in the presence of antinuclear antibodies.

Gross necropsy examinations: Hepatomegaly, small thymus and hyperplasia and darkening of the thyroid gland were treatment related changes. Lymphadenopathy was present in the sick 30 mg cats. The 30 mg cats that were allowed to recover were comparable to the controls except that the male had enlarged thyroid.

Histopathological examinations: The thyroid glands showed hyperplasia as expected for an antithyroid drug. Livers showed nonspecific changes including inflammation. The kidneys had some inflammatory changes, increased medullary interstitial tissue and dilated cortical tubules sometimes containing casts. The thymus glands showed involution and occasionally germinal centers that are seen with autoimmune disease. Some of the treated males had immature testes. The 30 mg group cat that was euthanized after nonspecific illness had a small area of mucosal erosion in the stomach along with lymphocytic infiltration of the muscle layer.

Organ weights: A reduction in the weight of the thymus, brain and spleen was observed in treated groups with a weight increase noted in the thyroids and liver which was considered to be attributable to treatment ($p < 0.10$).

d. Conclusions: FELIMAZOLE Coated Tablets at 30 mg per day is poorly tolerated and causes lymphadenopathy, immune mediated anemia and thrombocytopenia. This is 6X the starting dose of 2.5 mg twice daily. Doses of 10 and 20 mg per day resulted in inappetance/anorexia, lethargy, vomiting, loose stool, and changes in some hematology and serum chemistry variables.

IV. HUMAN FOOD SAFETY

This drug is intended for use in cats, 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 FELIMAZOLE Coated Tablets:

Not for use in humans. Keep out of reach of children. For use in cats only.
Wash hands with soap and water after administration to avoid exposure to drug. Do not break or crush tablets. Wear protective gloves to prevent direct contact with litter, feces, urine, or vomit of treated cats, and broken or moistened tablets. Wash hands after contact with the litter of treated cats.

Methimazole is a human teratogen and crosses the placenta concentrating in the fetal thyroid gland. There is also a high rate of transfer into breast milk. Pregnant women or women who may become pregnant, and nursing mothers should wear gloves when handling tablets, litter or bodily fluids of treated cats.

Methimazole may cause vomiting, gastric distress, headache, fever, arthralgia, pruritus, and pancytopenia. In the event of accidental ingestion/overdose, seek medical advice immediately and show the product label to the physician.

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 FELIMAZOLE Coated Tablets, when used according to the label, are safe and effective for the treatment of hyperthyroidism in cats.

A. Marketing Status

This product may be dispensed only by or on the lawful order of a licensed veterinarian. Adequate directions for lay use cannot be written because professional expertise is required to diagnose the condition and to monitor the safe use of the product, including treatment of any adverse reactions.

B. Exclusivity

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for FIVE years of marketing exclusivity beginning on the date of the approval because no active ingredient of the new animal drug has previously been approved.

C. Patent Information

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

For current information on patents, see the Animal Drugs @ FDA database (formerly the Green Book) on the FDA CVM internet website.

VII. ATTACHMENTS

Package Insert
2.5 mg
  Bottle Label
  Unit Carton
5.0 mg
  Bottle Label
  Unit Carton