Date of Approval:June 12, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA)

NADA 141-459

BRAVECTO®

(fluralaner topical solution)

Cats

This supplement provides for the addition of the indication for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

This supplement also provides for the addition of kittens 12 weeks of age and older, and weighing 2.6 pounds or greater to the existing indication for the killing of adult fleas and the treatment and prevention of flea infestations (*Ctenocephalides felis*) for 12 weeks.

Sponsored by:

Intervet, Inc.

Executive Summary

BRAVECTO® (fluralaner topical solution) is approved for killing adult fleas and the treatment and prevention of flea infestations (*Ctenocephalides felis*) in cats and kittens 12 weeks of age and older, and weighing 2.6 pounds or greater.

BRAVECTO® (fluralaner topical solution) is approved for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

BRAVECTO® is already approved to kill adult fleas (*Ctenocephalides felis*); treat and prevent flea infestations; and treat and control *Ixodes scapularis* (black-legged tick) and *Haemaphysalis longicornis* (Asian longhorned tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater. The drug is also approved to treat and control *Dermacentor variabilis* (American dog tick) infestations for 8 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

Safety and Effectiveness
For the treatment and prevention of flea infestations (Ctenocephalides felis) for 12 weeks in cats and kittens 12 weeks of age and older, and weighing 2.6 pounds or greater:

The sponsor conducted one laboratory study to show that BRAVECTO® is effective in the killing of adult fleas and the treatment of flea infestations in kittens 12 weeks of age and older. Kittens were experimentally infested with newly emerged, unfed, adult fleas on Day -1 and then every 4 weeks (Days 28, 56, and 84) for 12 weeks. On Day 0, kittens in the treatment groups were administered BRAVECTO® and kittens in the control groups were sham-dosed (same dosing procedures as the treatment groups, but no topical solution was administered). Flea counts were performed on Day 2 (48 hours after drug administration) and 48 hours after each subsequent infestation.

BRAVECTO® was ≥99.8% effective at treating fleas (reducing the number of live fleas) for 12 weeks, while kittens in the untreated control groups remained infested with live fleas at each flea count. No adverse reactions were reported in any kittens in the study.

The results of this study, along with data for the original approval of BRAVECTO® (NADA 141-459, dated July 20, 2016), including a flea adulticide laboratory dose confirmation study in adult cats, a simulated home environment (SHE) study, and a field study, demonstrates the effectiveness of BRAVECTO® for the prevention of flea infestations.

For the treatment and control of Amblyomma maculatum (Gulf Coast tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater:

The sponsor conducted two laboratory studies to show that BRAVECTO® is effective against *A. maculatum* tick infestations in cats. In each study, cats were experimentally infested with viable, unfed, adult ticks on Day -2 and then monthly for 3 months. On Day 0, cats in the treatment group were administered BRAVECTO® and cats in the control

group were sham-dosed (same dosing procedures as the treatment group, but no topical solution was administered). Tick counts were performed on Day 3 (72 hours after treatment) and 72 hours after each monthly infestation.

In both studies, BRAVECTO® was greater than 93% effective at controlling *A. maculatum* tick infestations (reducing the number of live ticks) for 3 months, while cats in the untreated control group remained infested with live ticks at each tick count.

BRAVECTO® was also effective in treating *A. maculatum* tick infestations. Compared to cats in the untreated control group, treated cats had a higher number of dead ticks for 3 months. No adverse reactions were reported in cats in the treatment group in either study.

The FOI Summary for the original approval of BRAVECTO®, dated July 20, 2016, contains a summary of target animal safety studies for cats and kittens.

Conclusions
Based on the data submitted by the sponsor for the approval of BRAVECTO®, the Food and Drug Administration (FDA) determined that the drug is safe and effective when used according to the labeling.

Table of Contents

I. GENERAL INFORMATION 5
II. EFFECTIVENESS 6
A. Dosage Characterization 7
B. Substantial Evidence 7
III. TARGET ANIMAL SAFETY 14
IV. HUMAN FOOD SAFETY 14
V. USER SAFETY 14
VI. AGENCY CONCLUSIONS 14
A. Marketing Status 14
B. Exclusivity 15
C. Supplemental Applications 15
D. Patent Information 15

I. GENERAL INFORMATION

A. File Number

NADA 141-459

B. Sponsor

Intervet, Inc.
126 E Lincoln Ave.
Rahway, NJ 07065

Drug Labeler Code: 000061

C. Proprietary Name

BRAVECTO®

D. Drug Product Established Name

fluralaner topical solution

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Solution

G. Amount of Active Ingredient

Each milliliter contains 280 mg of fluralaner.

H. How Supplied

BRAVECTO® is available in three strengths for use in cats (112.5, 250, and 500 mg fluralaner per tube). Each tube is packaged individually in a pouch. Product may be supplied in 1 or 2 tubes per carton.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

BRAVECTO® should be administered topically as a single dose every 12 weeks according to the **Dosage Schedule** below to provide a minimum dose of 18.2 mg/lb (40 mg/kg) body weight.

BRAVECTO® may be administered every 8 weeks in case of potential exposure to *Dermacentor variabilis* ticks.

Dosage Schedule:

Body Weight Ranges (lb)	Fluralaner content (mg/tube)	Tubes Administered
2.6 – 6.2	112.5	One
>6.2 – 13.8	250	One
>13.8 – 27.5*	500	One

* Cats over 27.5 lb should be administered the appropriate combination of tubes.

K. Route of Administration

Topical

L. Species

Cats

M. Indications

BRAVECTO® kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) for 12 weeks in cats and kittens 12 weeks of age and older, and weighing 2.6 pounds or greater.

BRAVECTO® is also indicated for the treatment and control of *Ixodes scapularis* (black-legged tick), *Haemaphysalis longicornis* (Asian longhorned tick), and *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

BRAVECTO® is also indicated for the treatment and control of *Dermacentor variabilis* (American dog tick) infestations for 8 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

N. Effect of Supplement

This supplement provides for the addition of the indication for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

This supplement also provides for the addition of kittens 12 weeks of age and older, and weighing 2.6 pounds or greater to the existing indication for the killing of adult fleas and the treatment and prevention of flea infestations (*Ctenocephalides felis*) for 12 weeks.

II. EFFECTIVENESS

Age related changes in pharmacokinetics following topical administration have not been evaluated in kittens. Pharmacokinetic studies demonstrate that oral administration of fluralaner results in a substantially lower peak plasma concentration (C_{max}) and area under the plasma concentration-time curve (AUC), and a shorter plasma elimination half-life (T½), in young puppies (8 to 9 weeks of age) compared to dogs aged 6 months and older, at approximately the same oral dose.

Laboratory studies conducted to demonstrate substantial evidence of effectiveness for flea and tick indications for the original approval of BRAVECTO® (NADA 141-459, dated July 20, 2016) were conducted with cats 6 months of age and older.

The effectiveness of BRAVECTO® for the treatment of flea infestations in kittens 12 weeks of age and older was demonstrated in one well-controlled laboratory study and studies conducted for the original approval of BRAVECTO® (refer to the NADA 141-459 FOI Summary, dated July 20, 2016). The flea adulticide laboratory dose confirmation study conducted in kittens 12 and 16 weeks of age (S16279-00) demonstrated effectiveness comparable to that observed in adult cats (S11140-01). Therefore, the simulated home environment study (S11429-00) and field study (S11158-00) conducted in adult cats support the effectiveness of BRAVECTO® at the minimum labeled dose of 40 mg/kg for the prevention of flea infestations in kittens 12 weeks of age and older, weighing 2.6 pounds or greater.

The effectiveness of BRAVECTO® against *Amblyomma maculatum* was demonstrated in two well-controlled laboratory studies. These studies demonstrated that BRAVECTO® is effective for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater.

A. Dosage Characterization

This supplemental approval does not change the previously approved dosage. The FOI Summary for the original approval of NADA 141-459 dated July 20, 2016, contains dosage characterization information for cats.

B. Substantial Evidence

For the Treatment and Prevention of Flea Infestations, Kittens 12 Weeks of Age and Older:

1. Laboratory Dose Confirmation Study

   Title: Evaluation of Efficacy in Growing Kittens Treated Once with BRAVECTO® (fluralaner) Topical Solution against Experimental Infestations of *Ctenocephalides felis*. (Study No. S16279-00)

   Study Dates: December 5, 2016 to December 13, 2024

   Study Location: Turlock, CA

   Study Design:

   Objective: To confirm the effectiveness of BRAVECTO® at the recommended minimum dose (40 mg/kg fluralaner) to kill adult fleas (*C. felis*) and treat flea infestations in growing kittens.

   Study Animals: Forty healthy kittens (domestic shorthair, 17 males and 23 females). The kittens in the 12-week-old group ranged from 11.3 to 12.1 weeks of age and 1.1 to 1.7

kg body weight. The kittens in the 16-week-old group ranged from 16.3 to 17.1 weeks of age and 1.1 to 2.3 kg body weight.

Experimental Design: Prior to allocation to treatment groups on Day -4, an initial flea infestation and count was conducted to evaluate susceptibility of each cat to experimental infestation (host suitability). For each of the two age-defined cohorts, kittens were ranked and blocked by live flea count, and one kitten from each block was randomly assigned to the untreated control group (10 cats) or the BRAVECTO® group (10 cats). The study was conducted in accordance with Good Clinical Practice (GCP) guidelines.

Drug administration was on Day 0. Flea infestations were conducted on Days -1, 28, 56, and 84. At each infestation, each kitten was infested with approximately 100 unfed, adult fleas. Flea counts were conducted on Day 2, 48 hours after drug administration, and on Days 30, 58, and 86, 48 hours after infestation. Fleas were not returned to the kittens after counting.

Drug Administration: On Day 0, BRAVECTO® was applied to 10 cats in the 12-week-old cohort treatment group and 10 cats in the 16-week-old cohort treatment group at doses as close as possible to 40 mg/kg fluralaner. Fluralaner doses administered were 38.9 to 41.0 mg/kg per kitten. Hair at the administration site was parted, and the topical solution was applied to the skin in one spot at the base of the skull. Kittens in both control groups were sham dosed.

Measurements and Observations: The primary variable for effectiveness was the counts of live fleas collected from the kittens. At flea counts on Days 2, 30, 58, and 86, fleas were removed, and the numbers of live fleas were recorded. General health observations were conducted on Day 0 at 1-, 3-, and 6- hours following drug administration and once daily thereafter. Treatment site observations were conducted on Days 1, 2, 3, 7, 14, 28, 56, and 84. Kittens were weighed on Day -2 for dose calculations and on Day 84. Flea counts and health observations were conducted by individuals masked to treatment.

Statistical Methods: A linear mixed model with age and treatment nested within age as fixed effects and block as a random effect was used to analyze live flea counts at each evaluation time point. The test of treatment effect was performed at a two-sided 5% significance level. Percent effectiveness against the control group was calculated based on least squares means.

Results: At each flea count day, at least 9 of the 10 cats in both control groups had an adequate infestation, defined as at least 50 live fleas (50% of the infestations of 100 fleas per cat).

The BRAVECTO® groups had a greater than 90% reduction in live flea counts at 48 hours following drug administration or infestation on Days 30, 58, and 86 (infestation on Day 84). On all count days following drug administration, live flea counts for the BRAVECTO® groups were significantly different ($p<0.001$) from the control group.

Table II.1: Study S16279-00; *C. felis* Live Flea Count 12-week-old Cohort Results

Day for Flea Counts	12-week-old Cohort Control Group Flea Counts*	12-week-old Cohort BRAVECTO® Group Flea Counts*	Percent Effectiveness*
2	65.9	0.0	100.0
30	73.0	0.0	100.0
58	68.7	0.1	99.9
86	74.0	0.0	100.0

* Flea counts are least squares means. Percent effectiveness is based on least squares means.

Table II.2: Study S16279-00; *C. felis* Live Flea Count 16-week-old Cohort Results

Day for Flea Counts	16-week-old Cohort Control Group Flea Counts*	16-week-old Cohort BRAVECTO® Group Flea Counts*	Percent Effectiveness*
2	77.4	0.0	100.0
30	70.2	0.0	100.0
58	62.9	0.0	100.0
86	62.2	0.1	99.8

* Flea counts are least squares means. Percent effectiveness is based on least squares means.

Adverse Reactions: No adverse reactions were reported in this study.

Conclusions: This study demonstrated the effectiveness of BRAVECTO® for the treatment of existing *C. felis* on kittens 12 and 16 weeks of age and older for up to 86 days when assessed 48 hours after drug administration or infestation, thus confirming the effectiveness of the 40 mg/kg dose in kittens. There was no decrease in flea adulticide effectiveness in kittens when compared to adult cats (S11140-01). Therefore, the simulated home (S11429-00) and field (S11158-00) studies that confirmed the 40 mg/kg dose for the prevention of flea infestations in adult cats can be used to conclude that BRAVECTO® is effective for the prevention of flea infestations in kittens.

For the Treatment and Control of Tick Infestations, Cats and Kittens 6 months of Age and Older:

2. Laboratory Dose Confirmation Study

Title: Evaluation of the Effectiveness of BRAVECTO® Topical Solution for Cats (fluralaner) against Experimental Infestations of *Amblyomma maculatum* in Cats. (Study No. S19171-00)

Study Dates: May 13, 2020 to March 28, 2025

Study Location: Waverly, NY

Study Design:

Objective: To confirm the effectiveness of BRAVECTO® at the recommended minimum dose (40 mg/kg fluralaner) for the treatment and control of *A. maculatum* infestations on cats.

Study Animals: Twenty healthy cats (domestic shorthair; 10 males and 10 females), 1.4 to 3.5 years of age, and 2.3 to 5.5 kg body weight.

Experimental Design: Prior to allocation to treatment groups on Day -3, an initial *A. maculatum* infestation and count was conducted to evaluate susceptibility of each cat to experimental infestation (host suitability). Cats were randomly assigned to the untreated control group (10 cats) or the BRAVECTO® group (10 cats). The study was conducted in accordance with Good Clinical Practice (GCP) guidelines.

Drug administration was on Day 0. Tick infestations were conducted on Days -2, 28, 58, and 88. At each infestation, each cat was infested with approximately 50 adult, unfed *A. maculatum* ticks (25 male and 25 female). To prevent grooming, Elizabethan collars were placed on cats prior to each infestation and, with the exception of the Day -2 infestation, remained on until tick counts were completed. Following the Day -2 infestation, the collars were removed on Day 0 prior to treatment to prevent the collars from interfering with the topical product. Tick counts were conducted on Day 3, 72 hours after drug administration, and on Days 31, 61, and 91, 72 hours after infestation. Ticks were not returned to the cats after counting.

Drug Administration: On Day 0, BRAVECTO® was applied to 10 cats in the BRAVECTO® group at doses as close as possible to 40 mg/kg fluralaner. Fluralaner doses administered were 39.4 to 41.0 mg/kg per cat. Hair at the administration site was parted, and the topical solution was applied to the skin in one spot at the base of the skull. Cats in the control group were sham dosed.

Measurements and Observations: The primary variable for effectiveness was the counts of live ticks collected from the cats. At tick counts on Days 3, 31, 61, and 91, ticks were removed, and the numbers of live and dead ticks were recorded. General health observations were conducted on Day 0 at 1, 3, and 6 hours following drug administration and once daily thereafter. Treatment site observations were conducted on Days 1, 2, 3, 7, and 14. Cats were weighed on Day -2 for dose calculations. Tick counts and health observations were conducted by individuals masked to treatment.

Statistical Methods: A linear mixed model analysis with treatment group as a fixed effect was used to analyze live tick counts at each time point. The test of treatment effect was performed at a two-sided 5% significance level. Percent effectiveness against the control group was calculated based on least squares means.

Results: On Days 31, 61, and 91, at least 8 cats in the control group had an adequate infestation, defined as at least 13 live *A. maculatum* ticks (25% of the infestations of 50 ticks per cat). On Day 3, only 4 of the 10 control cats were adequately infested. The inadequate infestation was attributed to removal of the Elizabethan collars on Day 0, which enabled cats to groom and remove ticks prior to the Day 3 tick count. Due to the inadequate infestation, the Day 3 tick counts were considered invalid and not included in the determination of effectiveness.

The BRAVECTO® group had greater than 90% reduction in live *A. maculatum* tick counts at 72 hours following infestation on Days 31, 61, and 91 (infestation on Day 88). On Days 31, 61, and 91 following infestation, live tick counts for the BRAVECTO® group were significantly different ($p<0.0001$) from the control group.

Table II.3: Study S19171-00; *A. maculatum* Live Tick Count Results

Day for Tick Counts	Control Group Live Tick Counts*	BRAVECTO® Group Live Tick Counts*	Percent Effectiveness
31	25.6	0.0	100
61	25.4	0.1	99.6
91	28.2	0.7	97.5

* Tick counts are least squares means. Percent effectiveness is based on least squares means.

On all count days following drug administration, dead tick counts for the BRAVECTO® group were higher than those of the control group.

Table II.4: Study S19171-00; *A. maculatum* Dead Tick Count Results

Day for Tick Counts	Control Group Dead Tick Counts*	BRAVECTO® Group Dead Tick Counts*
31	0.2	10.7
61	0.0	10.6
91	0.3	11.6

* Tick counts are arithmetic means.

Adverse Reactions: No adverse reactions were reported in this study.

Conclusions: This study demonstrated the effectiveness of BRAVECTO® for the control (reduced live ticks) and treatment (increased dead ticks) of *A. maculatum* from Days 31 to 91 when assessed 72 hours after infestation.

3. Laboratory Dose Confirmation Study

Title: Evaluation of the Effectiveness of BRAVECTO® Topical Solution for Cats (fluralaner) against Experimental Infestations of *Amblyomma maculatum* in Cats. (Study No. S19172-00)

Study Dates: April 15, 2020 to July 21, 2023

Study Location: Turlock, CA

Study Design:

Objective: To confirm the effectiveness of BRAVECTO® at the recommended minimum dose (40 mg/kg fluralaner) for the treatment and control of *A. maculatum* infestations on cats.

Study Animals: Twenty healthy cats (domestic shorthair; 2 males and 18 females), 2.9 to 10.8 years of age, and 2.3 to 4.7 kg body weight.

Experimental Design: Prior to allocation to treatment groups on Day -4, an initial *A. maculatum* infestation and count was conducted to evaluate susceptibility of each cat to experimental infestation (host suitability). Cats were randomly assigned to the untreated control group (10 cats) or the BRAVECTO® group (10 cats). The study was conducted in accordance with Good Clinical Practice (GCP) guidelines.

Drug administration was on Day 0. Tick infestations were conducted on Days -2, 28, 58, and 88. At each infestation, each cat was infested with approximately 50 adult, unfed *A. maculatum* ticks (25 male and 25 female). To prevent grooming, Elizabethan collars were placed on cats prior to each infestation and, with the exception of the Day -2 infestation, remained on until tick counts were completed. Following the Day -2 infestation, the collars were removed on Day 0 prior to treatment to prevent the collars from interfering with the topical product. Tick counts were conducted on Day 3, 72 hours after drug administration, and on Days 31, 61, and 91, 72 hours after infestation. Ticks were not returned to the cats after counting.

Drug Administration: On Day 0, BRAVECTO® was applied to 10 cats in the treatment group at doses as close as possible to 40 mg/kg fluralaner. Fluralaner doses ranged from 39.6 to 40.2 mg/kg per cat. Hair at the administration site was parted, and the topical solution was applied to the skin in one spot at the base of the skull. Cats in the control group were sham dosed.

Measurements and Observations: The primary variable for effectiveness was the counts of live ticks collected from the cats. At tick counts on Days 3, 31, 61, and 91, ticks were removed, and the numbers of live and dead ticks were recorded. General health observations were conducted on Day 0 at 1, 3, and 6 hours following drug administration and once daily thereafter. Treatment site observations were conducted on Days 1, 2, 3, 7, and 14. Cats were weighed on Day -2 for dose calculations. Tick counts and health observations were conducted by individuals masked to treatment.

Statistical Methods: A linear mixed model analysis with treatment group as a fixed effect was used to analyze live tick counts at each time point. The test of treatment effect was performed at a two-sided 5% significance level. Percent effectiveness against the control group was calculated based on least squares means.

Results: At each tick count day, at least 9 of the 10 cats in the control group had an adequate infestation, defined as at least 13 live *A. maculatum* ticks (25% of the infestations of 50 ticks per cat).

The BRAVECTO® group had greater than 90% reduction in live *A. maculatum* tick counts at 72 hours following drug administration or infestation for 91 days (infestation on Day 88). On all count days following drug administration, live tick counts for the BRAVECTO® group were significantly different ($p<0.0001$) from the control group.

Table II.5: Study S19172-00; *A. maculatum* Live Tick Count Results

Day for Tick Counts	Control Group Live Tick Counts	BRAVECTO® Group Live Tick Counts	Percent Effectiveness
3	22.9	0.0	100
31	29.5	0.0	100
61	28.2	0.0	100
91	22.7	1.4	93.8

* Tick counts are arithmetic least squares means. Percent effectiveness is based on arithmetic least squares means.

On all count days following drug administration, dead tick counts for the BRAVECTO® group were higher than those of the control group.

Table II.6: Study S19172-00; *A. maculatum* Dead Tick Count Results

Day for Tick Counts	Control Group Dead Tick Counts*	BRAVECTO® Group Dead Tick Counts*
3	0.0	1.9
31	0.0	15.8
61	0.0	10.7
91	0.0	4.2

* Tick counts are arithmetic means.

Adverse Reactions: No adverse reactions were reported in this study.

Conclusion: This study demonstrated the effectiveness of BRAVECTO® for the control (reduced live ticks) and treatment (increased dead ticks) of *A. maculatum* for 91 days when assessed 72 hours after drug administration or infestation.

4. Additional Tick Laboratory Dose Confirmation Studies in Kittens

Two well-controlled laboratory dose confirmation studies against *Ixodes scapularis* were conducted in kittens 12 and 16 weeks of age. In one study, BRAVECTO® demonstrated a greater than 90% reduction in live ticks for 86 days when assessed 48 hours after drug administration or infestation. In a second study, BRAVECTO® failed to demonstrate a greater than 90% reduction in live ticks on Day 62 when assessed 48 hours after infestation; the study was terminated on Day 62.

Two well-controlled laboratory dose confirmation studies against *Dermacentor variabilis* were conducted in kittens 12 and 16 weeks of age. One study failed to demonstrate a greater than 90% reduction in live ticks on Day 58 when assessed 48 hours after infestation. In a second study, BRAVECTO® failed to demonstrate a greater than 90% reduction in live ticks on Day 63 when assessed 72 hours after infestation; the study was terminated on Day 63.

III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-459 dated July 20, 2016, contains target animal safety information for cats.

IV. HUMAN FOOD SAFETY

This drug is intended for use in cats. Because this new animal drug is not intended for use in food-producing animals, FDA 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 BRAVECTO®:

Human Warnings:

Not for human use. Keep this and all drugs out of the reach of children.

Do not contact or allow children to contact the application site until 2 hours post application.

Keep the product in the original packaging until use in order to prevent children from getting direct access to the product. Do not eat, drink, or smoke while handling the product. Avoid contact with skin and eyes. If contact with eyes occurs, then flush eyes slowly and gently with water. **If wearing contact lenses, eyes should be rinsed first, then remove contact lenses and continue rinsing, then seek medical advice immediately. Wash hands and contacted skin thoroughly with soap and water immediately after use of the product. If the product accidentally contacts skin and a sticky residue persists after washing, rubbing alcohol (70% isopropyl alcohol) can be applied to the area to remove the residue.**

The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

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 (FD&C Act) and 21 CFR part 514. The data demonstrate that BRAVECTO®, when used according to the label, is safe and effective for the effect of supplement in the General Information Section above.

A. Marketing Status

This product may be dispensed only by or on the lawful order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because professional expertise is required to monitor for and respond to adverse reactions in cats, and to define the appropriate treatment interval (8 or 12 weeks) based on the species of ticks the cat is likely to encounter.

B. Exclusivity

This supplemental approval for BRAVECTO® qualifies for THREE years of marketing exclusivity under section 512(c)(2)(F)(iii) of the FD&C Act because the supplemental application included effectiveness studies. This exclusivity begins as of the date of our approval letter and only applies to the indication "for the treatment and control of *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 pounds or greater" and for the addition of kittens 12 weeks of age and older, and weighing 2.6 pounds or greater to the existing indication for the killing of adult fleas and the treatment and prevention of flea infestations (*Ctenocephalides felis*) for 12 weeks.

C. Supplemental Applications

This supplement is a Category II supplement as defined in (21 CFR 514.106(b)(2)). This supplemental approval did not require a reevaluation of certain safety or effectiveness data in the application.

D. Patent Information

For current information on patents, see the Green Book Reports in the Animal Drugs @ FDA database.