

Date of Approval: March 16, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION (NADA)

NADA 141-599

BRAVECTO® QUANTUM

(fluralaner for extended-release injectable suspension)

Powder for extended-release injectable suspension

Dogs

This supplement provides for the addition of the indication for the treatment and control of *Haemaphysalis longicornis* (Asian longhorned tick) and *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 months in dogs and puppies 6 months of age and older.

Sponsored by:

Intervet, Inc.

Executive Summary

BRAVECTO® QUANTUM (fluralaner for extended-release injectable suspension) is approved for the treatment and control of *Haemaphysalis longicornis* (Asian longhorned tick) and *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 months in dogs and puppies 6 months of age and older. The Asian longhorned tick is a new tick species in the United States (U.S.). Not normally found in the Western Hemisphere, these ticks were reported for the first time in the U.S. in 2017.

BRAVECTO® QUANTUM (fluralaner for extended-release injectable suspension) is already approved to 1) kill adult fleas (*Ctenocephalides felis*); 2) treat and prevent flea infestations; and 3) treat and control tick infestations [*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick)] for 12 months in dogs and puppies 6 months of age and older. BRAVECTO® QUANTUM is also approved for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 months in dogs and puppies 6 months of age and older.

BRAVECTO® QUANTUM is an antiparasitic drug that is administered as a single subcutaneous injection every 12 months. It should be administered every 8 months in the case of potential exposure to *A. americanum* ticks.

Safety and Effectiveness

The sponsor conducted two laboratory studies each to show that BRAVECTO® QUANTUM is effective against *A. maculatum* and *H. longicornis* tick infestations in dogs 6 months of age and older. In each study, dogs were experimentally infested with viable, unfed, adult ticks on Day -2 and then periodically at 7- to 30-day intervals for 12 months. On Day 0, dogs in the treatment group were administered BRAVECTO® QUANTUM and dogs in the control group were sham-dosed (same dosing procedures as the treatment group, but no subcutaneous injection was given). Tick counts were performed on Day 2 (48 hours after treatment) and 48 hours after each subsequent infestation for *H. longicornis* or Day 3 (72 hours after treatment) and 72 hours after each subsequent infestation for *A. maculatum*.

In both studies conducted with *H. longicornis*, BRAVECTO® QUANTUM when assessed 48 hours after treatment or infestation was effective in controlling *H. longicornis* infestations (reducing the number of live ticks) for 365 days (12 months), while dogs in the control group remained infested with live ticks. BRAVECTO® QUANTUM was also effective at treating *H. longicornis* tick infestations (increasing the number of dead ticks) for 365 days (12 months). Compared to dogs in the control group, treated dogs had a higher number of dead ticks.

In one study conducted with *A. maculatum*, BRAVECTO® QUANTUM was effective at controlling *A. maculatum* infestations when assessed 72 hours after infestation for 365 days (12 months) starting on Day 7 but did not demonstrate effectiveness at Day 3 after treatment. Another study demonstrated that BRAVECTO® QUANTUM was effective at controlling *A. maculatum* infestations when assessed 72 hours after treatment or infestation for 365 days (12 months).

In both studies conducted with *A. maculatum*, BRAVECTO® QUANTUM was also effective at treating *A. maculatum* tick infestations for 12 months. Compared to dogs in the control group, treated dogs had a higher number of dead ticks.

A slight heat reaction at the injection site that was resolved by the following day was observed in one dog during one of the studies.

The FOI Summary for the original approval of BRAVECTO® QUANTUM dated July 10, 2025, contains a summary of target animal safety studies for dogs.

User Safety

The labeling for BRAVECTO® QUANTUM includes safety information for people who handle, administer, or are exposed to the drug and provides specific instructions in case of accidental self-injection, skin contact, and eye exposure.

Conclusions

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

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I. GENERAL INFORMATION

A. File Number

NADA 141-599

B. Sponsor

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

Drug Labeler Code: 000061

C. Proprietary Name

BRAVECTO® QUANTUM

D. Drug Product Established Name

fluralaner for extended-release injectable suspension

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Powder for extended-release injectable suspension

G. Amount of Active Ingredient

Each mL of constituted suspension contains 150 mg fluralaner

H. How Supplied

BRAVECTO® QUANTUM (fluralaner for extended-release injectable suspension) 20 mL vial product is available in a 1-pack presentation that includes one vial containing 2.51 grams of sterile fluralaner and one vial containing the required 15 mL of sterile vehicle for constitution.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

BRAVECTO® QUANTUM should be administered as a single subcutaneous dose every 12 months. BRAVECTO® QUANTUM should be administered every 8 months in the case of potential exposure to *Amblyomma americanum* ticks.

The subcutaneous dose volume is 0.1 mL of the constituted suspension/kg body weight (0.045 mL/lb). This volume provides a dose of 15 mg fluralaner/kg body weight

(6.8 mg/lb). The dog should be weighed at the time of dosing to calculate an accurate dose.

K. Route of Administration

Subcutaneous

L. Species

Dogs

M. Indication

BRAVECTO® QUANTUM kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and for the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Rhipicephalus sanguineus* (brown dog tick), *Haemaphysalis longicornis* (Asian longhorned tick), and *Amblyomma maculatum* (Gulf Coast tick)] for 12 months in dogs and puppies 6 months of age and older.

BRAVECTO® QUANTUM is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 months in dogs and puppies 6 months of age and older.

N. Effect of Supplement

This supplement provides for the addition of the indication for the treatment and control of *Haemaphysalis longicornis* (Asian longhorned tick) and *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 months in dogs and puppies 6 months of age and older.

II. EFFECTIVENESS

The effectiveness of BRAVECTO® QUANTUM against *Amblyomma maculatum* and *Haemaphysalis longicornis* was demonstrated in four well-controlled laboratory studies, two for each tick species, described below. These studies demonstrated that BRAVECTO® QUANTUM is effective for the treatment and control of *Amblyomma maculatum* (Gulf coast tick) and *Haemaphysalis longicornis* (Asian longhorned tick) infestations for 12 months in dogs and puppies 6 months of age and older.

A. Dosage Characterization

This supplemental approval does not change the previously approved 15 mg/kg as a single subcutaneous dose every 12 months for fleas and ticks (*Ixodes scapularis*, *Dermacentor variabilis*, and *Rhipicephalus sanguineus*) and every 8 months for *Amblyomma americanum*. The FOI Summary for the original approval of NADA 141-599 dated July 10, 2025, contains dosage characterization information for dogs.

B. Substantial Evidence

1. Treatment and Control of *Haemaphysalis longicornis* Infestations

- a. **Title:** Effectiveness of BRAVECTO® QUANTUM Against Experimental Infestations of *Haemaphysalis longicornis* Ticks on Dogs. (Study No. S22131-00)

Study Dates: November 8, 2022 to June 18, 2024

Study Location: Bloemfontein, South Africa

Study Design:

Objective: To confirm the effectiveness of BRAVECTO® QUANTUM at the recommended dose (15 mg/kg) for the treatment and control of infestations of *H. longicornis* in dogs.

Study Animals: Twenty healthy dogs (pure and mixed breed, 13 males and 7 females), 13 to 110 months of age, and 13.2 to 31.3 kg body weight.

Experimental Design: Prior to allocation to treatment groups on Day -6, an initial *H. longicornis* infestation and count was conducted to evaluate susceptibility of each dog to experimental infestation (host suitability). Dogs were randomly assigned to either an untreated control group (10 dogs) or a BRAVECTO® QUANTUM treatment group (10 dogs). 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, 12, 28, 58, 88, 118, 148, 178, 208, 238, 268, 298, 328, 335, 363, and 378. At each infestation, each dog in both treatment groups was infested with approximately 50 adult, unfed *H. longicornis* (U.S. source) ticks.

Tick counts were conducted on Day 2, 48 hours after drug administration, and on Days 14, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, 337, 365, and 380, 48 hours after *H. longicornis* infestations. Ticks were not returned to the dog after counting.

Drug Administration: On Day 0, the 10 dogs in the BRAVECTO® QUANTUM group were administered a subcutaneous injection in the dorsoscapular region, at a dose of 15 mg/kg (0.10 mL/kg). The injection volumes administered ranged from 1.4 to 2.4 mL. Dogs in the control group were sham-dosed.

Measurements and Observations: The primary variable for effectiveness was the counts of live ticks collected from the dogs.

At tick counts on Days 2, 14, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, 337, 365, and 380 ticks were removed, and the numbers of live and dead ticks were recorded. General health observations were conducted daily, and at approximately 1, 3, and 6 hours following drug administration. Each dog was observed for injection site reactions on Days 1, 2, 3, 4, 7, 10, and 14. Dogs were

weighed on Day -2 for dose calculations. Tick counts and health observations were conducted 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 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 the least squares means.

Results: At each tick count day, except for Days 330 and 337, at least 6 of the 10 dogs in the control group had an adequate infestation, defined as at least 13 live ticks (25% of the infestations of 50 ticks per dog). Therefore, the Day 330 and Day 337 tick counts were considered invalid and not included in the determination of effectiveness.

The BRAVECTO® QUANTUM group had a 100% reduction in live *H. longicornis* tick counts at 48 hours following infestation from Day 2 through Day 380. On all count days following drug administration, live *H. longicornis* tick counts for the BRAVECTO® QUANTUM group were significantly different ($p < 0.0001$) from the corresponding control group.

Table II.1. S22131-00 *H. longicornis* Live Tick Count and Percent Effectiveness

Day for Tick Counts	Control Group Live Tick Counts*	BRAVECTO® QUANTUM Group Live Tick Counts	Percent Effectiveness
2	24.3	0.0	100%
14	24.8	0.0	100%
30	19.9	0.0	100%
60	18.7	0.0	100%
90	26.6	0.0	100%
120	17.2	0.0	100%
150	19.8	0.0	100%
180	16.4	0.0	100%
210	14.9	0.0	100%
240	14.5	0.0	100%
270	20.2	0.0	100%
300	15.1	0.0	100%
365	12.6	0.0	100%
380	21.3	0.0	100%

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

On all count days except on Days 90, 210, 240, and 365, following drug administration, dead *H. longicornis* tick counts for the BRAVECTO® QUANTUM group were numerically greater from the corresponding control group.

Table II.2. S22131-00 *H. longicornis* Dead Tick Count Results

Day for Tick Counts	Control Group Dead Tick Counts*	BRAVECTO® QUANTUM Group Dead Tick Counts*
2	0.0	2.6
14	0.5	1.4
30	0.0	3.7
60	0.2	1.4
90	0.2	0.1
120	0.0	0.1
150	0.0	1.1
180	0.1	0.2
210	0.6	0.4
240	0.2	0.0
270	0.2	0.3
300	0.2	0.6
365	0.1	0.0
380	0.2	0.5

*Tick counts are arithmetic means.

Adverse Reactions: One dog in the BRAVECTO® QUANTUM group was observed with a slight heat reaction of the injection site on Day 7. A follow-up evaluation was conducted on the next day (Day 8) and the injection site was normal.

Conclusion: The study demonstrated the effectiveness of BRAVECTO® QUANTUM for the control (reduced live ticks) and treatment (increased dead ticks) of *H. longicornis* for 365 days (12 months) when assessed at 48 hours after treatment and infestation. A slight, transient, heat reaction at the injection site should be considered drug related.

- b. **Title:** Effectiveness of BRAVECTO® QUANTUM Against Experimental Infestations of *Haemaphysalis longicornis* Ticks on Dogs. (Study No. S22132-00)

Study Dates: November 7, 2022 to June 13, 2024

Study Location: Waverly, NY

Study Design:

Objective: To confirm the effectiveness of BRAVECTO® QUANTUM at the recommended dose (15 mg/kg) for the treatment and control of infestations of *H. longicornis* in dogs.

Study Animals: Twenty healthy dogs (beagles, 9 males and 11 females), 8 to 18 months of age, and 6.4 to 8.9 kg body weight.

Experimental Design: Prior to allocation to treatment groups on Day -4, an initial *H. longicornis* infestation and count was conducted to evaluate susceptibility of each dog to experimental infestation (host suitability). Dogs were randomly

assigned to either an untreated control group (10 dogs) or a BRAVECTO® QUANTUM treatment group (10 dogs). The study was conducted in accordance with GCP guidelines.

Drug administration was on Day 0. Tick infestations were conducted on Days -2, 12, 28, 58, 88, 118, 148, 178, 208, 238, 268, 298, 328, and 363. At each infestation, each dog in both treatment groups was infested with approximately 50 adult, unfed *H. longicornis* ticks.

Tick counts were conducted on Day 2, 48 hours after drug administration, and on Days 14, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, and 365, 48 hours after *H. longicornis* infestations. Ticks were not returned to the dog after counting.

Drug Administration: On Day 0, the 10 dogs in the BRAVECTO® QUANTUM group were administered a subcutaneous injection in the dorsoscapular region, at a dose of 15 mg/kg (0.10 mL/kg). The injection volumes administered ranged from 0.7 to 0.9 mL. Dogs in the control group were sham-dosed.

Measurements and Observations: The primary variable for effectiveness was the counts of live ticks collected from the dogs.

At tick counts on Days 2, 14, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, and 365 ticks were removed, and the numbers of live and dead ticks were recorded. General health observations were conducted daily, and at approximately 1, 3, and 6 hours following drug administration. Each dog was observed for injection site reactions on Days 1, 2, 3, 4, 7, 10, and 14. Dogs were weighed on Day -2 for dose calculations. Tick counts and health observations were conducted 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 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 the least squares means.

Results: At each tick count day, at least 6 of the 10 dogs in the control group had an adequate infestation, defined as at least 13 live ticks (25% of the infestations of 50 ticks per dog).

The BRAVECTO® QUANTUM group had a $\geq 92.7\%$ reduction in live *H. longicornis* tick counts at 48 hours following treatment or infestation through Day 365. On all count days following drug administration, live *H. longicornis* tick counts for the BRAVECTO® QUANTUM group were significantly different ($p \leq 0.0002$) from the corresponding control group.

Table II.3. S22132-00 *H. longicornis* Live Tick Count and Percent Effectiveness

Day for Tick Counts	Control Group Live Tick Counts*	BRAVECTO® QUANTUM Group Live Tick Counts	Percent Effectiveness
2	12.3	0.9	92.7%
14	39.5	0.0	100%
30	27.1	0.0	100%
60	15.7	0.0	100%
90	17.8	0.0	100%
120	28.5	0.0	100%
150	31.6	0.0	100%
180	22.0	0.0	100%
210	17.1	0.0	100%
240	23.5	0.0	100%
270	22.5	0.0	100%
300	24.9	0.0	100%
330	29.0	0.0	100%
365	18.3	0.0	100%

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

On all count days following drug administration, except on Days 210, 240, 300, and 330, dead *H. longicornis* tick counts for the BRAVECTO® QUANTUM group were numerically greater from the corresponding control group.

Table II.4. S22132-00 *H. longicornis* Dead Tick Count Results

Day for Tick Counts	Control Group Dead Tick Counts*	BRAVECTO® QUANTUM Group Dead Tick Counts*
2	1.6	7.4
14	0.0	2.5
30	0.0	1.1
60	0.0	0.5
90	0.0	0.7
120	0.2	0.4
150	0.0	0.8
180	0.0	4.1
210	1.2	1.0
240	0.7	0.6
270	0.0	0.4
300	0.1	0.1
330	0.0	0.0
365	0.2	1.5

*Tick counts are arithmetic means.

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

Conclusion: The study demonstrated the effectiveness of BRAVECTO® QUANTUM for the control (reduced live ticks) and treatment (increased dead ticks) of *H. longicornis* for 365 days (12 months) when assessed at 48 hours after treatment and infestation.

2. Treatment and Control of Amblyomma maculatum Tick Infestations

- a. **Title:** Effectiveness of BRAVECTO® QUANTUM Against Experimental Infestations of Amblyomma maculatum Ticks on Dogs. (Study No. S20042-00)

Study Dates: August 14, 2020 to August 18, 2022

Study Location: Greenbrier, AR

Study Design:

Objective: To confirm the effectiveness of BRAVECTO® QUANTUM at the recommended dose (15 mg/kg) for the treatment and control of infestations of *A. maculatum* in dogs.

Study Animals: Twenty healthy dogs (pure and mixed breed, 12 males and 8 females), 47 to 60 months of age, and 8.4 to 13.5 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 dog to experimental infestation (host suitability). Dogs were randomly assigned to either an untreated control group (10 dogs) or a BRAVECTO® QUANTUM treatment group (10 dogs). The study was conducted in accordance with GCP guidelines.

Drug administration was on Day 0. Tick infestations were conducted on Days -2, 4, 11, 27, 57, 87, 117, 147, 177, 207, 215, 237, 264, 294, 327, and 362. At each infestation, each dog in both treatment groups was infested with approximately 50 adult, unfed *A. maculatum* ticks.

Tick counts were conducted on Day 3, 72 hours after drug administration, and on Days 7, 14, 30, 60, 90, 120, 150, 180, 210, 218, 240, 267, 297, 330, and 365, 72 hours after *A. maculatum* infestations. Ticks were not returned to the dog after counting.

Drug Administration: On Day 0, the 10 dogs in the BRAVECTO® QUANTUM group were administered a subcutaneous injection in the dorsoscapular region, at a dose of 15 mg/kg (0.10 mL/kg). The injection volumes administered ranged from 0.8 to 1.3 mL. Dogs in the control group were sham-dosed.

Measurements and Observations: The primary variable for effectiveness was the counts of live ticks collected from the dogs.

At tick counts on Days 3, 7, 14, 30, 60, 90, 120, 150, 180, 210, 218, 240, 267, 297, 330, and 365 ticks were removed, and the numbers of live and dead

ticks were recorded. General health observations were conducted daily, and at approximately 1, 3, and 6 hours following drug administration. Each dog was observed for injection site reactions on Days 1, 2, 3, 4, 7, 10, and 14.

Dogs were weighed on Day -2 for dose calculations. Tick counts and health observations were conducted 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 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 the least squares means.

Results: At each tick count day, except for Day 210, at least 6 of the 10 dogs in the control group had an adequate infestation, defined as at least 13 live ticks (25% of the infestations of 50 ticks per dog). Therefore, the Day 210 tick count was considered invalid and not included in the determination of effectiveness. The tick infestation for Day 210 was repeated on Day 215, resulting in an adequate infestation at the subsequent count of Day 218.

The BRAVECTO® QUANTUM group had a ≥92.8% reduction in live *A. maculatum* tick counts at 72 hours following treatment or infestation through Day 365. On all count days following drug administration, live *A. maculatum* tick counts for the BRAVECTO® QUANTUM group were significantly different ($p \leq 0.0001$) from the corresponding control group.

Table II.5. S20042-00 *A. maculatum* Live Tick Count and Percent Effectiveness

Day for Tick Counts	Control Group Live Tick Counts*	BRAVECTO® QUANTUM Group Live Tick Counts	Percent Effectiveness
3	33.4	2.4	92.8%
7	38.8	0.0	100%
14	29.7	0.0	100%
30	30.0	0.1	99.7%
60	22.2	0.0	100%
90	32.8	0.0	100%
120	30.7	0.0	100%
150	27.3	0.1	99.6%
180	26.8	0.0	100%
218	37.7	0.4	98.9%
240	29.4	0.5	98.3%
267	23.4	0.2	99.1%
297	20.0	0.0	100%
330	30.0	0.3	99.0%
365	25.2	0.0	100%

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

On all count days following drug administration, dead *A. maculatum* tick counts for the BRAVECTO® QUANTUM group were significantly different ($p \leq 0.05$) from the corresponding control group.

Table II.6. S20042-00 *A. maculatum* Dead Tick Count Results

Day for Tick Counts	Control Group Dead Tick Counts*	BRAVECTO® QUANTUM Group Dead Tick Counts*
3	0.0	12.7
7	0.0	2.7
14	0.4	3.4
30	0.0	2.7
60	0.0	4.7
90	0.0	8.1
120	0.0	2.6
150	0.0	5.0
180	0.0	4.7
218	0.0	11.5
240	0.0	9.4
267	0.0	4.8
297	0.0	6.0
330	0.0	4.3
365	0.0	9.2

*Tick counts are arithmetic means.

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

Conclusion: The study demonstrated the effectiveness of BRAVECTO® QUANTUM for the control (reduced live ticks) and treatment (increased dead ticks) of *A. maculatum* for 365 days (12 months) when assessed at 72 hours after treatment and infestation.

- b. **Title:** Effectiveness of BRAVECTO® QUANTUM Against Experimental Infestations of *Amblyomma maculatum* Ticks on Dogs. (Study No. S20046-00)

Study Dates: November 8, 2022 to July 10, 2024

Study Location: Bloemfontein, South Africa

Study Design:

Objective: To confirm the effectiveness of BRAVECTO® QUANTUM at the recommended dose (15 mg/kg) for the treatment and control of infestations of *A. maculatum* in dogs.

Study Animals: Twenty healthy dogs (beagles, 11 males and 9 females), 52 to 110 months of age, and 12.0 to 18.4 kg body weight. One male dog in the untreated control group died on Day 101 due to suspected heart failure. The dog was not replaced so thereafter, the control group contained nine dogs.

Experimental Design: Prior to allocation to treatment groups on Day -6, an initial *A. maculatum* infestation and count was conducted to evaluate susceptibility of each dog to experimental infestation (host suitability). Dogs were randomly assigned to either an untreated control group (10 dogs) or a BRAVECTO® QUANTUM treatment group (10 dogs). The study was conducted in accordance with GCP guidelines.

Drug administration was on Day 0. Tick infestations were conducted on Days -2, 4, 11, 27, 57, 87, 117, 147, 177, 207, 237, 267, 297, 327, and 362. At each infestation, each dog in both treatment groups was infested with approximately 50 adult, unfed *A. maculatum* (U.S. source) ticks.

Tick counts were conducted on Day 3, 72 hours after drug administration, and on Days 7, 14, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, and 365, 72 hours after *A. maculatum* infestations. Ticks were not returned to the dog after counting.

Drug Administration: On Day 0, the 10 dogs in the BRAVECTO® QUANTUM group were administered a subcutaneous injection in the dorsoscapular region, at a dose of 15 mg/kg (0.10 mL/kg). The injection volumes administered ranged from 1.3 to 1.8 mL. Dogs in the control group were sham-dosed.

Measurements and Observations: The primary variable for effectiveness was the counts of live ticks collected from the dogs.

At tick counts on Days 3, 7, 14, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330, and 365 ticks were removed, and the numbers of live and dead ticks were recorded. General health observations were conducted daily, and at approximately 1, 3, and 6 hours following drug administration. Each dog was observed for injection site reactions on Days 1, 2, 3, 4, 7, 10, and 14.

Dogs were weighed on Day -2 for dose calculations. Tick counts and health observations were conducted 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 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 the least squares means.

Results: At each tick count day, at least 6 of the 9 or 10 dogs in the control group had an adequate infestation, defined as at least 13 live ticks (25% of the infestations of 50 ticks per dog).

The BRAVECTO® QUANTUM group had a $\geq 90\%$ reduction in live *A. maculatum* tick counts at 72 hours following infestation from Day 7 through Day 365 (infestation on Day 362) but failed to demonstrate $\geq 90\%$ effectiveness on Day 3 (72 hours post-treatment), compared to the corresponding control group. On all count days following drug administration, live *A. maculatum* tick counts for the BRAVECTO® QUANTUM group were significantly different ($p \leq 0.0003$) from the corresponding control group.

Table II.7. S20046-00 *A. maculatum* Live Tick Count and Percent Effectiveness

Day for Tick Counts	Control Group Live Tick Counts*	BRAVECTO® QUANTUM Group Live Tick Counts	Percent Effectiveness
3	20.3	2.1	89.7%
7	30.8	0.1	99.7%
14	26.1	0.0	100%
30	28.2	0.0	100%
60	29.4	0.0	100%
90	28.0	0.0	100%
120	31.4	0.1	99.7%
150	30.8	0.1	99.7%
180	37.6	0.1	99.7%
210	30.3	0.2	99.3%
240	32.8	0.2	99.4%
270	32.1	1.0	96.9%
300	30.4	0.0	100%
330	33.6	0.5	98.5%
365	27.2	0.1	99.6%

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

On all count days following drug administration, dead *A. maculatum* tick counts for the BRAVECTO® QUANTUM group were numerically greater from the corresponding control group.

Table II.8. S20046-00 *A. maculatum* Dead Tick Count Results

Day for Tick Counts	Control Group Dead Tick Counts*	BRAVECTO® QUANTUM Group Dead Tick Counts*
3	0.5	3.3
7	0.3	9.3
14	0.8	10.1
30	1.6	8.9
60	0.6	7.8
90	0.5	10.2
120	0.1	8.4
150	0.6	12.8
180	0.8	11.4
210	0.1	13.6
240	0.3	13.3
270	0.2	9.3
300	0.0	9.6
330	0.6	11.2
365	0.4	13.0

*Tick counts are arithmetic means.

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

Conclusion: The study failed to demonstrate initial effectiveness against *A. maculatum* at 3 days following treatment. Thereafter, the study demonstrated the effectiveness of BRAVECTO® QUANTUM for the control (reduced live ticks) and treatment (increased dead ticks) of *A. maculatum* for 365 days (12 months) when assessed at 72 hours after infestation.

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 141-599 dated July 10, 2025, contains target animal safety information for dogs.

IV. HUMAN FOOD SAFETY

This drug is intended for use in dogs. 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® QUANTUM:

User Safety Warnings:

Not for use in humans. Keep this and all drugs out of reach of children.

In case of accidental self-injection:

- Seek medical advice immediately and show the package insert or label to the physician.

In case of accidental skin contact:

- Wash the exposed skin with water for at least 15 minutes.
- If redness and swelling occur, seek medical advice immediately and show the package insert or label to the physician.

In case of accidental eye exposure:

- Wash the eyes with water for at least 15 minutes.
- If wearing contact lenses, rinse the eyes first, then remove contacts and continue to rinse with water.
- If redness and swelling occur, seek medical advice immediately and show the package insert or 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 (FD&C Act) and 21 CFR part 514. The data demonstrate that BRAVECTO® QUANTUM, 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 advise dog owners regarding use in breeding dogs, to properly administer the injection, to monitor for and respond to adverse reactions, and to define the appropriate treatment interval (8 versus 12 months) based on the species of ticks the dog is likely to encounter.

B. Exclusivity

This supplemental approval for BRAVECTO® QUANTUM 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 *Haemaphysalis longicornis* (Asian longhorned tick) and *Amblyomma maculatum* (Gulf Coast tick) infestations for 12 months in dogs and puppies 6 months of age and older.

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.