Date of Authorization: November 3, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006767

BRAVECTO®

(fluralaner)

Chewable Tablet

Dogs

Scope of Authorization: For the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.

Sponsored by:

Intervet, Inc.

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I. GENERAL INFORMATION

A. File Number

EUA 006767

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

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Chewable tablet

G. Amount of Active Ingredient

Each chewable tablet ("chew") contains 112.5, 250, 500, 1000, or 1400 mg fluralaner.

H. How Supplied

BRAVECTO® is available in five strengths (112.5, 250, 500, 1000, and 1400 mg fluralaner per chew). Each chew is packaged individually into aluminum foil blister packs sealed with a peelable paper backed foil lid stock. Product may be packaged in 1, 2, or 4 chews per package.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

BRAVECTO® should be administered orally as a single dose according to the **Dosage Schedule** below to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight.

BRAVECTO® should be administered with food.

Dosage Schedule

Body Weight Ranges (lb)	Fluralaner Content (mg)	Chews Administered
4.4 – 9.9	112.5	One
>9.9 – 22.0	250	One
>22.0 – 44.0	500	One
>44.0 – 88.0	1000	One
>88.0 – 123.0*	1400	One

*Dogs over 123.0 lb should be administered the appropriate combination of chews

K. Route of Administration

Oral

L. Species

Dogs

M. Food and Drug Administration (FDA) Approved Indications

BRAVECTO® (NADA 141-426) kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick)] for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

BRAVECTO® (NADA 141-426) is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

N. Emergency Authorized Use

For the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.

O. Limitations of Authorized Use

BRAVECTO® (fluralaner) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of BRAVECTO® (fluralaner) under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

II. EFFECTIVENESS

A. Dosage Characterization

This Emergency Use Authorization does not change the previously approved 11.4 mg/lb (25 mg/kg) minimum dose, given orally. The FOI Summary for the original approval of NADA 141-426, dated May 25, 2014, contains dosage characterization information for dogs.

B. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor demonstrated that it is reasonable to believe that BRAVECTO® may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, based on data from a field effectiveness study. The data support that it is reasonable to believe that BRAVECTO® may be effective for the treatment of infestations caused by New World screwworm (NWS; *C. hominivorax*) larvae (myiasis) in dogs and puppies.

Due to the severity of NWS infestations, the approved starting age and weight of 6 months and 4.4 lbs, respectively, is removed for this EUA to allow veterinarians to make an informed benefit/risk decision when treating NWS infestations in dogs and puppies below this age and weight. However, veterinarians should be aware that 8- to 9-week-old puppies had lower peak concentrations (C_{max}) compared to adult dogs, which may reduce effectiveness (refer to the Dosage Characterization section in the FOI Summary for the original approval, dated May 25, 2014).

Title: Evaluation of the Therapeutic Efficacy of BRAVECTO® Chewable Tablet against New World Screwworm (*Cochliomyia hominivorax*) Infestation in Dogs. (Study No. S25220-00)

Study Dates: January 14, 2026 to April 20, 2026

Study Locations:

Campo Grande, Mato Grosso do Sol, Brazil
Ilhéus, Bahia (BA), Brazil
Barra, BA, Brazil

Study Design:

Objective: To evaluate the effectiveness of BRAVECTO® against NWS (*C. hominivorax*) under field conditions in client-owned dogs.

Study Animals: Fifteen mixed-breed and purebred client-owned dogs (purebred dogs included German Shepherd, Lhasa Apso, Pit Bull and Labrador Retriever), 14 males and 1 female, between 4 months and 17 years old, weighing between 5.8 and 32.9 kg were enrolled.

Experimental Design: The study contained one treatment group. All dogs received BRAVECTO®, orally, at the labeled dose.

Drug Administration: The dog was dosed on Day 0 with the appropriate strength tablet, based on body weight (kg), according to the approved, labeled dosing table.

The chewable tablet was not shaved, split, or cut to prepare the doses.

The chewable tablet was offered to the dog for voluntary uptake. If the tablet was not taken up voluntarily by the dog, it could also be given with food, water, or directly into the mouth.

If the dog did not consume food within 1 hour prior to the intended dosing time, the dispenser offered food to the dog.

Measurements and Observations: For inclusion, each animal was evaluated, through visual observation, for the presence of *C. hominivorax* larvae in the wounds for myiasis diagnosis. The dog had its whole body examined systematically from the head, trunk, tail, ventral abdomen, and limbs by parting the hairs, palpation, and observation for wounds with maggots.

One of the larvae was collected and evaluated for identification and confirmation of the species.

The number of larvae present in the wound was visually estimated before treatment and the location of the lesions were recorded.

The wounds were evaluated 24 hours after the treatment for the presence of *C. hominivorax* larvae. The larvae were counted and recorded as dead or alive.

Results: All dogs entered the study with a range of estimated live larval counts between 2 and 100 and no estimated dead larvae. At 24 hours post-treatment, only dead larvae (range: 2 to 510) and no live larvae were collected from the wound(s) of the dogs. The larvicidal effectiveness was 100%. There was no information on whether larvae were expelled and quantified.

Ten of the 15 dogs (66%) had as much as a 10-fold increase in larval counts between the pre-treatment live larval estimate and the 24-hour dead larval count.

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

Conclusions: The results of this study demonstrate that BRAVECTO® may be effective for the treatment of infestations caused by New World screwworm (*C. hominivorax*) larvae (myiasis) in dogs and puppies. The limitations of this study include conduct in a limited population of 15 dogs. Additionally, the lack of a control group, information on expelled larvae and confidence in the pre-treatment larval estimate confound the ability to define a pure treatment effect and primary mechanism of action (larvicidal vs. expulsion), respectively.

III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this authorization. The FOI Summary for the original approval of NADA 141-426 dated May 25, 2014, contains a summary of target animal safety studies for dogs, including a margin of safety study in dogs 8 weeks old. The safety of BRAVECTO® has not been evaluated in dogs less than 8 weeks of

age or weighing less than 4.4 lbs. It is reasonable to believe that the known and potential benefits of BRAVECTO® outweigh the known and potential risks for dogs of all ages and weights because NWS myiasis is potentially fatal in dogs if left untreated, therefore justifying including dogs less than 8 weeks of age or weighing less than 4.4 lbs. in this authorization.

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 this authorization.

V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to BRAVECTO®:

Not for human use. Keep this and all drugs out of the reach of children. 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. Wash hands thoroughly with soap and water immediately after use of the product.

VI. AGENCY CONCLUSIONS

Based on the totality of scientific evidence available to FDA, including data from a laboratory effectiveness study, it is reasonable to believe that BRAVECTO®, when used as authorized, may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, and that the known and potential benefits of BRAVECTO® outweigh the known and potential risks, since NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae.

There are no adequate, approved[1] alternatives for dogs and puppies under 8 weeks of age or weighing less than 3.3 pounds because the product that is conditionally approved for the same use as BRAVECTO® is approved to treat NWS larvae (myiasis) in dogs and puppies at least 8 weeks of age and weighing at least 3.3 pounds. Additionally, there are no adequate, approved alternative products containing a single active ingredient. The conditionally approved product contains multiple active ingredients, use of which may increase the likelihood of adverse events in dogs recently treated with a heartworm preventative or other antiparasitic drug in the same class as one of the ingredients in the conditionally approved product. Therefore, BRAVECTO® containing only a single active ingredient may minimize the potential for adverse events in these dogs.

For additional information on all products authorized or conditionally approved for use to treat and/or prevent New World screwworm, please see FDA's "New World Screwworm:

[1] "Approved" products include conditionally approved products for purposes of EUAs issued under Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.

Information for Veterinarians" webpage at https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians.

A. Duration of Authorization: Revision and Revocation

This EUA will be effective until revoked under Section 564(g) of the FD&C Act or until the Secretary's declaration of emergency or threat justifying emergency authorized use is terminated (Section 564(f)(1)), with exception for continued use permissible under Section 564(f)(2). FDA may revoke or revise this authorization if emergency use of this animal drug for NWS myiasis is no longer justified, if the product no longer meets the criteria for issuance of an EUA under Section 564(c) of the FD&C Act, or other circumstances make such revocation or revision of the authorization appropriate to protect the public health or safety (Section 564(g)(2) of the FD&C Act).

B. Marketing Status

This product is authorized to be dispensed only by or on the order of a licensed veterinarian (Rx marketing status).