FDA U.S. FOOD & DRUG ADMINISTRATION

May 14, 2026

Intervet Inc.
d/b/a Merck Animal Health
Attention: Dr. Gareth Harris
Executive Director, Regulatory Affairs
126 E. Lincoln Avenue
Rahway, New Jersey, 07065

Re: NADA 141-599 Bravecto® Quantum (fluralaner for extended-release injectable suspension)

CMS #: 722653

Dear Dr. Harris:

The U.S. Food and Drug Administration (FDA) has reviewed your promotional communications for Bravecto Quantum (fluralaner for extended-release injectable suspension) including your veterinarian product website,[1] the consumer-directed website,[2] and your Pet Owner Checklist[3] (which is linked on your veterinarian product website), and noted false or misleading claims and representations about the safety and effectiveness of this product. These claims and representations misbrand your product within the meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 502(a) [21 U.S.C. 352(a)]; section 502(n) [21 U.S.C. 352(n)]; section 201(n) [21 U.S.C. 321(n)]; and 21 CFR 202.1(e)(5). Introducing or delivering a misbranded animal drug for introduction into interstate commerce violates section 301(a) of the FD&C Act [21 U.S.C. 331(a)], and is therefore a prohibited act. This violation is especially concerning because Bravecto Quantum is a long-acting drug in a class (isoxazoline) that is used frequently by veterinarians and pet owners.

Background

According to the Indications section of the FDA-approved package insert (PI):[4]

> 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*

[1] https://www.merck-animal-health-usa.com/products/bravecto-quantum/ (last accessed on May 11, 2026)
[2] https://us.bravecto.com/dogs/bravecto-quantum-for-dogs/ (last accessed on May 11, 2026)
[3] Identified by Merck as US-BRV-241200005 1019801
[4] This section does not include all the safety and risk information in the package insert for Bravecto Quantum and does not necessarily represent the risk information that should be included in the promotional communication(s) cited in this letter.

U.S. Food and Drug Administration
Center for Veterinary Medicine
CPK1
5001 Campus Drive
College Park, MD 20740-3835
www.fda.gov

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.

The PRECAUTIONS section of the PI states, in part:

Fluralaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders.

BRAVECTO QUANTUM is not effective against *Amblyomma americanum* ticks beyond 8 months after dosing (see **Effectiveness**).

Hypersensitivity reactions, including anaphylaxis, have been reported with the use of this product and should be treated immediately with the same measures used to treat hypersensitivity reactions to vaccines and other injectable products (see **Adverse Reactions**).

The safety of BRAVECTO QUANTUM has not been evaluated in breeding, pregnant and lactating dogs. Reproductive adverse events have been reported following use of Bravecto (fluralaner) Chews in breeding females including birth defects (including limb deformities and cleft palate), stillbirth, and abortion.

Before use in breeding female dogs, refer to the **Target Animal Safety** section.

False or Misleading Claims

Prescription drug advertisements and labeling (promotional communications) misbrand a drug if they are false or misleading in any particular. *See* FD&C Act sections 502(a), (n) [21 U.S.C 352(a), (n]). The determination of whether a promotional communication is misleading includes, among other things, not only representations made or suggested in the promotional communication, but also the extent to which the promotional communication fails to reveal facts material in light of the representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the promotional communication. *See* FD&C Act section 201(n) [21 U.S.C 321(n)] and 21 CFR 202.1(e)(5).

Misleading Claims of Effectiveness

The veterinarian product website, consumer-directed website, and pet owner checklist contain claims such as “The extended-release composition delivers effective levels of fluralaner for 12 months,” “Peace of mind for 365 days,” and “Your dog has 12 months of flea and tick protection” (the 12-month protection claims). These claims are misleading because, although Bravecto Quantum is approved to kill fleas and for the treatment and

control of flea infestations and certain tick species for 12 months, it is approved for the treatment and control of the lone star tick (*Amblyomma americanum*) for only 8 months. We acknowledge that these claims include an asterisk that directs readers to a statement found in small text on the websites and on the bottom of the first page of the Pet Owner Checklist explaining that Bravecto Quantum is indicated to protect against *A. americanum* for 8 months. However, the statement is not presented with a comparable prominence and readability as the "12-month protection claims." For the veterinarian product website, the reader must scroll nearly to the bottom of the website to find the statement, and for both the veterinarian product website and consumer-directed site, the statement is in smaller text than the 12-month protection claims. On the Pet Owner Checklist, the statement is on the first page, but in smaller text. The overall presentation of this information creates a misleading impression regarding product effectiveness, which is concerning for consumers who are relying on the product to control the lone star tick.

In addition, on the veterinarian product website, under the heading "Delivers effective, lasting protection against ticks," a bar graph depicts the "Average duration of efficacy studies against *A. americanum* (Lone Star Tick)." The graph indicates an average efficacy >90% from days 8 through 301. However, this efficacy claim is misleading. Three studies (hereafter referred to as Study 1, 2, or 3) were conducted to evaluate the effectiveness of Bravecto Quantum against the lone star tick. The Freedom of Information (FOI) Summary for Bravecto Quantum explains that, for Study 2, the *A. americanum* treatment groups were removed from the study early (i.e., after day 182) because the reduction in tick count was below the 90% effectiveness threshold for 2 consecutive counts (at days 151 and 182). The FOI Summary stated that Study 2 "failed to demonstrate adequate (≥90%) effectiveness consistently beyond 2 months."[5] Additionally, the FOI Summary noted that Study 3 demonstrated efficacy for 241 days (8 months) but failed to demonstrate adequate (≥90%) effectiveness consistently beyond 8 months. Based on these findings, FDA determined, and noted in the FOI Summary, that the combined data from the three studies demonstrates that Bravecto Quantum "is effective for the treatment and control of *A. americanum* infestations starting Day 8 through 8 months after treatment…."[6]

Further, in a meeting between the Center of Veterinary Medicine (CVM) and Merck held on January 26, 2023,[7] Merck inquired (b) (4)

(b) (4)

(b) (4) Therefore, CVM concluded, and stated in the Memorandum of Conference provided to you on March 10, 2023, that, collectively, the data from Studies 1, 2, and 3 may be used to support substantial evidence of effectiveness for an 8-month indication for the treatment and control of *A. americanum*. Thus, the presentation of the data in the bar graph (b) (4)

(b) (4) which is inconsistent with both the FOI Summary and CVM's position as articulated in the January 26, 2023 meeting.

Minimization of Risk

[5] U.S. Food and Drug Administration, Center for Veterinary Medicine, (2025, July 10), Freedom of Information Summary, NADA 141-599 Bravecto Quantum (fluralaner for extended-release injectable suspension), page 27.
[6] *Ibid.*, page 30
[7] See Memorandum of Conference, January 26, 2023, (b) (4)

The veterinary product website fails to present a fair balance of information relating to side effects, warnings, and precautions as required by 21 CFR 202.1(e)(5)(ii). For example, the website contains numerous videos, graphs, charts and other visuals discussing the benefits and effectiveness of Bravecto Quantum, such as the bright red bar graph (referenced above) showing the product's efficacy. However, the section titled "Demonstrated Safety of Bravecto Quantum" contains only the statement "Bravecto Quantum has been safely administered in numerous clinical studies to dogs of various ages, weights, and breeds, including mixed-breeds." We acknowledge that there is safety information presented in the Important Safety Information (ISI) section at the end of the website. However, this information is not presented until after numerous other visual aids describing effectiveness. Further, unlike the effectiveness information, there are no visual aids describing the risks or safety information pertinent to Bravecto Quantum.

Additional Comments

We offer the following additional comments about the promotion of Bravecto Quantum:

Important Safety Information (ISI)

- We note that the ISI section appearing at the bottom of the veterinarian product website and consumer-directed website presents safety information for all Bravecto products, including products for cats. These websites, however, discuss benefits and effectiveness only for Bravecto Quantum. The inclusion of risk information not relevant to Bravecto Quantum may make it difficult for readers to find information about important risks associated with Bravecto Quantum.

- In addition, the isoxazoline class statement for Bravecto Quantum is at the very end of the ISI section, separated from the information about Bravecto Quantum by the information concerning Bravecto products for cats. The location of the class statement makes it more likely that consumers and veterinarians will overlook it, as they may stop reading when they reach the section containing ISI specific to cats.

- The ISI section found on the veterinarian product website, consumer-directed website, and Pet Owner Checklist omits important safety and risk information found in the Precautions and Adverse Reactions sections of package insert. For example, the risk of hypersensitivity reactions, including anaphylaxis, is omitted.

Conclusion and Requested Response

For the reasons discussed above, your promotional materials misbrand Bravecto Quantum within the meaning of the FD&C Act. FD&C Act section 502(a), [21 U.S.C. 352(a)]; section 502(n) [21 U.S.C. 352(n)]; section 201(n) [21 U.S.C. 321(n)]; and 21 CFR 202.1(e)(5). Introducing or delivering misbranded new animal drugs for introduction into interstate commerce violates section 301(a) of the FD&C Act [21 U.S.C. 331(a)].

This letter notifies you of our concerns and provides you with an opportunity to address them. Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional

communications for Bravecto Quantum that contain representations like those described above, and explaining any plan for discontinuing use of such communications, or for ceasing distribution of Bravecto Quantum.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Please direct your response to the undersigned at the Food and Drug Administration, Center for Veterinary Medicine, Division of Pharmacovigilance and Surveillance, 5001 Campus Drive, CPK1, College Park, MD, 20740. Please send a courtesy copy by email to CVMSurveillance@fda.hhs.gov. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter #722653.

If you have any questions, please contact Dr. Kathryn Dennehy by email at kathryn.dennehy@fda.hhs.gov.

Sincerely,

LINDA A. WALTER-GRIMM -S

Digitally signed by LINDA A. WALTER-GRIMM -S
Date: 2026.05.14 09:06:48 -04'00'

Linda Walter-Grimm, DVM
Director, Division of Pharmacovigilance and Surveillance
Office Surveillance and Compliance
Center for Veterinary Medicine