Finding of No Significant Impact (FONSI)
in support of the Emergency Use Authorization (EUA)
for
Bravecto® Chews
(fluralaner)
in
Dogs and puppies
For the treatment of infestations caused by
New World screwworm (*Cochliomyia hominivorax)* larvae (myiasis)

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The Food and Drug Administration's Center for Veterinary Medicine (FDA-CVM) has considered the potential environmental impact of this action and has concluded that this action will not have a significant impact on the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared.

Intervet Inc is requesting the issuance of an emergency use authorization (EUA) for the use of Bravecto® (fluralaner) Chews for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies. Bravecto® Chews are administered orally as a single dose to provide for a minimum dose of 11.4 mg/lb (25 mg/kg) body weight. The product is dispensed by prescription.

The EUA was authorized to address the emerging public health threat posed by New World screwworm (NWS). FDA-CVM determined that the most efficient process to address FDA-CVM's obligations under the National Environmental Policy Act was to prepare a programmatic environmental assessment (PEA). FDA-CVM obtained agreement for these alternative arrangements from the Council on Environmental Quality.

FDA-CVM has prepared a PEA titled, "Programmatic environmental assessment for the use of antiparasitic animal drugs for the prevention and/or treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis)." A copy of the PEA can be found on FDA-CVM's website titled, "New World Screwworm: Information for Veterinarians."[1] FDA-CVM determined that the PEA provides sufficient evidence to support a finding of no significant impact (FONSI) for the issuance of an EUA for Bravecto® Chews.

The PEA considered the reasonably foreseeable environmental effects from approval of Conditional New Animal Drug Applications and authorizations for emergency use of antiparasitic animal drugs in both major and minor warm-blooded species to prevent and/or treat NWS infestations. The evaluation for major species was further split by evaluating the risk of impacts from cats, dogs and horses separately from livestock (cattle, swine and poultry) due to the differences in the expected use and environmental introduction and exposure of the antiparasitic animal drugs used in these species. For the purposes of the evaluation of Bravecto® Chews, only the assessment of impacts from dogs and puppies is considered herein because the EUA is proposed for dogs and puppies only. In addition, Bravecto® (fluralaner) Chews are currently

[1] https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians

approved[2] under New Animal Drug Application (NADA) 141-426 for the same conditions of use, except for the following: (1) there is no age or weight restriction for dogs under the EUA, (2) Bravecto® is only administered single dose under the EUA (rather than every 12 weeks under the NADA), and (3) the EUA will add a new antiparasitic indication for NWS. However, they are both used for antiparasitic purposes in dogs and puppies.

The PEA contains exposure and effects assessments and a risk characterization evaluating the potential for significant environmental impacts from the use of antiparasitic animal drugs in dogs for prevention and/or treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis). FDA-CVM determined that antiparasitic animal drugs used in companion animals, such as dogs and cats, are expected to result in only limited and geographically dispersed environmental exposure due to the relatively small population sizes of treated companion animals, as well as the individualized and controlled waste management practices typically employed by pet owners. As of October 2026, United States Department of Agriculture (USDA) had confirmed only five cases of NWS infestations in dogs in Texas and New Mexico, underscoring the low scale of infestation expected for this species. Following oral administration of Bravecto® Chews, residues of the drug and its metabolites can be excreted in the animal's urine and feces. However, most pet waste is collected and disposed of in a landfill where leachate is effectively contained under federal regulatory requirements (40 CFR 258.40). For example, most dog feces in outdoor settings are subject to collection ordinances in many municipalities across the United States (U.S.). This waste is predominantly sent to landfills. Even in cases where dogs defecate outdoors without collection, the density of dogs across both rural and urban areas is geographically dispersed, meaning that any residues deposited in the environment will be spread over large areas, substantially diluting the environmental concentration of fluralaner. Therefore, excretion pathways for dogs are expected to result in limited environmental introduction and exposure of fluralaner. Because the likelihood that environmental exposure from Bravecto® Chews used in dogs and puppies is expected to be limited, the risk of significant adverse effects on non-target organisms is also expected to be limited.

In addition, expected use of Bravecto® Chews, and therefore the expected environmental exposure, will be spatially limited to areas where there is an active NWS infestation or the potential for an infestation, primarily in the southern U.S., and use and exposure will diminish as NWS populations are reduced through the efforts coordinated by the USDA. USDA is working with other federal, state, and tribal governments to control, limit, and eradicate NWS in the U.S. through several coordinated approaches, including limiting animal imports at the U.S.-Mexico border; quarantining infested animals; tracking domestic animal movement; daily monitoring of livestock and wildlife; use of animal drugs and pesticides to treat, control and prevent NWS infestations; and the release of sterile flies.[3] The sterile fly program—already operational in Panama and Mexico and under construction in Texas—has been found to be the most effective

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[2] Bravecto® (fluralaner) Chews are currently approved under New Animal Drug Application (NADA) 141-426 for the following indications: Bravecto® 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® 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.
[3] USDA APHIS. April 2026. Response Playbook New World Screwworm. Version 2. https://www.aphis.usda.gov/sites/default/files/nws-response-playbook.pdf (date accessed: June 5, 2026)

method at eradicating NWS. For example, NWS was eradicated from the Southwestern U.S. in 1966 within approximately 4-5 years of sterile fly releases, and the 2016 Florida Keys outbreak was resolved in just 5 months. The regulatory time limit on this EUA also ensures the use of Bravecto® Chews will be limited for only the duration of the emergency use declaration. Additionally, Bravecto® Chews is currently approved for an almost identical use supporting that no reasonably foreseeable significant environmental effects are expected from the nationwide, indefinite use of fluralaner as an antiparasitic animal drug for use in dogs and puppies—a far broader scenario than what is expected under the EUA to treat and/or prevent NWS infestations.

Based on the information in the PEA, no reasonably foreseeable significant environmental effects are expected from the proposed use of Bravecto® (fluralaner) Chews in dogs and puppies for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis).

{see appended electronic signature page}

Matthew Lucia, DVM
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U.S. Food and Drug Administration

Electronic Signature
Addendum for Submission ID

Signing Authority (Role)	Letter Date
Matthew Lucia (Office Director)	10/28/2026

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