Finding of No Significant Impact (FONSI)
in support of the Emergency Use Authorization (EUA)
for
Credelio™
(lotilaner)
in
Dogs and puppies
for
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.

Credelio™ (lotilaner), sponsored by Elanco US Inc, was authorized for emergency use on October 24, 2025. Credelio™ is authorized for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies. Credelio™ is administered as chewable tablets once a month at a minimum dose of 9 mg/lb (20 mg/kg). The product is dispensed by prescription.

The EUA was authorized to address the emerging public health threat posed by New World screwworm (NWS). Given the need for FDA-CVM to act quickly to authorize the emergency use of Credelio™ to address the potential public health threat from NWS, there was not sufficient time for FDA-CVM to complete an adequate environmental assessment (EA) prior to taking these actions. Therefore, FDA-CVM invoked Title 21 Code of Federal Regulations (CFR) 25.16[1] for these actions, which allowed FDA-CVM to prepare the EA or EIS documents as soon as practicable without delaying these actions. 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."[2] FDA-

[1] 21 CFR 25.16 states: Public health and safety emergencies. -- There are certain regulatory actions that, because of their immediate importance to the public health or safety, may make full adherence to the procedural provisions of NEPA [National Environmental Policy Act] and CEQ's [Council on Environmental Quality] regulations impossible. For such actions, the responsible agency official shall consult with CEQ about alternative arrangements before the action is taken, or after the action is taken, if time does not permit prior consultation with CEQ.
[2] https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians

CVM determined that the PEA provides sufficient evidence to support a finding of no significant impact (FONSI) for the EUA for Credelio™.

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 Credelio™, only the assessment of impacts from dogs and puppies is considered herein because the EUA is approved for dogs and puppies only. In addition, Credelio™ (lotilaner) is currently approved[3] under New Animal Drug Application (NADA) 141-494 for the same conditions of use, except there is no age or weight restriction for dogs under the EUA, and the EUA added 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 August 2026, United States Department of Agriculture (USDA) had confirmed only four cases of NWS infestations in dogs in Texas and New Mexico, underscoring the low scale of infestation expected for these species. Following oral administration of Credelio™, 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 lotilaner. Therefore, excretion pathways for dogs are expected to result in limited environmental introduction and exposure of lotilaner. Because the likelihood that environmental exposure from Credelio™ 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 Credelio™, and therefore the expected environmental exposure, will be spatially limited to areas where there is an active NWS infestation or the potential for an

[3] Credelio™ is currently approved under New Animal Drug Application 141-494 for kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations [*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), *and Haemaphysalis longicornis* (longhorned tick)] for one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater. Credelio™ is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

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.[4] The sterile fly program—already operational in Panama and Mexico and under construction in Texas—has been found to be the most effective 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 Credelio™ will be limited for only the duration of the emergency use declaration. Additionally, Credelio™ is currently approved for an almost identical use supporting that no reasonably foreseeable significant environmental effects are expected from the nationwide, indefinite use of lotilaner 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 Credelio™ in dogs and puppies for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis).

{see appended electronic signature page}

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[4] 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)

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