

**Finding of No Significant Impact (FONSI)
in support of the Emergency Use Authorization (EUA)
for
Credelio™ CAT
(lotilaner)
in
Cats and kittens
For
the treatment of infestations caused by New World screwworm
(*Cochliomyia hominivorax*) larvae (myiasis)**

**Elanco US Inc
Indianapolis, IN**

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™ CAT (lotilaner), sponsored by Elanco US Inc, was authorized for emergency use on November 21, 2025. Credelio™ CAT is authorized for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens. Credelio™ CAT is administered as chewable tablets once a month at a minimum dose of 2.7 mg/lb (6 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™ CAT 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) 25.16¹ 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™ CAT.

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™ CAT, only the assessment of impacts from cats and kittens is considered herein because the EUA is approved for cats and kittens only. In addition, Credelio™ CAT (lotilaner) is currently approved³ under New Animal Drug Application (NADA) 141-528 for the same conditions of use, except there is no age or weight restriction for cats under the EUA, and the EUA added a new antiparasitic indication for NWS. However, they are both used for antiparasitic purposes in cats and kittens.

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 cats 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 no cases of NWS infestations in cats, underscoring the low scale of infestation expected for these species. Following oral administration of Credelio™ CAT, 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 domestic cat waste is collected in litter boxes, which is predominantly sent to landfills. Even in cases where cats defecate outdoors without collection, the density of cats 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 cats are expected to result in limited environmental introduction and exposure of lotilaner. Because the likelihood that environmental exposure from Credelio™ CAT used in cats and kittens 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™ CAT, 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.

³ Credelio™ CAT is currently approved under New Animal Drug Application 141-528 for kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of *Ixodes scapularis* (black-legged tick) infestations for one month in cats and kittens 8 weeks of age and older, and weighing 2.0 pounds or greater.

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™ CAT will be limited for only the duration of the emergency use declaration. Additionally, Credelio™ CAT 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 cats and kittens—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™ CAT in cats and kittens for treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis).

{see appended electronic signature page}

Matthew Lucia, DVM
Director
Office of New Animal Product Evaluation
Center for Veterinary Medicine
U.S. Food and Drug Administration

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)

**Electronic Signature
Addendum for Submission ID**

V-006664-Q-0002-OT

Signing Authority (Role)	Letter Date
Matthew Lucia (Office Director)	9/10/2026

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.