Finding of No Significant Impact (FONSI)
in support of the Emergency Use Authorization (EUA)
and revision to the EUA
for
Nitenpyram Tablets
(nitenpyram)
in
dogs, puppies, cats and kittens 2 pounds of body weight
or greater and 4 weeks of age and older
for
the treatment and prevention 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 these actions (Emergency Use Authorization (EUA) and a revision to the EUA) and has concluded that these actions will not have a significant impact on the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared.

Nitenpyram Tablets (nitenpyram), sponsored by Felix Pharmaceuticals Pvt Ltd, was authorized for emergency use on June 11, 2026. A revision to the EUA was issued on September 3, 2026, which provided for revised labeling. Nitenpyram Tablets are authorized for the treatment and prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older. Nitenpyram Tablets are administered by oral tablets. Cats and dogs weighing 2-25 lb should be administered one 11.4 mg tablet, and dogs weighing 25.1-125 lb should be administered one 57 mg tablet. For the treatment claim, a second dose should be administered 6 hours after the first. For effective treatment of New World screwworm fly larvae (maggots) in a wound, Nitenpyram Tablets should be used in addition to the physical removal of maggots (live and dead), by a veterinarian, remaining in the wound after treatment. For the prevention claim, Nitenpyram Tablets should be administered once daily. The product is dispensed over the counter.

The EUA and revision to the EUA were 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 Nitenpyram Tablets 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

[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.

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-CVM determined that the PEA provides sufficient evidence to support a finding of no significant impact (FONSI) for the EUA and revision to the EUA for Nitenpyram Tablets.

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 Nitenpyram Tablets, only the assessment of impacts from dogs and cats is considered herein since the EUA is approved for dogs and cats (including younger life stages, puppies and kittens) only. In addition, Nitenpyram Tablets (nitenpyram) are currently approved under Abbreviated New Animal Drug Application (ANADA) 200-858 for the same conditions of use.[3] The only difference between the two products is the indication; however, they are both used for antiparasitic purposes in dogs, puppies, 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 dogs and 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 only four cases of NWS infestations in dogs in Texas and New Mexico and zero confirmed cases in cats, underscoring the low scale of infestation expected for these species. Following oral administration of Nitenpyram Tablets, 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 and 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 or cats defecate outdoors without collection, the density of companion animals across both rural and urban areas is geographically dispersed, meaning

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

[3] Nitenpyram Tablets are approved to kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older.

that any residues deposited in the environment will be spread over large areas, substantially diluting the environmental concentration of nitenpyram. Therefore, excretion pathways for dogs and cats are expected to result in limited environmental introduction and exposure of nitenpyram. Because the likelihood that environmental exposure from Nitenpyram Tablets used in dogs and cats 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 Nitenpyram Tablets, 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.[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 Nitenpyram Tablets will be limited for only the duration of the emergency use declaration. Additionally, Nitenpyram Tablets are currently approved for an almost identical use supporting that no reasonably foreseeable significant environmental effects are expected from the nationwide, indefinite use of nitenpyram as an antiparasitic animal drug for use in dogs, puppies, 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 Nitenpyram Tablets in dogs, puppies, cats and kittens for treatment and prevention 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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