Finding of No Significant Impact (FONSI)
in support of the approval of a Conditional New Animal Drug Application (CNADA)
and a supplement to the CNADA
for
Dectomax®-CA1
(doramectin injection)
in
Cattle
for
prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis), and prevention of reinfestation for 21 days

Zoetis Inc
Kalamazoo, MI

The Food and Drug Administration's Center for Veterinary Medicine (FDA-CVM) has considered the potential environmental impact of these actions 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.

Dectomax®-CA1 (doramectin injection), sponsored by Zoetis Inc, was conditionally approved under new animal drug application (NADA) 141-616 on September 30, 2025. A supplement to the Conditional NADA (CNADA) was approved on March 13, 2026, which provided for revised labeling. Dectomax®-CA1 is conditionally approved for use in cattle for prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis), and prevention of reinfestation for 21 days. Dectomax®-CA1 is administered by subcutaneous or intramuscular injection in the neck region at a dose of 1 mL (10 mg doramectin) per 110 lb of body weight (200 mcg/kg). The product will be dispensed over the counter.

These CNADAs were approved to address the emerging public health threat posed by New World screwworm (NWS). Given the need for FDA-CVM to act quickly to conditionally approve Dectomax®-CA1 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

[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.

World screwworm (*Cochliomyia hominivorax*) larvae (myiasis)." A copy of the PEA can be found on FDA-CVM's website titled, "Animal Drugs @ FDA" under the Environmental Documents tab.[2] FDA-CVM determined that the PEA provides sufficient evidence to support a finding of no significant impact (FONSI) for the approval of the CNADA and supplement to the CNADA for Dectomax®-CA1.

The PEA considered the reasonably foreseeable environmental effects from approval of CNADAs 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 Dectomax®-CA1, only the assessment of impacts from livestock is considered herein since the CNADA is approved for cattle only. In addition, an EA, dated July 30, 1996 (referred to herein as the 1996 EA), supported a FONSI for the original NADA of Dectomax® (doramectin 1% injectable solution) Injectable Solution[2] for cattle under NADA 141-061 for the same conditions of use (route of administration, dosage, etc.) as those conditionally approved for Dectomax®-CA1. The only difference between the two products is the indication; however, they are both used for antiparasitic purposes in cattle.

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 livestock for prevention and/or treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis). Cattle represent the greatest potential source of environmental exposure to antiparasitic animal drugs used to prevent and/or treat NWS infestations due to their outdoor rearing in open feedlots and pastures, which increases their risk of exposure to NWS flies, and their production of a large volume of manure containing antiparasitic animal drug residues. Doramectin from Dectomax®-CA1 is expected to enter the environment from cattle through excretion of drug residues in manure.[3] For feedlot cattle, manure is collected and stored before being applied to cropland; for pasture-raised cattle, manure is excreted directly on the ground without storage. During rainfall, drug residues can leach or run off from manure into soil and adjacent waterways. As discussed in the PEA, the transport and fate of a drug in the environment depends heavily on its physical-chemical and fate properties. Doramectin has low water solubility (0.25 mg/L at 25°C) and a high organic carbon soil-water partition coefficient (K_{oc}) ranging from 7,520 to 86,900 L/kg (see Table B.1 of the PEA and the 1996 EA), indicating that doramectin tends to partition substantially to organic matter in manure, soil and sediment. Studies indicate that doramectin sorbs strongly to solids and is not expected to readily leach from manure or soil or remain in the water column of surface water bodies (1996 EA). Doramectin also undergoes rapid aquatic photodegradation with a half-life of only 4.45 hours under simulated sunlight (1996 EA), and aerobic degradation in soil results in a degradation half-life ranging from 61 to 79 days (see Table B.1 of the PEA and the 1996 EA).

Non-target invertebrates in the terrestrial and aquatic environments are the organisms most at risk from exposure to antiparasitic animal drugs, such as doramectin. Dung fauna are

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[2] https://animaldrugsatfda.fda.gov/adafda/views/#/environmentalAssessments

[3] Wash-off of topically applied drugs during rain events, sprinkler use, or when animals enter waterways was not considered for these actions because it is not a relevant route of exposure for Dectomax®-CA1, which is an injectable product. Dectomax®-CA1 is not topically applied.

particularly sensitive to doramectin, as they live in and feed on cattle dung pats in pasture. Dung fauna provide critical ecosystem services including manure decomposition, nutrient cycling, and greenhouse gas reduction. The PEA concluded no significant effects to dung fauna populations are likely to occur from the conditional approvals of antiparasitic animal drugs because many dung fauna do not rely exclusively on cattle dung, they occupy broad habitats and can recolonize from unaffected areas. The 1996 EA provided a detailed analysis on the effects of Dectomax®-CA1 on dung fauna and had the same conclusion as the PEA.

As discussed in the PEA, in aquatic environments, antiparasitic animal drugs can cause impacts to invertebrates (zooplankton and macro-invertebrates) dwelling in the water column and sediment depending on their water solubility and K_{oc} because these chemical characteristics influence exposure in the water or sediment compartments. Acute effects include mortality and immobilization; chronic effects include impaired growth and reproduction. These effects, if great enough, could cause impacts on the overall ecosystem diversity and structure. The 1996 EA found that no significant environmental effects are expected on aquatic invertebrates from the use of Dectomax® Injectable Solution.

FDA-CVM considered several other factors, as described in the PEA, that would limit the potential environmental effects of antiparasitic animal drugs, like Dectomax®-CA1, used in cattle to prevent and/or treat NWS infestations. Expected use of Dectomax®-CA1, and therefore the expected environmental exposure, is spatially limited to areas where there is an active NWS infestation or the potential for an infestation, primarily in the southern United States (U.S.), and use and exposure will diminish as NWS populations are reduced through the efforts coordinated by the U.S. Department of Agriculture (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 CNADA also ensures the use of Dectomax®-CA1 will be limited to 5 years. Additionally, the 1996 EA for full NADA approval of Dectomax® Injectable Solution for an almost identical use supported that no reasonably foreseeable significant environmental effects are expected from the nationwide, indefinite use of doramectin as an antiparasitic animal drug for use in cattle—a far broader scenario than what is expected under conditional approval to prevent and/or treat NWS infestations. Finally, the scientific literature supports that both dung fauna and aquatic invertebrate communities can recover following intermittent pulse exposures to antiparasitic chemicals. Dung beetles are strong fliers that recolonize from nearby unaffected pastures, and studies show population recovery within weeks to months after exposure ends. Aquatic invertebrate communities also recover, often within weeks to years, even after population reductions exceeding 90%, especially when connected to unaffected ecosystems.

Based on the information in the PEA and the 1996 EA for Dectomax® Injectable Solution (NADA 141-061), no reasonably foreseeable significant environmental effects are expected from the

[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)

proposed use of Dectomax®-CA1 in cattle for prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis), and prevention of reinfestation for 21 days.

{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

Electronic Signature
Addendum for Submission ID

Signing Authority (Role)	Letter Date
Matthew Lucia (Office Director)	08/11/2026

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