U.S. FOOD & DRUG ADMINISTRATION

May 19, 2026

Zoetis Inc.
Attention: John Hallberg, DVM, PhD
Senior Director of Regulatory Affairs
333 Portage St.
Kalamazoo, MI 49007

Re: Emergency Use Authorization 006700

Dear Dr. Hallberg:

This letter is in response to the request by Zoetis Inc. (Zoetis) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of DECTOMAX/DECTOMAX-CA1 (doramectin injection)[1] for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

On August 18, 2025, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025, declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to Section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.[2]

DECTOMAX (doramectin injection) is an antiparasitic drug that is indicated under NADA 141-061 for the treatment and control of nematode and arthropod parasites in cattle and swine. DECTOMAX-CA1 (doramectin injection) is the same antiparasitic drug, is indicated under NADA 141-616, and conditionally approved for the prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and the prevention of reinfestation for 21 days in cattle.

Based on the totality of scientific evidence available to the FDA, including dose confirmation studies, pharmacokinetic studies, margin of safety studies, and published scientific literature, it

[1] Unless specified by name, products sold under separate distributor's labeling per 21 CFR 514.80(b)(5)(iii) (i.e., with a different proprietary name) are not subject to this EUA. A request must be made to change to the scope of this authorization for such products.
[2] See U.S. Department of Health and Human Services, Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm, August 20, 2025: https://www.federalregister.gov/documents/2025/08/20/2025-15918/declaration-of-emergency-pursuant-to-the-federal-food-drug-and-cosmetic-act-for-new-world-screwworm

is reasonable to believe that DECTOMAX/DECTOMAX-CA1 (doramectin injection) may be effective for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of DECTOMAX/DECTOMAX-CA1 outweigh the known and potential risks of such product, since NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the FD&C Act are met, I am authorizing the emergency use of DECTOMAX/DECTOMAX-CA1 (doramectin injection) for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, as described in this authorization and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of DECTOMAX/DECTOMAX-CA1 for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, when administered as described in this authorization, meets the criteria for issuance of an authorization under Section 564(c) of the FD&C Act, because:

1. NWS can cause a serious or life-threatening disease or condition to animals and humans;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that DECTOMAX/DECTOMAX-CA1 may be effective in treating and/or preventing NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of DECTOMAX/DECTOMAX-CA1 when used to prevent and/or treat NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved,[3] and available alternative to the emergency use of DECTOMAX/DECTOMAX-CA1 for the prevention and treatment of infestations caused

[3] "Approved" products include conditionally approved products for purposes of EUAs issued under Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.

by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the FD&C Act, that the scope of this authorization is limited as follows:

- DECTOMAX/DECTOMAX-CA1, as covered by this authorization, will be used only for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, over the counter. DECTOMAX/DECTOMAX-CA1 may be administered by subcutaneous injection only in dairy cattle and deer, by intramuscular injection only in swine and horses, and by subcutaneous or intramuscular injection in sheep.

- The use of DECTOMAX/DECTOMAX-CA1 covered by this authorization must be in accordance with the authorized Fact Sheets.

Product Description

DECTOMAX/DECTOMAX-CA1 is a highly active, broad-spectrum parasiticide. It contains doramectin, a fermentation-derived macrocyclic lactone. The authorized DECTOMAX/DECTOMAX-CA1 (doramectin injection) Fact Sheets/label are clearly marked for the approved indications and for NWS under Emergency Use Authorization with a website address and QR code that links to the authorized Fact Sheet(s).

Store below 30°C (86°F).

DECTOMAX/DECTOMAX-CA1 is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to all users:

- Fact Sheet: Emergency Use Authorization of DECTOMAX/DECTOMAX-CA1 (doramectin injection) for New World Screwworm (NWS) Dairy Cattle, Swine, Sheep, and Deer

- Fact Sheet: Emergency Use Authorization of DECTOMAX/DECTOMAX-CA1

[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

(doramectin injection) for New World Screwworm (NWS) Horses

I have concluded, pursuant to Section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of DECTOMAX/DECTOMAX-CA1, when used for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, and used in accordance with this authorization, outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the FD&C Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that DECTOMAX/DECTOMAX-CA1 may be effective for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that DECTOMAX/DECTOMAX-CA1, as described in this authorization, meets the criteria set forth in Section 564(c) of the FD&C Act concerning safety and potential effectiveness.

The emergency use of this product under an EUA must be consistent with, and may not exceed, the terms of this authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the FD&C Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the FD&C Act, DECTOMAX/DECTOMAX-CA1 is authorized for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, except for horses under one year of age and lactating sheep, as described in this authorization, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the FD&C Act, I am establishing the following conditions on this authorization:

A. Zoetis will ensure that the authorized DECTOMAX/DECTOMAX-CA1, accompanied with the authorized Fact Sheets, is distributed to authorized distributor(s)[5] consistent with the terms and conditions of this EUA, and that authorized distributor(s) will limit distribution to other authorized distributors and end users.

B. Zoetis will ensure that if a sticker is used on the labeling, the sticker contains a website address and QR code that link to the authorized Fact Sheets and that the sticker is placed in a blank space or does not obscure any important use or safety information.

C. Zoetis and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.

D. Zoetis and authorized distributor(s) will provide to each authorized distributor immediately downstream in the supply chain a copy of this Letter of Authorization and promptly communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (e.g., its authorized Fact Sheets).

E. Zoetis may request changes to this authorization, including to the authorized Fact Sheets for DECTOMAX/DECTOMAX-CA1. Requests for changes must be submitted to the Office of New Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.[6]

F. Reporting Adverse Drug Experiences and Product/Manufacturing Defects:

   Zoetis will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Zoetis will attempt to determine whether the use of DECTOMAX/DECTOMAX-CA1 was related to the EUA and will put this categorization, as well as the reason for use, in the narrative description of the adverse event. Zoetis will submit the reports electronically using either of the options that are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage (www.fda.gov/IndustryReportAnimalAE).

   Submitted reports must state in the "Narrative of Adverse Event" field: "DECTOMAX/DECTOMAX-CA1 use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at CVMAESupport@fda.hhs.gov for any questions related to electronic reporting or for assistance with setting up a Safety Reporting Portal account.

[5] The term "distributors" includes all parties in the supply chain between the recipient of this authorization letter and the end user, excluding veterinary facilities and veterinarians who only provide product to veterinarians and end users at their facility. "Authorized distributors" are all distributors who otherwise lawfully obtain and distribute the product, unless Zoetis places limits on distribution in writing (e.g., via contract or written notice accompanying the product).
[6] Changes that do not necessitate revision to this letter (e.g., changes to the Fact Sheets, changes related to current good manufacturing practice requirements, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

G. Through a process of inventory control, Zoetis and authorized distributor(s) will maintain records regarding distribution of the authorized DECTOMAX/DECTOMAX-CA1 (i.e., lot numbers, quantity, receiving site, receipt date).

H. Zoetis and authorized distributor(s) will maintain records in connection with this EUA for at least two years following the termination of the declaration or the revocation of the authorization, or until notified by HHS or FDA, whichever is sooner, and will make such records available to FDA for inspection upon request.

I. Zoetis (and any other person engaged in manufacturing, packing, or holding) will comply with all other FD&C Act requirements applicable to the approved product, DECTOMAX/DECTOMAX-CA1, including, but not limited to, requirements related to registration and listing, drug quality, and the requirement to manufacture using the processes, facilities, controls, and equipment specified in the approved application,[7] unless such requirements are specifically waived or modified in this authorization. Zoetis, and authorized distributor(s) who distribute EUA product under separate distributor labeling, if any, shall update their drug listing to reflect the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

Conditions of Authorization Related to Advertisements and other Promotional Descriptive Printed Matter

J. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of DECTOMAX/DECTOMAX-CA1, shall be consistent with the authorized Fact Sheets[8] and the terms set forth in this EUA, as well as comply with FD&C Act Section 502(a). Additionally, the sponsor and authorized distributor(s) shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.

K. Zoetis and authorized distributor(s) may not imply that DECTOMAX/DECTOMAX-CA1 is FDA approved or conditionally approved for the authorized use by making statements such as “DECTOMAX/DECTOMAX-CA1 is safe and effective for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer.” Zoetis and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of DECTOMAX/DECTOMAX-CA1 that provide accurate descriptions of safety and effectiveness information summarized in the

[7] Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.
[8] If the authorized Fact Sheet references sections of a drug’s FDA-approved labeling, the entirety of each section is considered part of the Fact Sheet, except as otherwise specified. Advertising and promotional materials may not use general references to approved labeling in lieu of summarizing or restating its contents when a summary or restatement is otherwise needed to comply with applicable requirements.

authorized Fact Sheets. Such materials must include any limitations of information submitted to support this authorization.

L. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of DECTOMAX/DECTOMAX-CA1 shall be accompanied by the authorized Fact Sheets and the applicable approved labeling (e.g., package insert attached to the vial), and shall clearly and conspicuously state that:

- DECTOMAX/DECTOMAX-CA1 has not been approved for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal.
  DECTOMAX/DECTOMAX-CA1 has not been approved for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer.

- DECTOMAX/DECTOMAX-CA1 has been authorized by FDA under an EUA for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer; and

- DECTOMAX/DECTOMAX-CA1 is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of DECTOMAX/DECTOMAX-CA1 under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revised or revoked sooner.

M. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter must be submitted to the CVM OSC DER eSubmitter Program at the time of initial dissemination (publication or broadcast). Each submission of promotional labeling or advertisements must be accompanied by a completed Form FDA 2301.

If FDA notifies Zoetis or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Zoetis or authorized distributor(s) must discontinue and/or cease distribution of such advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter in accordance with FDA's notification. Furthermore, as part of its notification, FDA may also require Zoetis or authorized distributor(s) to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective as described herein until the declaration that circumstances exist justifying the authorization of the emergency use of animal drugs during the NWS public health emergency is terminated under Section 564(b)(2) of the FD&C Act or the EUA is revised or revoked under Section 564(g) of the FD&C Act.

Sincerely,

{see appended electronic signature page}
Timothy Schell, Ph.D.
Director
Center for Veterinary Medicine
U.S. Food and Drug Administration

Enclosures:
Freedom of Information Summary
Fact Sheets (2)