August 13, 2026

Zoetis Inc.
Attention: Elizabeth Rigoni, DVM, MPH, Dipl ACVPM
Associate Director, VMRD Global Regulatory Affairs
333 Portage St.
Kalamazoo, MI 49007

Re: Emergency Use Authorization 006691

Dear Dr. Rigoni:

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 Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets)[1] for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, 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 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]

Simparica TRIO is an oral antiparasitic that is indicated under NADA 141-521 for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*) and hookworm (L4, immature adult, and adult *Ancylostoma caninum* and adult *Uncinaria stenocephala*) infections. Simparica TRIO kills adult fleas (*Ctenocephalides felis*) and is indicated under NADA 141-521 for the treatment and prevention of flea infestations, the prevention of *Dipylidium caninum* (tapeworm) infections as a direct result of killing *Ctenocephalides felis* vector fleas on the treated dog, and the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick) for one month in dogs and puppies 8 weeks of age and older,

[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 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

and weighing 2.8 pounds or greater. Simparica TRIO is indicated under NADA 141-521 for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks. Simparica TRIO is not approved for the treatment of NWS myiasis in dogs and puppies.

Based on the totality of scientific evidence available to the FDA, including data from a laboratory effectiveness study, it is reasonable to believe that Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) may be effective for the treatment of NWS myiasis in dogs and puppies, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Simparica TRIO outweigh the known and potential risks of such product for dogs of all ages and weights, since NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to extensive tissue damage caused by *Cochliomyia hominivorax* larvae, therefore justifying including dogs less than 8 weeks of age or less than 2.8 pounds in this authorization.

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 Simparica TRIO for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, 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 Simparica TRIO for the treatment of NWS myiasis in dogs and puppies, 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 Simparica TRIO may be effective in treating NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of Simparica TRIO when used to treat NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved,[3,4] and available alternative to the emergency use of Simparica TRIO for the treatment of NWS myiasis in dogs and puppies.[5]

[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.
[4] Other therapeutics are currently conditionally approved for the same use as Simparica TRIO. However, there is no adequate, approved alternative for dogs and puppies under 8 weeks of age or weighing less than 3.3 pounds because the product that is conditionally approved for the same use as Simparica TRIO is conditionally approved to treat NWS myiasis in dogs and puppies at least 8 weeks of age and weighing at least 3.3 pounds. Additionally, there is no adequate, approved alternative product that can be administered without food. The conditionally approved product must be administered with food. Simparica TRIO offers the ability to administer with or without food, which provides an option for dogs who are not eating due to the NWS myiasis or other conditions.
[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

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:

- Simparica TRIO, as covered by this authorization, will be used only for the treatment of NWS myiasis by a veterinarian by prescription in dogs and puppies; and

- The use of Simparica TRIO covered by this authorization must be in accordance with the authorized Fact Sheet.

Product Description

Simparica TRIO is an oral parasiticide for use in dogs and puppies. The recommended minimum dose is 0.54 mg/lb (1.2 mg/kg) sarolaner, 0.011 mg/lb (24 µg/kg) moxidectin, and 2.27 mg/lb (5 mg/kg) pyrantel (as pamoate salt). Simparica TRIO is available in six flavored tablet sizes. The authorized Simparica TRIO carton labeling is 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.

Store at or below 30°C (86°F).

Simparica TRIO is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to veterinarians, and others who may administer the product:

- Fact Sheet for Veterinarians: Emergency Use Authorization of Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) for New World Screwworm (NWS)

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 Simparica TRIO, when used for the treatment of NWS myiasis in dogs and puppies 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 Simparica TRIO may be effective for the treatment of infestations caused by NWS myiasis in dogs and puppies 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 Simparica TRIO, 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, Simparica TRIO is authorized for the treatment of NWS myiasis in dogs and puppies 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 Simparica TRIO, accompanied with the authorized Fact Sheet, is distributed to veterinary facilities[6] and veterinarians, or authorized distributor(s),[7] 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 Sheet 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 veterinary facilities and veterinarians.

D. Zoetis and authorized distributor(s) will ensure that the terms and conditions of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, veterinary facilities, and veterinarians) involved in distributing or receiving authorized Simparica TRIO. Zoetis will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (e.g., its authorized Fact Sheet).

E. Zoetis may request changes to this authorization, including to the authorized Fact Sheet for Simparica TRIO. Requests for changes must be submitted to the Office of New Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.[8]

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[6] Veterinary facilities include veterinary hospitals, veterinary clinics, and other establishments providing veterinary care. If a veterinarian is not associated with a veterinary facility, the veterinarian then assumes the obligations of the veterinary facility.

[7] 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).

[8] Changes that do not necessitate revision to this letter (e.g., changes to the Fact Sheet, changes related to current good manufacturing practice requirements, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

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 Simparica TRIO 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 should state in the "Narrative of Adverse Event" field: "Simparica TRIO 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.

G. Through a process of inventory control, Zoetis and authorized distributor(s) will maintain records regarding distribution of the authorized Simparica TRIO (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, Simparica TRIO, 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,[9] 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 for Veterinary Facilities and Veterinarians

J. Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of this Letter of Authorization. Authorized Fact Sheets will be made available to veterinarians, and veterinary facilities and veterinarians will ensure that the client is aware that the drug is authorized for emergency use, but not approved, for the treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.

[9] Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.

K. Veterinary facilities and veterinarians receiving Simparica TRIO will track serious adverse events potentially related to Simparica TRIO use under this EUA and must report these to FDA in accordance with the Fact Sheet for Veterinarians. Report by (1) contacting Zoetis at 1-888-963-8471, (2) downloading and submitting Form FDA 1932a available at https://www.fda.gov/reportanimalae, or (3) contacting FDA at 1-888-FDA-VETS to request this form. Include the statement "Simparica TRIO use for NWS under an EUA" under the "Describe Adverse Event/Product Problem/Product Use Error" heading, followed by a detailed account of the adverse event.

L. Veterinary facilities will maintain health records that include the following information: client name, patient name, patient age, disease manifestation, number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs coadministered. The records shall be maintained in a manner that allows veterinary facilities to identify in a reasonable time which patients received drugs subject to this EUA.

M. Veterinary facilities will maintain any records associated 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. Such records will be made available to Zoetis, HHS, and FDA for inspection upon request.

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

N. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of Simparica TRIO shall be consistent with the authorized Fact Sheet[10] and the terms set forth in this EUA, as well as comply with FD&C Act Sections 502(a) and 502(n), and 21 CFR Part 202. 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.

O. Zoetis and authorized distributor(s) may not imply that Simparica TRIO is FDA approved or conditionally approved for the authorized use. 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 Simparica TRIO that provide accurate descriptions of safety and effectiveness information summarized in the authorized Fact Sheet. Such materials must include any limitations of information submitted to support this authorization.

P. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of Simparica TRIO shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:

[10] If the authorized Fact Sheet references sections of a drug's FDA-approved labeling, the entirety of each section is considered part of the authorized 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.

- Simparica TRIO has not been approved for the treatment of NWS myiasis in dogs and puppies;

- Simparica TRIO has been authorized by FDA under an EUA for the treatment of NWS myiasis in dogs and puppies; and

- Simparica TRIO is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Simparica TRIO 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.

Q. 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 Sheet