Date of Authorization: August 13, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006691

Simparica TRIO®

(sarolaner, moxidectin, and pyrantel chewable tablets)

Dogs

Scope of Authorization: For the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.

Sponsored by:

Zoetis Inc.

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I. GENERAL INFORMATION

A. File Number

EUA 006691

B. Sponsor

Zoetis Inc.
333 Portage St.
Kalamazoo, MI 49007

Drug Labeler Code: 054771

C. Proprietary Name

Simparica TRIO®

D. Drug Product Established Name

sarolaner, moxidectin, and pyrantel chewable tablets

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Chewable Tablet

G. Amount of Active Ingredient

Each chewable tablet contains:

3 mg sarolaner/ 0.06 mg moxidectin/ 12.5 mg pyrantel (as pamoate salt)
6 mg sarolaner/ 0.12 mg moxidectin/ 25 mg pyrantel (as pamoate salt)
12 mg sarolaner/ 0.24 mg moxidectin/ 50 mg pyrantel (as pamoate salt)
24 mg sarolaner/ 0.48 mg moxidectin/ 100 mg pyrantel (as pamoate salt)
48 mg sarolaner/ 0.96 mg moxidectin/ 200 mg pyrantel (as pamoate salt)
72 mg sarolaner/ 1.44 mg moxidectin/ 300 mg pyrantel (as pamoate salt)

H. How Supplied

Simparica TRIO® (sarolaner, moxidectin, and pyrantel chewable tablets) is available in six flavored tablet sizes. Each tablet size is available in packages of one, three, or six tablets.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Simparica TRIO® is given orally at the recommended minimum dose of 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).

Dosage Schedule

Body Weight (lbs)	Sarolaner per Tablet (mg)	Moxidectin per Tablet (mg)	Pyrantel per Tablet (mg)	Number of Tablets Administered
2.8 to 5.5	3	0.06	12.5	One
5.6 to 11	6	0.12	25	One
11.1 to 22	12	0.24	50	One
22.1 to 44	24	0.48	100	One
44.1 to 88	48	0.96	200	One
88.1 to 132	72	1.44	300	One
>132	Administer the appropriate combination of tablets			

K. Route of Administration

Oral

L. Species

Dogs

M. Food and Drug Administration (FDA) Approved Indications

Simparica TRIO® (NADA 141-521) is indicated 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 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, and weighing 2.8 pounds or greater. Simparica TRIO® is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

N. Emergency Authorized Use

For the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.

O. Limitations of Authorized Use

Simparica TRIO® (sarolaner, moxidectin, and pyrantel chewable tablets) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Simparica TRIO® (sarolaner, moxidectin, and pyrantel chewable tablets) under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

II. EFFECTIVENESS

A. Dosage Characterization

This Emergency Use Authorization does not change the previously approved doses of 0.54 mg/lb sarolaner (1.2 mg/kg), 0.011 mg/lb moxidectin (24 µg/kg), and 2.27 mg/lb pyrantel (5 mg/kg) (as pamoate salt), given orally. The FOI Summary for the original approval of NADA 141-521, dated February 27, 2020, contains dosage characterization information for dogs.

B. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor demonstrated that it is reasonable to believe that Simparica TRIO® may be effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies based on a laboratory effectiveness study. The evidence supporting effectiveness is based on a laboratory effectiveness study. Collectively, the data support that it is reasonable to believe that Simparica TRIO® may be effective for the treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in dogs and puppies.

1. **Title:** Assessment of Efficacy of Antiparasitic Product Composed of Sarolaner, Moxidectin and Pyrantel (as pamoate salt) in the Treatment of Myiasis caused by *Cochliomyia hominivorax* larvae in Experimentally Infested Dogs. (Study No. A162R-BR-25-F08)

   Study Date(s): June 16, 2025 to September 25, 2025

   Study Location(s): Rio De Janeiro, Brazil

   Study Design:

   Objective: To evaluate the effectiveness of Simparica TRIO® in treating myiasis caused by *C. hominivorax* larvae in experimentally infested dogs.

   Study Animals: Twelve beagles, 24 to 107 months of age and weighing 9.9 to 18.3 kg.

Experimental Design: On Day -2, under local and general anesthesia, each dog received a 2 cm surgical wound on the neck. On Day -1, the wounds were infested with approximately 50 *C. hominivorax* first instar larvae. On Day 0, dogs were allocated into two groups and either treated with Simparica TRIO® (at the minimum labeled dose of 1.2 mg/kg sarolaner) or food pellets (control). The study was divided into three batches, each consisting of four dogs (two dogs from each treatment group).

Drug Administration: Drug administration was on Day 0. Dogs were fasted for at least 12 hours before treatment and remained without food for approximately 3 additional hours after treatment. Dogs in the treated group received a combination of tablets to deliver a sarolaner dose as close to 1.2 mg/kg, without underdosing. The sarolaner doses ranged from 1.2 to 1.4 mg/kg. Dogs in the control group underwent the same procedures but were offered a food pellet.

Measurements and Observations: On Day 0, every 15 minutes for the first hour, every hour at 2 through 6 hours, and at 12 and 24 hours after treatment, *C. hominivorax* larvae expelled from the wound into the cage trays were counted, categorized as live or dead, and classified according to instar. On Day 1 (24 hours post-treatment), dogs were anesthetized and the remaining *C. hominivorax* larvae were manually recovered from the wound, counted, categorized as live or dead, and classified according to instar. The wounds were cleaned and treated with an antibiotic ointment.

Statistical Method: Effectiveness was determined based on the percent reduction in live, recovered *C. hominivorax* larvae counts on Day 1 in the Simparica TRIO® group compared to the control group.

Percent Effectiveness = 100 x (cc - ct)/cc

Where cc = Arithmetic mean of live, recovered larvae counts in the control group and

ct = Arithmetic mean of live, recovered larvae counts in the Simparica TRIO® group

Result(s):

1. Expelled Live and Dead Larvae Counts:
   Overall, the dogs in the control group expelled fewer live and dead larvae than the dogs in the treated group during the 24-hour study. All of the expelled larvae (both live and dead) from the Simparica TRIO® group were second instar larvae. Expelled larvae (both live and dead) from the control group were second or third instar larvae.

Table II.1: Expelled Live and Dead Mean Larval Counts

Treatment Group	Arithmetic Mean Live Larval Count	Arithmetic Mean Dead Larval Count
Control	2.5	0.33
Simparica TRIO®	12.2	1.8

2. Recovered Larvae on Day 1:
   All 6 control dogs and 3 out of 6 treated dogs had recovered larvae on Day 1. In the control group, no dead larvae were recovered and the number of live, recovered larvae ranged from 6 to 54 (arithmetic mean = 30.7). In the treated group, no live larvae were recovered and the number of dead, recovered larvae ranged from 0 to 13 (arithmetic mean = 2.5). The percent effectiveness of Simparica TRIO®, based on the absence of live, recovered larval counts on Day 1, compared to the control group, was 100%.

   All recovered larvae in the control group were third instar. In the treated group, all recovered larvae were second instar except for one (dead) third-instar larva.

3. Additional Parameters:
   The larval expulsion rate (number of live and dead expelled larvae/total number of larvae (expelled and recovered) x 100) and average larvicidal effectiveness (number of dead (expelled and removed) larvae/total number of larvae (expelled and recovered)) were both higher in treated dogs compared to control dogs.

Table II.2: Larval Expulsion Rate and Larvicidal Effectiveness

Treatment Group	Larval Explusion Rate (% (range))	Larvicidal Effectiveness (% (range))
Control	8.5% (0-16.7%)	1.0% (0-16.7%)
Simparica TRIO®	84.8% (38.1-100%)	26.3% (3.3-61.8%)

Adverse Reactions: One treated dog vomited food 3 hours after Simparica TRIO® administration.

Conclusions: The results of the study demonstrate that Simparica TRIO® may be effective for the treatment of infestations caused by New World screwworm (*C. hominivorax*) larvae (myiasis) in dogs and puppies. The primary mechanism of action against *C. hominivorax* appears to be live larval expulsion. Vomiting should be considered a drug-related adverse reaction.

III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this authorization. The FOI Summary for the original approval of NADA 141-521, dated February 27, 2020, contains a summary of target animal safety studies for dogs. The safety of Simparica TRIO® has not been evaluated in dogs less than 8 weeks of age or less than 2.8 lbs. It is reasonable to believe that the known and potential benefits of Simparica TRIO® outweigh the known and potential risks for dogs of all ages and weights because NWS is potentially fatal in dogs if left untreated, therefore justifying including dogs less than 8 weeks of age or less than 2.8 lbs. in this authorization.

IV. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for this authorization.

V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to Simparica TRIO®:

Not for use in humans. Keep this and all drugs out of reach of children.

VI. AGENCY CONCLUSIONS

Based on the totality of scientific evidence available to FDA, including data from a laboratory effectiveness study, it is reasonable to believe that Simparica TRIO®, when used as authorized, may be effective for the treatment of NWS larvae (myiasis) in dogs and puppies, and that the known and potential benefits of Simparica TRIO® outweigh the known and potential risks, 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.

There is no adequate, approved,[1] and available alternative to the product for the treatment of NWS larvae (myiasis) in dogs and puppies. 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 larvae (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.

For additional information on all products authorized or conditionally approved for use to treat and/or prevent New World screwworm, please see FDA's "New World Screwworm: Information for Veterinarians" webpage at https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians.

A. Duration of Authorization: Revision and Revocation

This EUA will be effective until revoked under Section 564(g) of the FD&C Act or until the Secretary's declaration of emergency or threat justifying emergency authorized use is terminated (Section 564(f)(1)), with exception for continued use permissible under Section 564(f)(2). FDA may revoke or revise this authorization if emergency use of this animal drug for NWS myiasis is no longer justified, if the product no longer meets the criteria for issuance of an EUA under Section 564(c) of the FD&C Act, or other circumstances make such revocation or revision of the authorization appropriate to protect the public health or safety (Section 564(g)(2) of the FD&C Act).

[1] "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.

B. Marketing Status

This product is authorized to be dispensed only by or on the order of a licensed veterinarian (Rx marketing status).