

This Order takes effect at 5:00 p.m. Eastern Daylight Time on Sunday, October 11, 2026. For individuals intending to travel to the United States by air, the Order will apply to flights departing after 4:59 p.m. Eastern Daylight Time on Sunday, October 11, 2026.

\* \* \* \* \*

In testimony whereof, the Assistant Secretary for Health, U.S. Department of Health and Human Services, has hereunto set his hand at Washington, DC this 9th day of October, 2026.

Dated:

Admiral Brian Christine, MD,  
*Assistant Secretary for Health (ASH) and  
 Head of the United States Public Health  
 Service (USPHS) Commissioned Corps,  
 Department of Health and Human Services.*

## Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data so that the public can provide input that may inform the forthcoming public health risk assessment and whether any subsequent exercise of this authority is necessary.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comment by email.

## Authority

The authority for this order is Sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268), as amended.

**Brian Christine,**

*Admiral, Assistant Secretary for Health (ASH) and Head of the United States Public Health Service (USPHS) Commissioned Corps,  
 Department of Health and Human Services.*

[FR Doc. 2026-21036 Filed 10-14-26; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2026-N-0004]

### Authorization of Emergency Use for Four Animal Drugs for the Prevention and Treatment of New World Screwworm; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the issuance of four Emergency Use Authorizations (EUA or Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for new animal products. FDA has issued one EUA for an animal product as requested by Elanco US Inc. for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*; NWS) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn. FDA has issued one EUA for an animal product as requested by Zoetis Inc. for the treatment of infestations caused by NWS (myiasis) in dogs and puppies. FDA has issued one EUA for an animal product as requested by Bimeda Animal Health Ltd. for the prevention of infestations caused by NWS (myiasis) in cattle. FDA has issued one EUA for an animal product as requested by Sergeant's Pet Care Products LLC for the treatment and prevention of infestations caused by NWS (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older. The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the August 18, 2025, determination by the Secretary of Health and Human Services (HHS) 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 U.S. citizens living abroad and that involves NWS. On the basis of such determination, the Secretary of HHS declared on August 18, 2025, that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

**DATES:** The Authorizations are effective on their dates of issuance: August 7, 2026, August 13, 2026, August 27, 2026, and September 3, 2026, respectively.

**ADDRESSES:** Submit written requests for single copies of the EUAs to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

### FOR FURTHER INFORMATION CONTACT:

Crystal Groesbeck, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240-402-0819, [Crystal.Groesbeck@fda.hhs.gov](mailto:Crystal.Groesbeck@fda.hhs.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

#### II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents (CBRN); (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (i) a CBRN; or (ii) an agent or agents that may cause, or are otherwise associated with, an

imminently life-threatening and specific risk to U.S. military forces;<sup>1</sup> (C) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents; or (D) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on FDA's website. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

Under section 564(c) of the FD&C Act, FDA may issue an EUA only if, after

consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA<sup>2</sup> concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

### III. The Authorizations

The Authorizations follow the August 18, 2025, determination by the Secretary of HHS 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 U.S. citizens living abroad

<sup>1</sup> In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine, within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration (see section 564(b)(6) of the FD&C Act).

<sup>2</sup> The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

and that involves NWS. On the basis of such determination, the Secretary of HHS declared, on August 18, 2025, that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals. Notice of the Secretary's determination and declaration was provided in the **Federal Register** on August 20, 2025 (90 FR 40609). Having concluded that the criteria for the issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has issued four authorizations for the emergency use of animal products. On August 7, 2026, FDA issued an EUA to Elanco US Inc. for the animal product CLiK Extra (dicyclanil topical suspension) wound spray, subject to the terms of its Authorization. On August 13, 2026, FDA issued an EUA to Zoetis Inc. for the animal product Simparica TRIO (sarolaner, moxidectin, and pyrantel chewable tablets), subject to the terms of its Authorization. On August 27, 2026, FDA issued an EUA to Bimeda Animal Health Ltd. for the animal product Bimectin (ivermectin) injection, subject to the terms of its Authorization. On September 3, 2026, FDA issued an EUA to Sergeant's Pet Care Products LLC for the animal product CAPSTAR (nitenpyram) tablets, subject to the terms of its Authorization.

The initial Authorizations, included below in their entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provide explanations of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuance of the Authorizations can be found on FDA's web page at: <https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians>.

### IV. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

BILLING CODE 4164-01-P



August 07, 2026

Elanco US Inc.  
Attention: Jennifer Schofield, DVM, CPH  
Director, Regulatory  
450 Elanco Circle  
Indianapolis, IN 46221

**Re: Emergency Use Authorization 006723**

Dear Dr. Schofield:

This letter is in response to the request by Elanco US Inc. (Elanco) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of CLiK Extra (dicyclanil topical suspension) wound spray<sup>1</sup> for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured<sup>2</sup> wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, 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.<sup>3</sup>

CLiK Extra is a topical insect growth regulator. CLiK Extra is not FDA-approved for any indication.

Based on the totality of scientific evidence available to the FDA, including data from foreign approvals, dose determination studies, a margin of safety study, and scientific literature, it is reasonable to believe that CLiK Extra (dicyclanil topical suspension) wound spray may be effective for application on or around wounds for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, as described in this authorization, and when used under the conditions

<sup>1</sup> 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.

<sup>2</sup> Definitions for "captive wildlife" and "captured wildlife" can be found in the last section of the USDA APHIS New World Screwworm Response Playbook, accessible at <https://www.aphis.usda.gov/animal-emergencies/nws>

<sup>3</sup> 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>

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described in this authorization, the known and potential benefits of CLiK Extra 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 CLiK Extra for application on or around wounds for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, 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 CLiK Extra for application on or around wounds for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, 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 CLiK Extra may be effective in preventing NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of CLiK Extra when used to prevent NWS outweigh the known and potential risks of such product; and
3. There is no adequate, approved,<sup>4</sup> and available alternative to the emergency use of CLiK Extra for application on or around wounds for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn.<sup>5</sup>

## II. Scope of Authorization

<sup>4</sup> "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. There are no approved products to treat or prevent NWS in sheep, goats, swine, camelids, cervids, American bison, bighorn sheep, and Sonoran pronghorn. Although there are conditionally approved products for the prevention and treatment of NWS in cattle, CLiK Extra provides an important option for preventing NWS in cattle because it offers a different drug class for topical application. Cattle are at particular risk of infestation by NWS, and a diverse and sufficient supply of products is needed to adequately address an incursion in the United States.

<sup>5</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

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

- CLiK Extra, as covered by this authorization, will be used only for over the counter use for application on or around wounds for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn; and
- The use of CLiK Extra covered by this authorization must be in accordance with the authorized Fact Sheet.

#### Product Description

CLiK Extra is a topical insect growth regulator. It contains dicyclanil at a concentration of 65 mg/mL. The authorized CLiK Extra bottle label is clearly marked for NWS under Emergency Use Authorization with a website address and QR code that links to the authorized Fact Sheet.

Store at or below 86°F (30°C). Do not freeze. Protect from light. Store in original container tightly closed in a dry, cool place.

CLiK Extra 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 CLiK Extra (dicyclanil topical suspension) Wound Spray 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 CLiK Extra, when used for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, 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 CLiK Extra may be effective for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, 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 CLiK Extra,

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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, CLiK Extra is authorized for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, 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. Elanco will ensure that the authorized CLiK Extra, accompanied with the authorized Fact Sheet, is distributed to authorized distributor(s)<sup>6</sup> 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. Elanco 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. Elanco and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.
- D. Elanco 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 Sheet).
- E. Elanco may request changes to this authorization, including to the authorized Fact Sheet for CLiK Extra. Requests for changes must be submitted to the Office of New

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<sup>6</sup> 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 Elanco places limits on distribution in writing (e.g., via contract or written notice accompanying the product).

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Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.<sup>7</sup>

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

Elanco will report to FDA all product/manufacturing defects<sup>8</sup> within 3 days, all serious adverse events<sup>9</sup> and medication errors<sup>10</sup> associated with the use of the authorized CLiK Extra that are reported to Elanco within 15 days, and all non-serious adverse drug events within 90 days. Submit the reports electronically using either of the following options which are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage ([www.fda.gov/IndustryReportAnimalAE](http://www.fda.gov/IndustryReportAnimalAE)).

Option 1: Submit reports through the Safety Reporting Portal (SRP).

Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG).

Submitted reports must state in the "Narrative of Adverse Event" field: "CLiK Extra use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at [CVMAESupport@fda.hhs.gov](mailto: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, Elanco and authorized distributor(s) will maintain records regarding distribution of the authorized CLiK Extra (i.e., lot numbers, quantity, receiving site, receipt date).**

**H. Elanco 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.**

<sup>7</sup> Changes that do not necessitate revision to this letter (e.g., changes to the Fact Sheet(s); changes related to current good manufacturing practice requirements, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

<sup>8</sup> Product defect/manufacturing defect is the deviation of a distributed product from the standards specified in the approved application, or any significant chemical, physical, or other change, or deterioration in the distributed drug product, including any microbial or chemical contamination. A manufacturing defect is a product defect caused or aggravated by a manufacturing or related process. A manufacturing defect may occur from a single event or from deficiencies inherent to the manufacturing process. These defects are generally associated with product contamination, product deterioration, manufacturing error, defective packaging, damage from disaster, or labeling error. For example, a labeling error may include any incident that causes a distributed product to be mistaken for, or its labeling applied to, another product.

<sup>9</sup> Serious adverse event is an adverse event that is fatal, or life-threatening, or requires professional intervention, or causes an abortion, or stillbirth, or infertility, or congenital anomaly, or prolonged or permanent disability, or disfigurement.

<sup>10</sup> Medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

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- I. Elanco and any person engaged in manufacturing, packing, or holding will comply with all FD&C Act requirements for animal drugs, including, but not limited to, registration and listing and drug quality requirements (e.g., current good manufacturing practice requirements)<sup>11</sup> unless such requirements are specifically waived or modified in this authorization. Sponsor and any person engaged in manufacturing, packing, or holding shall only manufacture CLiK Extra using the processes, facilities, controls, and equipment specified in the file for this EUA request at the time of authorization, and no changes may be implemented until accepted by FDA.<sup>12</sup>

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 CLiK Extra, shall be consistent with the authorized Fact Sheet<sup>13</sup> 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. Elanco and authorized distributor(s) may not imply that CLiK Extra is FDA approved, conditionally approved, or indexed for the authorized use. Elanco and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of CLiK Extra 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.
- L. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of CLiK Extra shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:
- CLiK Extra has not been approved for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn;

<sup>11</sup> Among other requirements, all expiration dates shall be established in accordance with 21 CFR 211.137.

<sup>12</sup> Any request submitted via an update to the file is considered accepted after 30 calendar days unless FDA provides notice to the contrary.

<sup>13</sup> 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.

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- CLiK Extra has been authorized by FDA under an EUA for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn; and
- CLiK Extra is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of CLiK Extra 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 your Type VII Veterinary Master File as a G submission at the time of initial dissemination (publication or broadcast). When submitting, identify the submission as promotion and advertising material.

If FDA notifies Elanco or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Elanco 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 Elanco 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

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903  
[www.fda.gov](http://www.fda.gov)



**FDA U.S. FOOD & DRUG  
ADMINISTRATION**

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)<sup>1</sup> 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.<sup>2</sup>

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,

<sup>1</sup> 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.

<sup>2</sup> 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>

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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,<sup>3,4</sup> and available alternative to the emergency use of Simparica TRIO for the treatment of NWS myiasis in dogs and puppies.<sup>5</sup>

<sup>3</sup> "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.

<sup>4</sup> 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.

<sup>5</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

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## 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.

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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<sup>6</sup> and veterinarians, or authorized distributor(s),<sup>7</sup> 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.<sup>8</sup>

<sup>6</sup> 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.

<sup>7</sup> 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).

<sup>8</sup> 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.

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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](http://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](mailto: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,<sup>9</sup> 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.

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<sup>9</sup> Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.

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- 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<sup>10</sup> 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:

<sup>10</sup> 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.

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- 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

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903  
[www.fda.gov](http://www.fda.gov)



**FDA U.S. FOOD & DRUG  
ADMINISTRATION**

August 27, 2026

Bimeda Inc.  
Attention: Stephanie Batliner  
VP R&D and Regulatory Affairs North America  
U.S. Agent for Bimeda Animal Health Ltd.  
1B The Herbert Building, The Park  
Carrickmines, Dublin 18  
Ireland

**Re: Emergency Use Authorization 006729**

Dear Ms. Batliner:

This letter is in response to the request on behalf of Bimeda Animal Health Ltd. (Bimeda) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of Bimectin (ivermectin) injection<sup>1</sup> for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal,<sup>2</sup> 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.<sup>3</sup>

Bimectin (ivermectin) injection is an antiparasitic drug that is indicated under ANADA 200-447 for the treatment and control of a variety of internal and external parasites in cattle, swine, reindeer, and American bison. Bimectin injection is not approved for the prevention of NWS myiasis.

Based on the totality of scientific evidence available to the FDA, including summaries of data

<sup>1</sup> Bimectin (ivermectin) injection is also distributed by Aspen Veterinary Resources, LTD; Durvet, Inc.; and MWI under the proprietary names IVERMAX, Ivermectin, and Vetrimec 1%, respectively. All references to Bimectin in this letter include each of the drugs sold under the aforementioned proprietary names. This authorization is limited to Bimectin, IVERMAX, Ivermectin, and Vetrimec 1%. Except those previously named, any other products sold under separate distributor's labeling per 21 CFR 514.80(b)(5)(iii) are not subject to this EUA. A request must be made to change the scope of this authorization for any additional products.

<sup>2</sup> Hereinafter, "cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal" will be referred to as "certain cattle".

<sup>3</sup> 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>

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from studies performed on ivermectin injection, it is reasonable to believe that Bimectin (ivermectin) injection may be effective for the prevention of NWS myiasis in certain cattle, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Bimectin injection 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 Bimectin injection for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal, 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 Bimectin injection for the prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle, 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 Bimectin injection may be effective in preventing NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of Bimectin injection when used to prevent NWS outweigh the known and potential risks of such product; and
3. There is no adequate, approved,<sup>4</sup> and available alternative<sup>5</sup> to the emergency use of Bimectin injection for the prevention of infestations caused by NWS larvae (myiasis)

<sup>4</sup> "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.

<sup>5</sup> While there are therapeutics conditionally approved for prevention of infestations caused by NWS larvae (myiasis) in cattle, they are not considered adequate and available alternatives for the purpose of this analysis. The existing conditionally approved injectable product is not an available alternative because there are insufficient quantities to meet the demands of a widescale incursion of NWS into the United States. The conditionally approved topical product is not an adequate alternative because it is a different pharmacological class with a different route of administration, and its label restricts use to cattle two months of age and older. Furthermore, because this topical product requires a prescription, it is not a readily available alternative, as the requirement for veterinary intervention could delay administration. There is a significant benefit to expedient administration of a preventative product, particularly if animals nearby are infested. Thus, FDA concluded that this additional over-the-counter injectable macrocyclic lactone product indicated for prevention of NWS in cattle is needed to meet the demands of a widescale incursion of NWS into the United States.

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when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle.<sup>6</sup>

## 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:

- Bimectin injection, as covered by this authorization, will be dispensed over the counter and used only for subcutaneous administration within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle; and
- The use of Bimectin injection covered by this authorization must be in accordance with the authorized Fact Sheet.

## Product Description

Bimectin injection is derived from the avermectins, a family of broad-spectrum antiparasitic agents. The authorized Bimectin injection labeling (vial labels, carton labeling, and package insert) 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 20°C to 25°C (68°F to 77°F). Protect product from light.

Bimectin injection 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 Bimectin (ivermectin) Injection for New World Screwworm (NWS)<sup>7</sup>

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 Bimectin injection, when used for the prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle 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 Bimectin injection may be effective for the prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

<sup>6</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

<sup>7</sup> IVERMAX, Ivermectin, and Vetrimec 1% will be accompanied by the IVERMAX Fact Sheet, Ivermectin Fact Sheet, and Vetrimec 1% Fact Sheet, respectively. Hereinafter, when we refer to the Bimectin Fact Sheet we are including all four Fact Sheets which differ only in the product name and distributor.

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Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Bimectin injection, 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, Bimectin injection is authorized for the prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle 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. Bimeda will ensure that the authorized Bimectin injection, accompanied with the authorized Fact Sheet, is distributed to authorized distributor(s)<sup>8</sup> 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. Bimeda 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. Bimeda and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.
- D. Bimeda 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 Sheet).
- E. Bimeda may request changes to this authorization, including to the authorized Fact Sheet for Bimectin injection. Requests for changes must be submitted to the Office of Generic Animal Drugs. Such changes require appropriate authorization prior to implementation.<sup>9</sup>

<sup>8</sup> 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 Bimeda places limits on distribution in writing (e.g., via contract or written notice accompanying the product).

<sup>9</sup> Changes that do not necessitate revision to this letter (e.g., changes to the Fact Sheet(s), changes related to current good manufacturing practice requirements, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

Bimeda Animal Health Ltd.

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

Bimeda will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Bimeda will attempt to determine whether the use of Bimectin injection 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. Bimeda 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](http://www.fda.gov/IndustryReportAnimalAE)).

Submitted reports must state in the "Narrative of Adverse Event" field: "Bimectin injection use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at [CVMAESupport@fda.hhs.gov](mailto: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, Bimeda and authorized distributor(s) will maintain records regarding distribution of the authorized Bimectin injection (i.e., lot numbers, quantity, receiving site, receipt date).
- H. Bimeda 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. Bimeda (and any other person engaged in manufacturing, packing, or holding) will comply with all other FD&C Act requirements applicable to the approved product, Bimectin injection, 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,<sup>10</sup> unless such requirements are specifically waived or modified in this authorization. Bimeda, 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 Bimectin injection, shall be consistent with the authorized Fact Sheet<sup>11</sup> and the terms set forth in this EUA, as well as

<sup>10</sup> Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.

<sup>11</sup> 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.

Bimeda Animal Health Ltd.  
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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. Bimeda and authorized distributor(s) may not imply that Bimectin injection is FDA approved, conditionally approved, or indexed for the authorized use. Bimeda and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Bimectin injection 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.
- L. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of Bimectin injection shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:
- Bimectin injection has not been approved for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle;
  - Bimectin injection has been authorized by FDA under an EUA for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle; and
  - Bimectin injection is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Bimectin injection 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 Bimeda or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Bimeda 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 Bimeda or authorized distributor(s) to issue corrective communication(s).

Bimeda Animal Health Ltd.

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**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



**FDA U.S. FOOD & DRUG  
ADMINISTRATION**

September 3, 2026

Sergeant's Pet Care Products LLC  
Attention: Teri Gasper  
Regulatory Affairs Manager, OTC Drugs  
10077 S. 134th St.  
Omaha, NE 68138

**Re: Emergency Use Authorization 006688**

Dear Ms. Gasper:

This letter is in response to the request by Sergeant's Pet Care Products LLC (Sergeant's) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of CAPSTAR (nitenpyram) tablets<sup>1</sup> 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, 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.<sup>2</sup>

CAPSTAR is an oral antiparasitic that is indicated under NADA 141-175 to kill adult fleas and is 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. CAPSTAR is not approved for the treatment and prevention of NWS myiasis.

Based on the totality of scientific evidence available to the FDA, including data from published literature, it is reasonable to believe that CAPSTAR (nitenpyram) tablets may be effective for the treatment and prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of CAPSTAR outweigh the known and

<sup>1</sup> 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.

<sup>2</sup> 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>

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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 CAPSTAR for the treatment and prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, 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 CASTAR for the treatment and prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, 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 CAPSTAR may be effective in treating and preventing NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of CAPSTAR when used to treat and prevent NWS outweigh the known and potential risks of such product; and
3. There is no adequate, approved,<sup>3</sup> and available alternative<sup>4</sup> to the emergency use of CAPSTAR for the treatment and prevention of infestations caused by NWS (*Cochliomyia*

<sup>3</sup> "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.

<sup>4</sup> There are no approved alternatives for the treatment and prevention of NWS myiasis in cats and kittens.

There are no approved alternatives for the treatment and prevention of NWS myiasis in dogs and puppies between 4 and 8 weeks of age or weighing between 2 and 3.3 pounds because the conditionally approved product is indicated for the treatment of NWS in dogs and puppies at least 8 weeks of age and weighing at least 3.3 pounds.

Additionally, there are no adequate approved over the counter (OTC) products for dogs and puppies, and OTC marketing will allow the product to be available in circumstances where access to a veterinarian is limited.

Furthermore, there are no approved products with a single active ingredient for the treatment and prevention of NWS myiasis in dogs and puppies; CAPSTAR contains a single active pharmaceutical ingredient, whereas the conditionally approved product contains multiple active ingredients. The presence of multiple active ingredients in the conditionally approved product may increase the likelihood of adverse events in dogs and puppies that have recently been treated with a heartworm preventative or other antiparasitic drug in the same pharmacological class as one of the conditionally approved product's active ingredients. Because CAPSTAR contains only a single active ingredient that is not in that drug class, its use may minimize the potential for adverse events in these dogs.

Lastly, CAPSTAR acts through a mechanism of action that is distinct from each of the active ingredients in the conditionally approved product. Because no approved alternative product works through the same mechanism of action as CAPSTAR, the conditionally approved product is not an adequate therapeutic substitute in circumstances where the CAPSTAR distinct mechanism of action is clinically relevant.

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*hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older.<sup>5</sup>

## 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:

- CAPSTAR, as covered by this authorization, will be used only for over the counter use in dogs and cats 2 pounds of body weight or greater and 4 weeks of age and older; and
- The use of CAPSTAR covered by this authorization must be in accordance with the authorized Fact Sheet.

## Product Description

CAPSTAR is an oral tablet for dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older. CAPSTAR (nitenpyram) tablets belongs to the chemical class of neonicotinoids and kills adult fleas. The authorized CAPSTAR 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 controlled room temperature, between 59° and 77°F (15°-25°C).

CAPSTAR 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 Capstar (nitenpyram) 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 CAPSTAR, when used for the treatment and prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older 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 CAPSTAR may be effective for the treatment and prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

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<sup>5</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

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Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that CAPSTAR, 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, CAPSTAR is authorized for the treatment and prevention of infestations caused by NVWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older 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. Sergeant's will ensure that the authorized CAPSTAR, accompanied with the authorized Fact Sheet, is distributed to authorized distributor(s)<sup>6</sup> 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. Sergeant's will ensure that if a sticker is used on the labeling, that 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. Sergeant's and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.
- D. Sergeant's 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 Sheet).
- E. Sergeant's may request changes to this authorization, including to the authorized Fact Sheet for CAPSTAR. Requests for changes must be submitted to the Office of New Animal

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<sup>6</sup> The term "distributors" includes all parties in the supply chain between the recipient of this authorization letter and the end user. "Authorized distributors" are all distributors who otherwise lawfully obtain and distribute the product, unless Sergeant's places limits on distribution in writing (e.g., via contract or written notice accompanying the product).

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Product Evaluation. Such changes require appropriate authorization prior to implementation.<sup>7</sup>

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

Sergeant's will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Sergeant's will attempt to determine whether the use of CAPSTAR 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. Sergeant's 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](http://www.fda.gov/IndustryReportAnimalAE)).

Submitted reports should state in the "Narrative of Adverse Event" field: "CAPSTAR use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at [CVMAESupport@fda.hhs.gov](mailto: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, Sergeant's and authorized distributor(s) will maintain records regarding distribution of the authorized CAPSTAR (i.e., lot numbers, quantity, receiving site, receipt date).

H. Sergeant's 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. Sergeant's (and any other person engaged in manufacturing, packing, or holding) will comply with all other FD&C Act requirements applicable to the approved product, CAPSTAR, 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,<sup>8</sup> unless such requirements are specifically waived or modified in this authorization. Sergeant's, and authorized distributors 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.

<sup>7</sup> Changes that do not necessitate revision to this letter (e.g., changes to the Fact Sheet(s), changes related to current good manufacturing practice requirements, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

<sup>8</sup> Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.

Sergeant's Pet Care Products LLC

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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 CAPSTAR, shall be consistent with the authorized Fact Sheet<sup>9</sup> 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. Sergeant's and authorized distributor(s) may not imply that CAPSTAR is FDA approved, conditionally approved, or indexed for the authorized use. Sergeant's and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of CAPSTAR 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.
- L. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of CAPSTAR shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:
- CAPSTAR has not been approved for the treatment and prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older;
  - CAPSTAR has been authorized by FDA under an EUA for the treatment and prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older; and
  - CAPSTAR is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of CAPSTAR 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.

<sup>9</sup> 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.

Sergeant's Pet Care Products LLC  
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If FDA notifies Sergeant's or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Sergeant's 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 Sergeant's 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

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903  
[www.fda.gov](http://www.fda.gov)

**Grace R. Graham,**  
*Deputy Commissioner for Policy, Legislation,  
and International Affairs.*

[FR Doc. 2026-21084 Filed 10-14-26; 8:45 am]

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