

April 27, 2026

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

Re: Emergency Use Authorization 006653

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 Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder),¹ hereinafter referred to as “Negasunt”, for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

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

Negasunt is a topical ectoparasiticide and antimicrobial. Negasunt is not FDA-approved for any indication.

Based on the totality of scientific evidence available to the FDA, including information from foreign studies and other information submitted in support of this EUA and publicly available information, it is reasonable to believe that Negasunt may be effective for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Negasunt outweigh the known and potential risks of such

¹ Unless specified by name, products sold under separate distributor’s labeling per 21 CFR 514.80(b)(5)(iii) (i.e., with a different proprietary name) are not subject to this EUA. A request must be made to change to the scope of this authorization for such products.

² See U.S. Department of Health and Human Services, Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm, August 20, 2025:
<https://www.federalregister.gov/documents/2025/08/20/2025-15918/declaration-of-emergency-pursuant-to-the-federal-food-drug-and-cosmetic-act-for-new-world-screwworm>

product. Additionally, it was concluded that residues in food products derived from cattle, swine, goats, sheep, and captive wild and exotic food-producing mammals treated with Negasunt will not represent a public health concern when the product is used as authorized.

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 Negasunt for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals, 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 Negasunt for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals, 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 Negasunt may be effective in preventing or treating NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of Negasunt when used to prevent or treat NWS outweigh the known and potential risks of such product; and
3. There is no adequate, approved,³ and available alternative⁴ to the emergency use of Negasunt for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals.⁵

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

⁴ There are no approved products for swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals. Although there are conditionally approved products for the prevention and treatment of NWS in cattle, Negasunt provides an important option for treating and preventing NWS in cattle because it offers an alternative route of administration and dosage form as a topical powder applied to wounds. Cattle and other hoof stock are at particular risk of infestation by NWS, and a wide diversity and sufficient supply of products are needed to adequately address an NWS incursion in the United States.

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

II. Scope of Authorization

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

- Negasunt, as covered by this authorization, is limited to the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals;⁶ and
- The use of Negasunt covered by this authorization is limited to:
 - employees of federal, state, local, and federally recognized tribal agencies, and persons working under their authority and at their direction (hereinafter “agencies”); or
 - by or on the order of a licensed veterinarian in NWS infested zones and adjacent surveillance zones as defined by USDA;⁷ and
- The use of Negasunt covered by this authorization must be in accordance with the enclosed authorized Fact Sheet.

Product Description

Negasunt is a dry, fine, blue powder that contains 3% coumaphos, 2% propoxur, and 5% sulfanilamide. The authorized Negasunt 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 25°C (77°F), excursions permitted to 40°C (104°F). Protect from light. Do not freeze.

Negasunt 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 specified in this EUA.

- Fact Sheet: Emergency Use Authorization of Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder) 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 Negasunt, when used for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals and used in accordance with this authorization, outweigh its known and potential risks.

⁶ A milk discard time has not been established for this product; do not use in animals producing milk for human consumption. A withdrawal period has not been established for this product in pre-ruminating calves; treated calves and calves born to treated cows must not be processed for veal.

⁷ Zone descriptions can be found in the USDA APHIS New World Screwworm Response Playbook, Key Activity 02: Reduce Spread to Non-Infested Animals and Prevent NWS from Establishing in New Areas accessible at <https://www.aphis.usda.gov/animal-emergencies/nws>

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 Negasunt may be effective for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals 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 Negasunt, 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, Negasunt is authorized for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals 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. In a manner consistent with this EUA, Elanco and authorized distributors will ensure that Negasunt, accompanied by the authorized Fact Sheet, is only distributed to:
 1. authorized distributor(s);⁸
 2. federal, state, local, and tribal agencies; and
 3. veterinary facilities⁹ and veterinarians licensed
 - a. in U.S. states which contain or have contained NWS infested zones (as defined by USDA);
 - b. in U.S. states bordering such states; or
 - c. in U.S. states immediately adjacent to Mexico.

⁸ 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). The term "authorized distributors" includes federal, state, local, and tribal agencies only if they further distribute the product to other authorized distributors, other agencies, veterinarians or veterinary facilities, any of whom are not operating under their authority.

⁹ 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.

- B. Elanco will ensure that if a sticker is used on the container, that the sticker contains a website address and QR code that link to the authorized Fact Sheet, and that any existing labeling (e.g., foreign market labeling, including primary and secondary packaging labeling) is removed or totally obscured to the extent any content does not entirely conform with terms of this EUA. Elanco will ensure the labeling meets all the requirements of FD&C Act Section 502 (excluding 502(f)), Section 503, and 21 CFR Part 201 and that all relabeling operations are conducted in accordance with current good manufacturing practice (CGMP) requirements.
- C. Elanco and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to agencies, veterinary facilities, and veterinarians.
- D. Elanco and authorized distributor(s) will ensure that the terms and conditions of this EUA are made available to all agencies, authorized distributors, veterinary facilities, and veterinarians involved in distributing or receiving authorized Negasunt. Elanco 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. Elanco may request changes to this authorization, including to the authorized Fact Sheet for Negasunt. Requests for changes must be submitted to the Office of New Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.¹⁰
- F. Reporting Adverse Drug Experiences and Product/Manufacturing Defects:

Elanco will report to FDA all product/manufacturing defects¹¹ within 3 days, all serious adverse events¹² and medication errors¹³ associated with the use of the authorized Negasunt 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).

¹⁰ Changes that do not necessitate revision to this letter (e.g., changes to the Fact Sheet, changes related to CGMP requirements, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

¹¹ 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.

¹² 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.

¹³ 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.

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

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

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

- G. Through a process of inventory control, Elanco and authorized distributor(s) will maintain records regarding distribution of the authorized Negasunt (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 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. 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)¹⁴ unless such requirements are specifically waived or modified in this authorization. Elanco and any person engaged in manufacturing, packing, or holding shall only manufacture Negasunt 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.¹⁵

Conditions of Authorization for Agencies, Veterinary Facilities, and Veterinarians that administer, dispense, or prescribe Negasunt

- J. Agencies, 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 agency employees and persons working under their authority and at their direction and veterinarians. Agencies, veterinary facilities, and veterinarians will ensure that the client (including animal owner or caretaker) is aware that the drug is authorized for emergency use, but not approved, for the prevention and treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.
- K. Agencies, veterinary facilities, and veterinarians receiving Negasunt will track serious adverse events in humans or animals potentially related to Negasunt use under this EUA and must report these to FDA or Elanco in accordance with the Fact Sheet. Report by (1) contacting Elanco US at 1-888-545-5973, (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 “Negasunt use for NWS under an EUA” under

¹⁴ Among other requirements, all expiration dates shall be established in accordance with 21 CFR 211.137.

¹⁵ Any request submitted via an update to the file is considered accepted after 30 calendar days unless FDA provides notice to the contrary.

the “Describe Adverse Event/Product Problem/Product Use Error” heading, followed by a detailed account of the adverse event.

- L. Agencies and veterinary facilities will maintain health records for the authorized use in this Letter of Authorization that include the following information: person administering or applying the product, client name (including animal owner or caretaker), patient identification (individual animal identification or group identification as appropriate),¹⁶ species and breed, patient age or age range, disease manifestation or clinical signs, number of doses prescribed or administered per patient or group, lot number of the product prescribed or administered, and other drugs coadministered. The records shall be maintained in a manner that allows agencies and veterinary facilities to identify in a reasonable time which patients or group of animals received drugs subject to this EUA.
- M. Agencies and veterinary facilities will ensure that any records associated with this EUA are maintained 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 Elanco, 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 Negasunt shall be consistent with the authorized Fact Sheet 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, Elanco 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 and take reasonable measures to limit promotion to veterinarians only in states/regions where the product can be distributed to them as specified in this Letter of Authorization.
- O. Elanco and authorized distributor(s) may not imply that Negasunt is FDA approved for the authorized use by making statements such as “Negasunt is safe and effective for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals.” 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 Negasunt that provide accurate descriptions of safety and effectiveness information summarized in the authorized Fact Sheet, including user safety and warning information. Such materials must include any limitations of the results and information.
- P. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of Negasunt shall be accompanied by the authorized Fact Sheet and shall clearly and conspicuously state that:
- Negasunt has not been approved by FDA for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae

¹⁶ This may be captured as it relates to a herd if administered to a group of animals.

(myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals;

- Negasunt has been authorized by FDA under an EUA for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals;
- Negasunt is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Negasunt 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; and
- Negasunt's distribution is limited as defined in Condition A and use by state licensed veterinarians has additional geographical limitations as described in the Scope of Authorization (Section II).

Q. Elanco will submit all advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter to the 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 the FDA notifies Elanco or authorized distributors that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Elanco or authorized distributors 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 distributors 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