Fact Sheet: Emergency Use Authorization of Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder) for New World Screwworm (NWS)

Emergency Use Authorization Spanish translation: http://negasunt-nws.com/Spanish
Autorización de Uso de Emergencia traducción al español: http://negasunt-nws.com/Spanish

Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder)
coumaphos 3%, propoxur 2%, sulfanilamide 5%
ectoparasiticide and antimicrobial

WARNING: Neurotoxicity
Read full Fact Sheet for complete information.

- Coumaphos and propoxur can cause neurotoxicity. May be fatal if swallowed. May be fatal if inhaled. Harmful if absorbed through skin. Causes moderate eye irritation. Do not breathe dust. Avoid contact with eyes, skin, or clothing.
- Use only with appropriate personal protective equipment: coveralls worn over long-sleeve shirt and long pants, shoes, socks, and protective eyewear; chemical-resistant gloves made of barrier laminate, butyl rubber (≥ 14 mils), nitrile rubber (≥14 mils), neoprene rubber (>14 mils), natural rubber (≥14 mils), polyethylene, polyvinyl chloride (PVC) (≥14 mils), or Viton (>14 mils); and a minimum of a NIOSH-approved elastomeric half mask respirator consisting of protection factor (PF) 10 fitted with organic vapor (OV) cartridges and combination R or P filters; or a NIOSH-approved gas mask with OV canisters; or a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters.
- This product is toxic to mammals, birds, fish, and aquatic invertebrates.

Original EUA Authorized Date: 04/27/2026

Emergency Use Authorization of Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder) for NWS

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder) 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 Powder is not approved for this use.

For use by employees of federal, state, local, and federally recognized tribal agencies, and persons working under their authority and at their direction. Also for use by or on the order of a licensed veterinarian in NWS infested zones and adjacent surveillance zones as defined by the U.S. Department of Agriculture (USDA).[1]

[1] 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

Limitations of Authorized Use

It is a violation of federal law to use this drug product other than as directed in this authorized Fact Sheet.

Treated animals must not be slaughtered for human consumption within 28 days of the last treatment.

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.

Do not use in horses intended for human consumption.

Do not use in domestic indoor pets (e.g., dogs, cats, rodents, rabbits) nor in residences.

Do not use in birds.

Do not use in free-ranging wildlife.

For use by employees of federal, state, local, and federally recognized tribal agencies, and persons working under their authority and at their direction. Also for use by or on the order of a licensed veterinarian in NWS infested zones and adjacent surveillance zones as defined by USDA.

To avoid overexposure, each individual person cannot treat more than 3 large wounds (>2 inches diameter) a day or more than 30 small superficial wounds (≤2 inches diameter) a day (or an equivalent thereof) with Negasunt Powder or any other coumaphos-containing products.

Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder) is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder) under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

Federal law prohibits the extra-label use of this drug.

Justification for Emergency Use of Drugs During the New World Screwworm Emergency

The Secretary of the U.S. Department of Health and Human Services (HHS) has:

- 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 NWS (*Cochliomyia hominivorax*); and

- declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals.[2]

An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances declared by the Secretary of HHS to justify emergency use authorization, including, among others, a determination that there is a public health emergency or a significant potential for a public health emergency that may affect national security and that involves a biological agent.[3]

Criteria for issuing an EUA include:

- The biological agent(s) can cause a serious or life-threatening disease or condition;
- Based on the totality of available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that:
    - the product may be effective in diagnosing, preventing, or treating the serious or life-threatening disease or condition; and
    - 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; and
- There is no adequate, approved,[4] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[5]

Product Description

Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder) is a blue fine powder. Each gram of Negasunt Powder contains 30 mg coumaphos, 20 mg propoxur, and 50 mg sulfanilamide.

Dosage and Administration

Apply topically to sufficiently cover the open wound. Application every 2 to 3 days may be needed for larger superficial or deep wounds. Apply until granulation tissue has formed and evidence of healing is apparent.

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[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

[3] Emergency Use Authorization of Medical Products and Related Authorities | FDA (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities

[4] "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.

[5] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Information Supporting Emergency Use Authorization

Based on the totality of scientific evidence available to 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 Powder (coumaphos, propoxur, and sulfanilamide topical powder) 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, and when used under the conditions described in this authorization, the known and potential benefits of Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder) outweigh the known and potential risks.

Two effectiveness studies conducted in Brazil in 2010 support treatment and prevention indications against NWS myiasis in cattle. These studies utilized Tambero, a spray formulation containing 3% coumaphos and 2% propoxur, instead of Negasunt Powder, which also includes 5% sulfanilamide and is a powder formulation. Tambero was applied once to animals in the treated groups at a dose of 0.72 grams (equivalent to one spray). Control group animals were untreated. Both studies utilized the same control group (n=6), while each study had its own treated group (n=6).

For both studies, animals were observed daily for four days after larval infestations were applied to surgically created wounds. Wounds were evaluated for the presence/absence of live larvae. 100% efficacy was demonstrated in both studies. In the prevention study, treated animals received Tambero on the wounds and then the wounds were infested with first instar larvae on Day 0. No treated animals were observed with live larvae in wounds for up to four days after surgical incisions were made. In the treatment study, treated animals received Tambero two days after wound infestation with first instar larvae on Day 0. No treated animals were observed with live larvae in wounds 24 hours after Tambero administration. All six control animals were confirmed to have active myiasis. No adverse events were reported during these studies.

Although these two studies utilized a relatively small number of animals, study procedures and data could not be verified, and both studies utilized Tambero, not Negasunt Powder, it is reasonable to believe that based on these studies, Negasunt Powder may be effective in preventing and treating infestations caused by New World screwworm (*C. hominivorax*) larvae (myiasis). It is also reasonable to conclude that the addition of sulfanilamide in Negasunt Powder would not negatively impact the effectiveness of coumaphos and propoxur for the prevention and treatment of myiasis and may contribute to wound healing by mitigating secondary bacterial infections.

Two margin of safety studies conducted in Brazil in 2010 evaluated the safety of Tambero. One study used 40 cattle (20 male, 20 female) aged 12 to18 months, while the other study used 40 horses (20 male, 20 female) aged 3 to 7 years. Both studies followed a randomized design with treatment groups receiving either 0X (control), 1X (1.44 g), 2X (2.88 g), or 3X (4.32 g) doses applied topically once to 5 cm surgical incisions. The studies demonstrated acceptable safety profiles across all dose levels tested. No adverse behavioral changes or local reactions were observed in either species during the study periods. However, similar to the effectiveness studies, these studies had significant deficiencies that limit their extrapolation to the use of Negasunt Powder in the U.S. Tambero was used in the studies, not Negasunt Powder, study procedures and data could not be verified, the investigations did not follow Good Laboratory

Practice standards typically used in safety studies, and critical safety parameters recommended in regulatory guidance were omitted.

Safety information was also taken from several studies conducted to evaluate other aspects of the drug product. The two Brazilian effectiveness studies described above reported no local reactions or adverse events during the experimental period. Similarly, for residue studies performed in Australia and Brazil in 2023, in which Tanidil was applied once to a surgically created wound (1.44 g), and then applied again approximately 48 hours later, it was reported that the cattle did not experience any adverse events.

Additionally, the scientific literature available on the use of Negasunt Powder was evaluated to further inform the target animal safety risk profile. No direct clinical safety data for Negasunt Powder was found but literature review provided anecdotal evidence of successful clinical use in other countries and insight into the toxicity profiles of its individual active ingredients. Risk characterization indicates a low probability of adverse effects given the localized topical application route and short duration of use, though uncertainty exists regarding absorption and cumulative exposure. The scientific evidence combined provides enough information to reasonably conclude that the potential benefits of Negasunt Powder outweigh the known and potential risks.

FDA evaluated relevant human food safety information and concluded that food products obtained from treated animals are safe for human consumption when the conditions of use granted by the EUA are followed, including the withdrawal period listed below.

Contraindications

Sulfonamides are contraindicated in animals that are hypersensitive to them and in animals with severe renal or hepatic impairment.

WARNINGS AND PRECAUTIONS

Withdrawal Periods and Residue Warnings
Treated animals must not be slaughtered for human consumption within 28 days of the last treatment.
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.

User Safety Warnings

Not for use in humans. Keep out of reach of children.

WARNING: May be fatal if swallowed. May be fatal if inhaled. Harmful if absorbed through skin. Causes moderate eye irritation. Do not breathe dust. Avoid contact with eyes, skin, or clothing.

To avoid overexposure, each individual person cannot treat more than 3 large wounds (>2 inches diameter) a day or more than 30 small superficial wounds (≤2 inches diameter) a day (or an equivalent thereof) with Negasunt Powder or any other coumaphos-containing product.

Wear all required personal protective equipment (PPE) when handling and applying this product. Only protected handlers may be in the area during application. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Do not apply in a confined, non-ventilated area. Provide thorough ventilation.

Respirator fit testing, medical qualification, and training
Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is:

- fit-tested and fit-checked,
- trained, and
- examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn.

A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use conditions change. Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements.

Personal Protective Equipment
Applicators and other exposed persons must wear:

- coveralls worn over long-sleeve shirt and long pants,
- shoes and socks,
- protective eyewear,
- chemical-resistant gloves made of barrier laminate, butyl rubber (≥ 14 mils), nitrile rubber (≥14 mils), neoprene rubber (>14 mils), natural rubber (≥14 mils), polyethylene, polyvinyl chloride (PVC) (≥14 mils), or Viton (>14 mils), and
- a minimum of a NIOSH-approved elastomeric half mask respirator consisting of protection factor (PF) 10 fitted with organic vapor (OV) cartridges and combination R or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters.

Remove PPE immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Wash hands thoroughly before eating, drinking, chewing gum, using tobacco, or using the toilet. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other materials heavily contaminated with this product's dust. Do not reuse them.

FIRST AID	
If Swallowed:	• Call a poison control center or doctor immediately for treatment advice. • Have the person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If Inhaled:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15–20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes:	• Hold eye open and rinse slowly and gently with water for 15–20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
Contains an organophosphate that inhibits cholinesterase. Have the product container or label with you when calling a poison control center or doctor or going for treatment. If you need immediate medical attention, call the Poison Control Center at 1-800-222-1222 or a doctor.	

Note To Physician: Atropine sulfate by injection is antidotal. Pralidoxime chloride (2-PAM) is also antidotal and may be administered in conjunction with atropine.

Sulfanilamide, the antibiotic in Negasunt Powder, can cause allergic reactions in sensitized individuals, which can include skin rash, hives, and itching. More severe reactions, while rare, can occur, including anaphylactic reactions, blood dyscrasias, severe cutaneous reactions, gastrointestinal reactions, hepatitis and hepatocellular necrosis, central nervous system (CNS) reactions, and toxic nephrosis. At the first sign of hypersensitivity, skin rash or other reactions, the user should discontinue exposure to Negasunt Powder.

To obtain Safety Data Sheets (SDS), contact Elanco Product & Veterinary Support at 1-800-428-4441 or visit https://www.elanco.com/us/elanco-safety-data-sheets.

Animal Safety Warnings and Precautions

For external use only on animals. Do not apply directly to areas such as waterers, feed troughs, or mangers. Do not contaminate water, feed, troughs, feed handling equipment, or milk or meat handling equipment.

Use with caution in very young, weak, or debilitated animals.

Overuse may increase the risk of adverse events. In the case of overdose, treat with atropine sulfate or 2-PAM as soon as possible.

Environmental Warnings

This product is toxic to mammals, birds, fish, and aquatic invertebrates. Any product that washes from treated animals may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate. Do not discharge into waters or habitats that may contain federally listed threatened or endangered plants and/or animals.

Other Warnings

Do not use in horses intended for human consumption.

Do not use in domestic indoor pets (e.g., dogs, cats, rodents, rabbits) or in residences.

Do not use in birds.

Do not use in free-ranging wildlife.

Federal law prohibits the extra-label use of this drug.

Resistance can develop to any drug used to treat or prevent NWS myiasis. Reports in scientific literature provide evidence of the development of resistance to organophosphates such as coumaphos in *C. hominivorax* populations in South America. When using Negasunt Powder for the treatment or prevention of infestations caused by NWS myiasis, effectiveness should be closely monitored.

Adverse Reactions

Clinical signs in veterinary species associated with organophosphate and carbamate toxicity include frequent urination and defecation, muscle twitching, and watering eyes, followed by salivation, diarrhea, vomiting, and muscle weakness. This can proceed to anorexia, miosis or mydriasis, dyspnea, and bradycardia or tachycardia, and can also include more rapid involuntary muscle twitching and scattered fasciculations, followed by severe weakness and paralysis.

Contact Information

As described in the Letter of Authorization, federal, state, local, and federally recognized tribal agencies, and persons working under their authority and at their direction, veterinary facilities, and veterinarians will track all **SERIOUS ADVERSE EVENTS*** in humans or animals potentially related to Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder) use under this EUA and must report these to FDA using one of these options:

(1) by contacting Elanco US at 1-800-428-4441,

(2) by downloading and submitting Form FDA 1932a as instructed in https://www.fda.gov/reportanimalae, or

(3) by contacting FDA at 1-888-FDA-VETS to request this form.

When reporting adverse events on Form FDA 1932a, include the following elements when applicable and/or available:

- Patient demographics (e.g., age, species and breed, sex, weight)
- Overall health status, number of animals treated, and number affected
- On page 5, under the "**Adverse Event/Product Problem/Product Use Error**" heading, begin the long narrative with the statement: "Negasunt Powder use for NWS under an EUA"
- Information about the serious adverse event (e.g., signs and symptoms, test/laboratory data, timing of drug administration in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping/reducing the dosage, evidence of reappearance after reintroduction, clinical outcomes).
- Patient's pre-existing medical conditions and use of concomitant products
- Information about the product (e.g., dosage, route of administration, lot number)

*Serious adverse events are defined as:

- Death,
- a life-threatening adverse event,
- an event that causes an abortion, stillbirth, or infertility,
- a congenital anomaly or birth defect in offspring of treated animals,
- a prolonged or permanent disability (e.g., persistent or significant incapacity or disruption of normal life functions), or
- an event that requires professional intervention (e.g., important medical events that may require a medical/surgical intervention to prevent a death, life-threatening event, hospitalization, disability).

Reporting of lack of effectiveness, nonserious adverse events, or product quality defects is strongly encouraged via the described procedures, including the information identified above.

Additional Information for Agencies, Veterinary Facilities, and Veterinarians:

Federal, state, local, and federally recognized tribal agencies, and persons working under their authority and at their direction (hereinafter "agencies"), veterinary facilities, and veterinarians will ensure that they are aware of and adhere to the terms of the Letter of Authorization. This Fact Sheet 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.

Agencies and veterinary facilities will maintain health records 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), 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 groups of animals received drugs subject to this EUA.

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 US Inc., HHS, and FDA for inspection upon request.

Net Contents

100 g

How Supplied

150 mL bottle with atomizer insert

Storage and Disposal

Store at or below 25°C (77°F), excursions permitted to 40°C (104°F). Protect from light. Do not freeze.

Do not contaminate water, food, or feed by storage or disposal.

Store only in original tightly sealed container and out of reach of children.

Wastes resulting from the use of this product, including opened containers, may be disposed of on site or at an approved waste disposal facility. Any unopened containers must be returned to the distributor for disposal or disposed of in accordance with local, state, and federal regulations.

Nonrefillable container. Do not reuse or refill the container. Triple rinse container (or equivalent) and offer for recycling, if available. Otherwise, dispose of container in a sanitary landfill or by incineration if allowed by state and local authorities.

Manufactured for:
Elanco US Inc.
450 Elanco Circle
Indianapolis, IN 46221

Revision Date: 04/27/2026

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 alternative[4] 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.

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[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 facilities[9] 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 defects[11] within 3 days, all serious adverse events[12] and medication errors[13] 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).

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[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

Electronic Signature Addendum for Submission ID

V-006653-A-0000-OT

Signing Authority (Role)	Letter Date
Timothy Schell (Center Director)	4/27/2026

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