4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-6182]

Authorization of Emergency Use for Two 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 two Emergency Use Authorizations (EUA) (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 Health and Hygiene (Pty) Ltd. for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) (NWS) larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals. FDA has issued one EUA for an animal product as requested by Elanco US Inc. 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. 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: April 24, 2026, and April 27, 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.

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;[1] (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,

[1] 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).

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[2] 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

[2] 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.

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 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 two authorizations for the emergency use of animal products. On April 24, 2026, FDA issued an EUA to Health and Hygiene (Pty) Ltd. for the animal product F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment), subject to the terms of its Authorization. On April 27, 2026, FDA issued an EUA to Elanco US Inc. for the animal product Negasunt Powder (coumaphos, propoxur, and sulfanilamide topical powder), 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.

U.S. FOOD & DRUG ADMINISTRATION

April 24, 2026

Animal Clinical Investigation, LLC
Attention: Kristen Khanna, PhD, MBA
CEO
U.S. Agent for Health and Hygiene (Pty) Ltd
4445 Willard Ave
Sixth Floor
Chevy Chase, MD 20815

Re: Emergency Use Authorization 006677

Dear Dr. Khanna:

This letter is in response to the request you submitted on behalf of Health and Hygiene (Pty) Ltd (Health and Hygiene) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment)[1] for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, horses, minor species[2] of hoof stock, raptors and other wild birds, pet birds, 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.[3]

F10 Antiseptic Barrier Ointment with Insecticide is a topical ectoparasiticide and antiseptic drug that is indexed under Minor Species Index File (MIF) 900-011 for use as a topical antiseptic for surface wounds, to repel flies, and to treat infestations due to fly strike in raptors, pet birds, captive

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[1] Unless specified by name, 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 to the scope of this authorization for such products.
[2] Minor species are all animals, other than humans, that are not one of the major species. They include animals such as zoo animals, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, and game birds, among others. The term 'major species' means cattle, horses, swine, chickens, turkeys, dogs, and cats.
[3] 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

small mammals, captive reptiles, and captive exotic/zoo mammals.[4] F10 Antiseptic Barrier Ointment with Insecticide is not approved or indexed for the prevention and treatment of NWS myiasis.

Based on the totality of scientific evidence available to the FDA, including information submitted in support of MIF 900-011 and this EUA, as well as publicly available information, it is reasonable to believe that F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) may be effective for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, 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 F10 Antiseptic Barrier Ointment with Insecticide 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 F10 Antiseptic Barrier Ointment with Insecticide for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, 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 F10 Antiseptic Barrier Ointment with Insecticide for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, 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 F10 Antiseptic Barrier Ointment with Insecticide may be effective in preventing and treating NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of F10 Antiseptic Barrier Ointment with Insecticide when used to prevent and treat NWS outweigh the known and potential risks of such product; and

[4] See FDA's webpage "The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species" at https://www.fda.gov/animal-veterinary/minor-useminor-species/index-legally-marketed-unapproved-new-animal-drugs-minor-species

3. There is no adequate, approved[5], and available alternative[6] to the emergency use of F10 Antiseptic Barrier Ointment with Insecticide for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals.[7]

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:

- F10 Antiseptic Barrier Ointment with Insecticide, as covered by this authorization, will be used only for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals; and

- The use of F10 Antiseptic Barrier Ointment with Insecticide covered by this authorization must be in accordance with the authorized Fact Sheet.

Product Description

F10 Antiseptic Barrier Ointment with Insecticide is a synthetic pyrethroid ectoparasiticide with antiseptic. The authorized F10 Antiseptic Barrier Ointment with Insecticide jar 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 between 15° to 30°C (59° to 86°F) in dry conditions.

F10 Antiseptic Barrier Ointment with Insecticide 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 F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) 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 F10 Antiseptic Barrier Ointment with Insecticide, when used for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet

[5] "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.
[6] There are no approved products for horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals. Although there are conditionally approved products for the prevention and treatment of NWS in cattle, F10 Antiseptic Barrier Ointment with Insecticide provides an important option for treating and preventing NWS in cattle because it is a topical ointment product that is applied locally, directly to wounds. Cattle and other hoof stock 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.
[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

birds, and captive wild, exotic, and zoo mammals 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 F10 Antiseptic Barrier Ointment with Insecticide may be effective for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, 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 F10 Antiseptic Barrier Ointment with Insecticide, 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, F10 Antiseptic Barrier Ointment with Insecticide is authorized for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, 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. Health and Hygiene will ensure that the authorized F10 Antiseptic Barrier Ointment with Insecticide, accompanied with the authorized Fact Sheet, is distributed to authorized distributor(s)[8] 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. Health and Hygiene will ensure that if a sticker is used on the jar, 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. Health and Hygiene and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.

[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 Health and Hygiene places limits on distribution in writing (e.g., via contract or written notice accompanying the product).

D. Health and Hygiene 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. Health and Hygiene may request changes to this authorization, including to the authorized Fact Sheet for F10 Antiseptic Barrier Ointment with Insecticide. Requests for changes must be submitted to the Office of New Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.[9]

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

Health and Hygiene will report to FDA all product/manufacturing defects[10] within 3 days, all serious adverse events[11] and medication errors[12] associated with the use of the authorized F10 Antiseptic Barrier Ointment with Insecticide that are reported to Health and Hygiene 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).

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: "F10 Antiseptic Barrier Ointment with Insecticide 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.

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[9] 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.

[10] Product defect/manufacturing defect is the deviation of a distributed product from the standards specified in the indexed file, 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.

[11] 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.

[12] 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.

G. Through a process of inventory control, Health and Hygiene and authorized distributor(s) will maintain records regarding distribution of the authorized F10 Antiseptic Barrier Ointment with Insecticide (i.e., lot numbers, quantity, receiving site, receipt date).

H. Health and Hygiene 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. Health and Hygiene 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),[13] unless such requirements are specifically waived or modified for the authorized product in this authorization. Health and Hygiene and any person engaged in manufacturing, packing or holding shall only manufacture F10 Antiseptic Barrier Ointment with insecticide 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.[14]

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 F10 Antiseptic Barrier Ointment with Insecticide shall be consistent with the authorized Fact Sheet[15] 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. Health and Hygiene and authorized distributor(s) may not imply that F10 Antiseptic Barrier Ointment with Insecticide is FDA approved, conditionally approved, or indexed for the authorized use by making statements such as "F10 Antiseptic Barrier Ointment with Insecticide is safe and effective for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals". Health and Hygiene and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of F10 Antiseptic Barrier Ointment with Insecticide 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.

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[13] Among other requirements, all expiration dates shall be established in accordance with 21 CFR 211.137.
[14] Any request submitted via an update to the file is considered accepted after 30 calendar days unless FDA provides notice to the contrary.
[15] If the authorized Fact Sheet references sections of the drug's labeling (as contained in its index listing), 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 the labeling in lieu of summarizing or restating its contents when a summary or restatement is otherwise needed to comply with applicable requirements.

L. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of F10 Antiseptic Barrier Ointment with Insecticide shall be accompanied by the authorized Fact Sheet, and shall clearly and conspicuously state that:

- F10 Antiseptic Barrier Ointment with Insecticide has not been approved or indexed for the prevention and treatment of infestations caused by NWS myiasis in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals;

- F10 Antiseptic Barrier Ointment with Insecticide has been authorized by FDA under an EUA for the prevention and treatment of infestations caused by NWS myiasis in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals; and

- F10 Antiseptic Barrier Ointment with Insecticide is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of F10 Antiseptic Barrier Ointment with Insecticide 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 Health and Hygiene or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Health and Hygiene 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 Health and Hygiene 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

U.S. FOOD & DRUG ADMINISTRATION

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

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[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]

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[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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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