Date of Authorization: April 27, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

Original Emergency Use Authorization (EUA)

EUA 006653

Negasunt™ Powder

(coumaphos, propoxur, and sulfanilamide topical powder)

Topical Powder

Cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals

Scope of Authorization: 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

Sponsored by:

Elanco US Inc.

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I. GENERAL INFORMATION

A. File Number

EUA 006653

B. Sponsor

Elanco US Inc.
450 Elanco Circle
Indianapolis, IN 46221

Drug Labeler Code: 058198

C. Proprietary Name

Negasunt™ Powder

D. Drug Product Established Name

coumaphos, propoxur, and sulfanilamide topical powder

E. Pharmacological Category

Ectoparasiticide and antimicrobial

F. Dosage Form

Topical powder

G. Amount of Active Ingredient

Coumaphos 30 mg/g, propoxur 20 mg/g, and sulfanilamide 50 mg/g

H. How Supplied

150 mL bottle

I. Dispensing Status

Prescription (Rx): For use by or on the order of a licensed veterinarian in New World screwworm (NWS) infested zones and adjacent surveillance zones as defined by U.S. Department of Agriculture (USDA).[1]

Limited non-prescription use: For use by employees of federal, state, local, and federally recognized tribal agencies, and persons working under their authority and at their direction.

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[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

J. Dosage Regimen

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

K. Route of Administration

Topical

L. Species

Cattle, swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals

M. Emergency Authorized Use

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

N. Limitations of Authorized Use

It is a violation of federal law to use this drug product other than as directed in the 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, 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.

II. EFFECTIVENESS

A. Study Supporting a Prevention Indication

1. **Title**: Prophylactic Efficacy of Bayer Tambero Formula Against Experimental Infections by L1 Larvae of *Cochliomyia hominivorax* in Cattle After Surgical Incision

   Study Dates: May 18, 2010 to May 26, 2010

   Study Location: Minas Gerais, Brazil

   Study Design:

   Objective: The objective of this study was to evaluate the prophylactic efficacy of Tambero against experimental infestations of *C. hominivorax* in cattle after surgical incision.

   Study Animals: Twelve intact male cattle were used, aged between 12 and 15 months, identified through numbered ear tags on the right ear and buttons with the same number on the left ear. All came from the same place of origin and were clinically healthy.

   Experimental Design: The cattle were randomized into two experimental groups with six animals per group. All study animals had two skin incisions 4 cm in length made, one on each side of the neck, on Day 0. The control animals were then infested with 100 first instar larvae of *C. hominivorax* in each wound. The treated animals received application of Tambero over the wounds and then these animals were infested with 100 first instar larvae of *C. hominivorax* in each wound. Animals were observed for a period of five days. Control animals were administered a “rescue” treatment with a topical product after Day 4.

   Drug Administration: The test article was Tambero, consisting of coumaphos and propoxur, manufactured by Bayer S.A., February 2010. The Tambero treated group received one spray (0.72 g) of Tambero topically on the surgical incision. The control group received no treatment.

Measurements and Observations: The cattle were observed once daily for five days after infestation. The wounds were evaluated for presence/absence of larvae.

Statistical Methods: Percent prevention was determined by comparing the number of wounds with larvae to the number of wounds without larvae on each day post-infestation. For statistical analysis, the INSTAT program, 1998, was used.

Results: The Tambero-treated group had 100% prevention of myiasis. None of the six treated animals had live larvae in each of the two wounds per animal for four days post-infestation. All six control animals had larvae in each of the two wounds per animal for four days post-infestation. Control animals received rescue treatment on Day 4 so further analysis could not be conducted.

Adverse Reactions: No adverse reactions were reported in this study.

Conclusion: Tambero applied once topically on a wound at a dose of 0.72 g was 100% effective in preventing myiasis for four days post-infestation in cattle. The product used in this study is a different dosage form (spray) and contains only two out of the three drugs included in Negasunt™ Powder (sulfanilamide was not evaluated). The study report is lacking information on many parameters typically assessed in effectiveness studies as well as explanations of methods used to minimize bias and assure data quality. Though limited by those issues, it is reasonable to believe that Negasunt™ Powder may be effective in preventing infestations caused by New World screwworm (*C. hominivorax*) larvae (myiasis). It is also reasonable to believe that the addition of sulfanilamide in Negasunt™ Powder would not negatively impact the effectiveness of coumaphos and propoxur and may contribute to wound healing through mitigating secondary bacterial infections. As Negasunt™ Powder is for use on an infested wound and acts directly on NWS larvae, it is reasonable to believe that effectiveness will be similar in target species other than cattle, e.g., swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals.

B. Study Supporting a Treatment Indication

1. **Title**: Efficacy of Bayer S.A. Tambero Formula Against Experimental Infections by L1 Larvae of *Cochliomyia hominivorax* in Cattle After Surgical Incision

   Study Dates: May 18, 2010 to May 26, 2010

   Study Location: Minas Gerais, Brazil

   Study Design:

   Objective: The objective of this study was to evaluate the efficacy of Tambero against experimental infestations of *C. hominivorax* in cattle after surgical incision.

   Study Animals: Twelve intact male cattle were used, aged between 12 and 15 months, identified through numbered ear tags on the right ear and buttons with

the same number on the left ear. All came from the same place of origin and were clinically healthy.

Experimental Design: The cattle were randomized into two experimental groups with six animals per group. All study animals had two skin incisions 4 cm in length made, one on each side of the neck, on Day 0. Then all study animals were infested with 100 first instar larvae of *C. hominivorax* in each wound. On Day 2, the Tambero-treated animals received application of Tambero over the wounds. After infestation, all animals were observed for 48 hours.

Drug Administration: The test article was Tambero, consisting of coumaphos and propoxur, manufactured by Bayer S.A., February 2010. The Tambero treated group received one spray (0.72 g) of Tambero topically on the surgical incision. The control group received no treatment.

Measurements and Observations: The cattle were observed daily for 48 hours after treatment administration on Day 2. The wounds were evaluated for presence/absence of larvae.

Statistical Methods: Percent efficacy was determined by comparing the number of wounds with larvae to the number of wounds without larvae on each day post-treatment. For statistical analysis, the INSTAT program, 1998, was used.

Results: Twenty-four hours post-treatment, no animals in the Tambero-treated group had wounds with live larvae. All of the six control animals had live larvae in each of the two wounds per animal up to Day 4, then rescue treatment was administered. Therefore, there was 100% treatment efficacy in the Tambero-treated group.

Adverse Reactions: No adverse reactions were reported in this study.

Conclusion: Tambero applied topically once on a wound at a dose of 0.72 g was 100% effective in treating myiasis in cattle. The product used in this study is a different dosage form (spray) and contains only two out of the three drugs included in Negasunt™ Powder (sulfanilamide was not evaluated). The study report is lacking information on many parameters typically assessed in effectiveness studies as well as explanations of methods used to minimize bias and assure data quality. Though limited by those issues, it is reasonable to believe that Negasunt™ Powder may be effective in treating infestations caused by New World screwworm (*C. hominivorax*) larvae (myiasis). It is also reasonable to believe that the addition of sulfanilamide in Negasunt™ Powder would not negatively impact the effectiveness of coumaphos and propoxur and may contribute to wound healing through mitigating secondary bacterial infections. As Negasunt™ Powder is for use on an infested wound and acts directly on NWS larvae, it is reasonable to believe that effectiveness will be similar in target species other than cattle, e.g., swine, goats, sheep, horses, donkeys, domestic hybrid equids, and captive wild, exotic, and zoo mammals.

III. TARGET ANIMAL SAFETY

A. Foreign Margin of Safety Studies

1. **Title:** Safety Evaluation of The Formulation Called Tambero, Bayer S.A., Administered Topically in Cattle After Surgical Incision

   Study Dates: June 8, 2010 to June 22, 2010

   Study Location: Minas Gerais, Brazil

   Study Design:

   Objective: The objective of this study was to evaluate the safety of Tambero administered topically on cattle after surgical incision.

   Study Animals: Forty cattle were used (20 female, 20 male), aged between 12 to 18 months. All came from the same place of origin and were clinically healthy.

   Experimental Design: The cattle were randomized into four experimental groups. Use of blocking and masking is unknown. The study was conducted according to the principles of Good Clinical Practices (VICH GL9 - GCP). The number of animals included in the experiment was justified according to VICH GL 43 Target Animal Safety- Pharmaceuticals, July 2008.

   Drug Administration: The test article was Tambero, consisting of coumaphos and propoxur, manufactured by Bayer S.A., February 2010. The 1X treatment group received two sprays (1.44 g) of Tambero topically on a surgical incision 5 cm in length. The 2X group received four sprays (2.88 g) and the 3X group received six sprays (4.32 g). The control group received no treatment. There were five males and five females in each group.

   Measurements and Observations: The cattle were evaluated on study days D-7, D0, D+1, D+3 and D+7. Vital signs were recorded (rectal temperature, heart rate, respiratory rate, lymph node palpation, ocular mucosa evaluation) and clinical signs of systemic toxicity were noted as present or absent. Complete blood count and an abbreviated serum biochemistry were performed on study days D-7, D0, D+1, D+3 and D+7.

   Statistical Methods: A completely randomized design was used with split-plots over time with 4 treatments, 10 replicates per treatment, evaluated at five time points (D-7, D0, D+1, D+3, and D+7). The variables analyzed were blood parameters, rectal temperature, respiratory rate, and heart rate. The data were subjected to analysis of variance and subsequently to Tukey's test at 5% significance level.

   Results: No alterations in animal behavior were observed during the experimental period. There were no clinically relevant differences between treated groups and the control group for mean temperature, heart rate, and respiratory rate on all evaluation days. No alterations were observed in mucous membrane coloration or lymph node palpation of cattle during the entire study period. There were no clinically relevant differences between treated groups and

the control group in hematologic parameters. There were no clinically relevant differences between treated groups and the control group for all time points for aspartate aminotransferase (AST), gamma-glutamyltransferase (GGT), total protein, urea, and creatinine mean values, as well as the mean serum acetylcholinesterase values. No clinical signs of systemic toxicity were reported during the study.

Conclusion: Tambero applied topically on an open surgical wound at 1.44 g, 2.88 g, and 4.32 g was safe for cattle. The product used in this study is a different dosage form (spray) and contains only two out of the three drugs included in Negasunt™ Powder. This target animal safety study is lacking data on many parameters typically assessed in target animal safety studies and the study report is lacking explanation of methods used to minimize bias and assure data quality. Though limited by those issues, the study did not show any safety concerns in cattle treated with Tambero when used at any of the dose levels tested.

2. **Title:** Safety Evaluation of The Formulation Named Tambero, Bayer S.A., Administered Topically in Equines After Surgical Incision

   Study Dates: August 9, 2010 to August 23, 2010; FSR dated September 2010

   Study Location: Minas Gerais, Brazil

   Study Design:

   Objective: The objective of this study was to evaluate the safety of Tambero administered topically on horses after surgical incision.

   Study Animals: Forty horses were used (20 female, 20 male), aged between 3 and 7 years. All came from the same place of origin and were clinically healthy.

   Experimental Design: The horses were randomized into four experimental groups. Use of blocking and masking is unknown. The study was conducted according to the principles of Good Clinical Practices (VICH GL9 - GCP). The number of animals included in the experiment was justified according to VICH GL 43 Target Animal Safety- Pharmaceuticals, July 2008.

   Drug Administration: The test article was Tambero, consisting of coumaphos and propoxur, manufactured by Bayer S.A., February 2010. The 1X treatment group received two sprays (1.44 g) of Tambero topically on a surgical incision 5 cm in length. The 2X group received four sprays (2.88 g) and the 3X group received six sprays (4.32 g). The control group received no treatment. There were five males and five females in each group.

   Measurements and Observations: The horses were evaluated on study days D-7, D0, D+1, D+3, and D+7. Vital signs were recorded (rectal temperature, heart rate, respiratory rate, lymph node palpation, ocular mucosa evaluation) and clinical signs of systemic toxicity were noted as present or absent, except for sialorrhea, which was scored from 0 to 5. Complete blood count and an abbreviated serum biochemistry were performed on study days D-7, D0, D+1, D+3, and D+7.

Statistical Methods: A completely randomized design was used with split-plots over time with 4 treatments, 10 replicates per treatment, evaluated at five time points (D-7, D0, D+1, D+3, and D+7). The variables analyzed were blood parameters, rectal temperature, respiratory rate, and heart rate. The data were subjected to analysis of variance and subsequently to Tukey's test at 5% significance level.

Results: No alterations in animal behavior were observed during the experimental period. There were no clinically relevant differences between treated groups and the control group for mean temperature, heart rate and respiratory rate on all evaluation days. No alterations were observed in mucous membrane coloration or lymph node palpation of horses during the entire study period. There were no clinically relevant differences between treated groups and control in hematologic parameters. There were no clinically relevant differences between treated groups and the control group for all time points for aspartate aminotransferase (AST), gamma-glutamyltransferase (GGT), total protein, urea, and creatinine mean values, as well as the mean serum acetylcholinesterase values. No clinical signs of systemic toxicity were reported during the study.

Conclusion: Tambero applied topically on an open surgical wound at 1.44 g, 2.88 g, and 4.32 g was safe for horses. The product used in this study is a different dosage form (spray) and contains only two out of the three drugs included in Negasunt™ Powder. This target animal safety study is lacking data on many parameters typically assessed in target animal safety studies and the study report is lacking explanation of methods used to minimize bias and assure data quality. Though limited by those issues, the study did not show any safety concerns in horses treated with Tambero when used at any of the dose levels tested. It is reasonable to believe that the safety profile of the active ingredients applied topically would be similar in donkeys and domestic hybrid equids.

B. Foreign Field Effectiveness Studies Summary

A study titled “Efficacy of Negasunt Dusting Powder in Healing of Maggot Wounds in Clinical Cases of Different Species”, conducted in India in 2001, evaluated fifty clinical cases across multiple species (bovine n=15, canine n=20, equine n=8, caprine/ovine n=7) presenting with maggot-infested wounds. The treatment protocol included wound debridement and cleaning followed by Negasunt™ Powder application. No adverse events were reported. This report provides anecdotal evidence that treatment with Negasunt™ Powder, along with wound cleaning and debridement, leads to wound healing. However, this study represents a case series, it is an observational, descriptive study, rather than a masked, controlled study, and it is lacking bias minimization methods, quality assurance measures, and control groups.

Two effectiveness studies (treatment and prevention) were conducted in cattle in Brazil using the Tambero spray formulation; these are described in detail above under the Effectiveness Section. In these studies, the treated groups had one spray (0.72 g) of Tambero applied topically on a surgically created wound once. In both studies, there were no safety concerns identified with Tambero when used at the dose level tested.

C. Foreign Residue Studies Summary

Two residue studies were conducted to evaluate tissue and milk residue depletion following topical application of Tanidil powder (3% coumaphos and 2% propoxur, equivalent to Tambero). The meat residue study was conducted in Australia in 2023 and enrolled 26 Angus beef cattle that received Tanidil (1.44 g) applied to 5 cm² skin excisions on study Days 0 and 2. No health concerns, adverse events, or treatment-related clinical signs were observed during the study period.

The milk residue study was conducted in Brazil in 2023 and enrolled twenty-two Holstein or crossbred dairy cows that received Tanidil (1.44 g) on 5 cm² shoulder excisions on study Days 0 and 2, with a nine-day observation period. No abnormalities, adverse events, or application site reactions were observed throughout the study duration.

In both studies, there were no safety concerns identified with Tanidil when used at the dosage tested.

D. Scientific Literature Summary

The scientific literature review revealed no direct safety data for Negasunt™ Powder but provided insight into the toxicity profiles of its individual active ingredients and anecdotal evidence of successful clinical use. Multiple case reports from various countries describe successful treatment of myiasis in diverse species (cattle, dogs, bears, deer, camels, horses, sheep, and goats) using Negasunt™ Powder, with all animals reportedly recovering without adverse events, though these reports lack control groups and may reflect publication bias toward positive outcomes. Literature on coumaphos, an organophosphate that irreversibly inhibits acetylcholinesterase, demonstrates it has a narrow margin of safety. Propoxur, a carbamate that reversibly inhibits acetylcholinesterase, shows evidence of dermal absorption (6 to 21% in various species) but is generally considered safer than coumaphos. Sulfanilamide safety data is limited for topical use, though a Canadian-approved topical cream containing 3.8% sulfanilamide for multiple species provides regulatory precedent, and historical studies of oral use in cattle demonstrate dose-dependent toxicity. The literature supports the potential for toxicity of Negasunt™ Powder at higher doses, but extrapolation to the proposed topical powder use is challenging due to differences in drug concentrations, routes of exposure, dosing regimens, and unknown absorption profiles. The overall safety profile is likely limited primarily by coumaphos toxicity rather than the other components.

E. Risk Assessment

The risk assessment for Negasunt™ Powder identifies the primary hazard as potential systemic absorption of coumaphos and propoxur leading to acute neurotoxicosis, with coumaphos presenting greater concern due to irreversible inhibition (if left untreated) compared to propoxur's reversible inhibition of acetylcholinesterase. Additionally, sulfanilamide may cause localized dermatological reactions in animals sensitive to the drug. The dose-response relationship remains incompletely characterized but is expected to follow a steep linear progression due to cumulative cholinesterase inhibition effects, with exposure levels varying based on wound characteristics, application methodology, and treatment frequency. 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. This risk is balanced against the therapeutic benefits of prevention and treatment of NWS infestations that would improve animal welfare and reduce mortality. Risk mitigation strategies include the incorporation of a bittering agent to prevent oral ingestion and comprehensive labeling restrictions including contraindications for animals with renal/hepatic impairment or sulfonamide hypersensitivity, external use only warnings, and prohibition of feed/water contamination to ensure safe use across the proposed multi-species indication. Additionally, the use of the drug will be limited to employees of federal, state, local, and federally recognized tribal agencies, and persons working under their authority and at their direction, and to use by or on the order of a licensed veterinarian in NWS infested zones and adjacent surveillance zones as defined by USDA.

IV. HUMAN FOOD SAFETY

A. Microbial Food Safety

Background and Outcome of Risk Assessment

The hazardous agents identified and considered in the qualitative risk assessment were sulfanilamide-resistant zoonotic bacterial pathogens. Resistance to the sulfonamide class (sulfanilamide is a member) is common in human and veterinary medical practice. It was estimated that the probability of the proposed topical use of Negasunt™ Powder that will result in the emergence or selection of a hazardous agent will be low.

Due to various food-producing animal species being included in this EUA, a conservative approach was taken to determine a qualitative estimate of both food commodity consumption and contamination (i.e., exposure to the hazardous agent). Based on human consumption data published annually by USDA's Economic Research Service,[2] a qualitative ranking of high is appropriate. Based on *Salmonella* and *E. coli* animal-derived food commodity contamination rates published annually by the USDA's Food Safety and Inspection Service,[3] a conservative qualitative estimate of medium is appropriate. Thus, there is a qualitative rank of high representing the probability of human exposure to the hazardous agent.

Sulfonamides are ranked as 'important' in Guidance for Industry #152 due to their use in treating non-serious infections in humans.

Decision Statement

Based on an integration of release, exposure, and consequence assessments, a risk estimation of medium was initially determined. However, considering the limitations on use expected for this EUA, the risk estimation was adjusted and concluded to be

[2] https://www.ers.usda.gov/data-products/food-availability-per-capita-data-system
[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-152-evaluating-safety-antimicrobial-new-animal-drugs-regard-their-microbiological-effects

low. No additional conditions of use or labeling restrictions based on microbial food safety or antimicrobial resistance are warranted.

B. Toxicology and Residue Chemistry

The human food safety assessment for Negasunt™ Powder relied on two residue studies submitted by the sponsor and publicly available scientific information including evaluations from the U.S. Environmental Protection Agency (EPA), the Joint Food and Agricultural Organization (FAO)/World Health Organization (WHO) Meeting on Pesticide Residues (JMPR), and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Key references used in the evaluation are listed below:

1. Baakman M., et al. (1987). Pharmacokinetics of sulphanilamide and its three acetyl metabolites in dairy cows and calves. Vet. Q., 9: 143-154.

2. Elanco. (2023). Residue Determination in Edible Tissues of Cattle Following Topical Application of Tanidil™. Study Number ELA220944.

3. Elanco. (2023). Milk residue depletion of Tanidil™ (3% Coumaphos and 2% Propoxur) when administered by topical route to dairy cattle. Study Number ELA230953.

4. EPA: Propoxur: Human Health Draft Risk Assessment for Registration Review, Memorandum dated May 22, 2015 (D414135; Docket Number: EPA-HQ-OPP-2009-0806).

5. EPA: Coumaphos: Draft Human Health Risk Assessment for Registration Review, Memorandum dated March 22, 2016 (D409347; Docket Number: EPA-HQ-OPP-2008-0023).

6. Konar A., and Ivie G.W. (1988). Fate of [^{14}C]coumaphos after dermal application to lactating goats as a pour-on formulation. Am J. Vet. Res., 49: 488-492.

7. WHO (1968). Joint FAO/WHO Meeting on Pesticide Residues (JMPR) Evaluation of Coumaphos (FAO/PL:1968/M/9/1, WHO/FOOD ADD./69.35).

8. WHO (1972). Joint FAO/WHO Meeting on Pesticide Residues (JMPR) Coumaphos. Toxicology Evaluation of Some Pesticide Residues in Food. WHO Pesticide Residues Series No. 2.

9. WHO/FAO (1974). Propoxur. 1973 Evaluations of some pesticide residues in food. FAO/AGP/1973/M/9/1; WHO Pesticide Residue Series, No. 3.

10. WHO/FAO (1990). JMPR 1989 Propoxur Part II Toxicology evaluations of pesticide residues in food.

11. WHO (1990). Sulfadimidine. Toxicological Evaluation of Certain Veterinary Drug Residues in Food. WHO Food Additives Series No. 25. (FAS 25-JECFA 34/79).

12. WHO (1991). Joint FAO/WHO Meeting on Pesticide Residues (JMPR) Coumaphos. Toxicology Evaluation of Pesticide Residues in Food.

13. WHO (1994). Sulfadimidine. Toxicological Evaluation of Certain Veterinary Drug Residues in Food. WHO Food Additives Series No. 33. (FAS 33-JECFA 42/91).

FDA concluded that food products obtained from animals treated with Negasunt™ Powder are safe for human consumption when the conditions of use granted by the EUA are followed, including the withdrawal period.

Withdrawal Period

- A 28-day withdrawal period is assigned for cattle, swine, goats, sheep, and captive wild and exotic food-producing mammals.
- A milk discard time has not been established for this product. Do not use in lactating 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.

V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to Negasunt™ Powder:

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 products.

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 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, contact Elanco Product & Veterinary Support at 1-800-428-4441 or visit https://www.elanco.com/us/elanco-safety-data-sheets.

VI. AGENCY CONCLUSIONS

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, when used as authorized, may be 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; the known and potential benefits of Negasunt™ Powder when used as authorized outweigh the known and potential risks. New World screwworm 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. The benefit

of preventing or treating a potentially deadly disease outweighs the health risks of using this product in these species. 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™ Powder will not represent a public health concern when the product is used as authorized.

There is no adequate, approved,[4] and available alternative to the product for the prevention and treatment of NWS (myiasis) in these species. 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™ Powder 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 locally, directly to wounds.

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

A. Duration of Authorization: Revision and Revocation

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

B. Marketing Status

This product is authorized for use by employees of federal, state, local, and federally recognized tribal agencies, and persons working under their authority and at their direction, and also for use by or on the order of a licensed veterinarian (Rx marketing status) in NWS infested zones and adjacent surveillance zones as defined by USDA.

[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.