Fact Sheet: Emergency Use Authorization of CLiK Extra (dicyclanil topical suspension) Wound Spray for New World Screwworm (NWS)

Emergency Use Authorization Spanish Translation: www.clik-extra-nws.com/spanish
Autorización de Uso de Emergencia traducción al español: www.clik-extra-nws.com/spanish

CLiK Extra (dicyclanil topical suspension) wound spray contains 65 mg/mL of dicyclanil. CLiK Extra is an insect growth regulator, which is a type of ectoparasiticide.

Original EUA Authorized Date: 08/07/2026

Emergency Use Authorization of CLiK Extra (dicyclanil topical suspension) Wound Spray for NWS

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product CLiK Extra (dicyclanil topical suspension) wound spray for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured[1] wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn. CLiK Extra is not approved for this use.

Limitations of Authorized Use

It is a violation of Federal law to use this drug product other than as directed in this fact sheet.

Sheep, cattle, goats, swine, cervids, American bison, and bighorn sheep must not be slaughtered or harvested for human consumption within 86 days of treatment.

For captured cervids, captured American bison, and captured bighorn sheep, use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 86 days of treatment.

Treated Sonoran pronghorn and camelids may not be used for human consumption.

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.

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

Product Description

[1] Definitions for “captive wildlife” and “captured wildlife” can be found in the last section of the USDA APHIS New World Screwworm Response Playbook, accessible at https://www.aphis.usda.gov/animal-emergencies/nws

CLiK Extra (dicyclanil topical suspension) wound spray is a pink liquid. Each mL of CLiK Extra contains 65 mg dicyclanil, 200 mg propylene glycol, 100 mg medium-chain triglycerides, 20 mg distilled monoglycerides, 3.00 mg propyl parahydroxybenzoate, 2.50 mg polysorbate, 1.50 mg methyl parahydroxybenzoate (E218), 0.80 mg carbomer copolymer, 0.50 mg disodium edetate, 0.50 mg butylates hydroxytoluene, 0.05 mg ponceau 4R, sodium hydroxide, and purified water.

Directions

For external use only. Shake well before use. Clean the wound(s) prior to drug application. Apply on or around wound(s) using a Fan-Spray 10 mL topical applicator by Simcro Datamars. Use disposable gloves during application and wash hands thoroughly after use.

Use the following dosing table for maximum volume per animal based on body weight. If there are multiple wounds on a single animal, divide the total volume across all wounds as necessary. Small wounds may not need the total volume.

Bodyweight (kg)	**Total volume/animal (mL)**
10 – 20	Up to 20
21 – 30	Up to 24
31 – 50	Up to 30
> 50	Up to 36

Where possible, treated animals should be kept out of rain and away from waterways for at least one hour after treatment.

CLiK Extra will not treat an active NWS infestation. This drug is for prevention of NWS myiasis only. For prevention of myiasis associated with wounds, birth, and following surgical/husbandry procedures (e.g., dehorning, ear tagging, castration, tail docking, shearing), apply at the time of wound appearance/creation. If a wound is already infested, or an infestation develops after CLiK Extra administration, alternative treatment is necessary.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of NWS. Consult your veterinarian for appropriate wound care when CLiK Extra is administered to prevent myiasis.

Information Supporting Emergency Use Authorization

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

In sheep, one study conducted in Uruguay in 2012 to 2013 used the 50 mg/mL (5%) concentration of dicyclanil topical suspension in lambs. A treated group and an untreated control group contained 15 lambs each. All lambs were tail docked and the treated lambs had dicyclanil topical suspension applied directly to the tail docking site at a volume of 20 mL each. All lambs

were evaluated twice daily for 18 days for myiasis via natural infestation. No treated animals were reported with myiasis. By Day 13, 8 out of 15 control animals had myiasis. This study demonstrated dicyclanil topical suspension may be effective in preventing NWS myiasis in sheep.

Other available data in sheep are from the Australia and New Zealand registration dossiers, that include multiple dose determination studies and several large field studies demonstrating effectiveness against various blowfly species (e.g., *Lucilia sericata, L. cuprina*, and *Wohlfahrtia magnifica*) to support the prevention of blowfly strike indication. Although this information does not provide effectiveness data for NWS, these large studies demonstrate the safe use of 65 mg/mL (6.5%) concentration of dicyclanil topical suspension in sheep across the United Kingdom (data included in the Australian dossier), Australia, and New Zealand and in a wide range of sheep age, breed, body weight, and wool length. Adverse event reports were typical of issues common to sheep husbandry and were reported at similar rates across both treated and control groups across studies.

One margin of safety study in sheep (from the New Zealand dossier) conducted in Switzerland in 1996 evaluated the safety of dicyclanil topical suspension at the 50 mg/mL concentration. There were 8 sheep in each dose group and they were 3 months of age. Animals were randomly assigned to a negative control group or one of the following treated dose groups: 1X, 3X, or 10X, corresponding to 25 mL, 75 mL, and 250 mL dicyclanil topical suspension, respectively, for lambs weighing between 21 and 30 kg; and 30 mL, 90 mL, and 300 mL, respectively, for lambs weighing between 31 and 50 kg. The average dose in the 10X group equated to a 461 mg/kg dose of dicyclanil topical suspension. On Days 1, 8, and 15, the lambs received a single spray of dicyclanil topical suspension down the topline and around the breech. Necropsies occurred on Days 20 and 21. Parameters measured included regular general health observations, treatment day observations, physical examinations, feed intake, wool length, body weights, clinical pathology, gross necropsy, and histopathology. No adverse events related to the test article were reported.

Four studies were evaluated to support the effectiveness of dicyclanil topical suspension in cattle against NWS. Two dose determination studies were conducted in 2016 in Brazil using the 50 mg/mL concentration. In the first study, dicyclanil topical suspension was administered to animals in groups receiving various volumes applied to circular wounds created surgically on the neck and rump. There were 10 animals in each group. Animals were then continuously exposed to natural NWS infestations. None of the 10 animals that received 20 mL of dicyclanil topical suspension had myiasis up to and including Day 10. In the second dose determination study, following surgical castration, dicyclanil topical suspension was applied to the surgical site in 15 animals. On Day 8, 1 of the 15 animals that received 16 mL of dicyclanil topical suspension had myiasis. Both studies demonstrated dicyclanil topical suspension may be effective in preventing NWS myiasis in cattle.

The third study conducted in Uruguay in 2012 to 2013 used the 50 mg/mL concentration of dicyclanil topical suspension on 2-month-old calves following surgical castration. Animals were then exposed to natural NWS infestation and evaluated twice daily for 15 days. Seven calves received a total volume of 30 mL (15 mL in scrotal sac, 15 mL in periscrotal area) and 6 animals were untreated controls. While none of the treated animals were observed with myiasis during the study, only one control animal had myiasis, therefore indicating natural infestation pressure was not strong in this trial.

The fourth study was conducted in 1996 in Argentina in cattle five to six months of age. Twenty animals received 20 mL of 50 mg/mL dicyclanil topical suspension after surgical castration and twenty animals were untreated controls. After castration, all animals were exposed to natural NWS infestation. Animals were evaluated for 25 days. By the end of the study, 1 treated animal had myiasis on Day 19 compared to 16 out of the 20 control animals that had myiasis. These two papers demonstrated dicyclanil topical suspension may be effective in preventing NWS myiasis in cattle.

Although the available effectiveness data for dicyclanil topical suspension in sheep and cattle against NWS was conducted using the 50 mg/mL concentration and not the 65 mg/mL concentration, it was concluded the difference in concentration would not be expected to negatively impact the effectiveness of 65 mg/mL dicyclanil topical suspension, because at least the same level of effectiveness would be expected from a higher dosage of a topical drug applied directly to the wound.

There is no further safety data available in cattle. However, no adverse events were reported in the four effectiveness studies described previously.

Further pharmacokinetic and toxicological information on dicyclanil topical suspension was available from an EMA Dicyclanil Summary Report, dated 1999 (European Agency for the Evaluation of Medicinal Products, Veterinary Medicines Evaluation Unit). This report stated less than 5% of dicyclanil was systemically absorbed when applied to sheep. Additionally, toxicologic studies were summarized and reported the acute LD50 (median lethal dose) in rats by oral route was 520 mg/kg. The acute LD50 in rats by dermal route was reported as greater than 2000 mg/kg. This information supports that this drug has poor systemic absorption. Given the highest mg/kg dose an animal would receive is 130 mg/kg based on body weight and the dosing table provided under this authorization, this information supports the safety of dicyclanil topical suspension when applied topically in non-wooled animals.

There is no available effectiveness or safety data on the use of dicyclanil topical suspension on goats, swine, camelids, cervids, American bison, bighorn sheep, and Sonoran pronghorn. However, due to the low systemic absorption of this drug, its topical application and local action on a wound, and the toxicological evidence that demonstrated relatively high LD50 values in rats via both oral and dermal routes, it is reasonable to believe this drug, when applied topically around or on a wound in these species, may be effective in preventing NWS infestation. Additionally, for the ruminant species in this indication, it was concluded that the field data in sheep could provide extrapolated support of safety in other ruminant species in a drug that has limited systemic absorption.

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

WARNINGS

Withdrawal Periods and Residue Warnings:

Sheep, cattle, goats, swine, cervids, American bison, and bighorn sheep must not be slaughtered or harvested for human consumption within 86 days of treatment. For captured cervids, captured American bison, and captured bighorn sheep, use only when there is a reasonable certainty that the treated animal will not be slaughtered or harvested for human consumption within 86 days of treatment. Treated Sonoran pronghorn and camelids may not be used for human consumption. A milk discard time has not been established for this product. Do not use in animals producing milk for human consumption. A withdrawal period has not been established for this product in pre-ruminating calves. Treated calves and calves born to treated cows must not be processed for veal.

User Safety Warnings

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

Wash hands after use.

In case of accidental ingestion, do not induce vomiting. Seek medical advice immediately and show the Fact Sheet or the label to the physician.

Contact with skin and eyes should be avoided. Redness and irritation may develop after skin or eye contact. Use disposable gloves and protective clothing when handling this product and wash hands after use.

In case of skin contact, remove contaminated clothing and thoroughly wash the affected parts of the body with soap and water.

In case of accidental eye exposure:

- Wash the eyes with water for at least 15 minutes.
- If wearing contact lenses, rinse the eyes first, then remove contacts and continue to rinse with water.
- If redness and swelling occur, seek medical advice immediately and show the Fact Sheet or label to the physician.

Do not eat, drink, or smoke while using this product.

Residues remain on fleece and fiber for up to three months after treatment. Wear gloves when handling treated area(s) on the animal, and do not shear treated animals during that time.

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

Environmental Warnings

Treated animals should be kept away from surface waters for at least one hour after treatment. There is a serious risk to aquatic life if this advice is not followed. Dicyclanil may adversely affect aquatic organisms. Do not permit water runoff from feed lots to enter lakes, streams or ponds. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Reporting Side Effects

Reporting of side effects potentially related to CLiK Extra use under this EUA is strongly encouraged.

Report side effects, lack of effectiveness, and product defects using any of these methods:

1. Contact Elanco Animal Health at 1-800-428-4441,
2. Download and submit Form FDA 1932a available at https://www.fda.gov/reportanimalae, or
3. Contact FDA at 1-888-FDA-VETS to request this form.

When reporting side effects on Form FDA 1932a, provide the following information when available:

- Age, species and breed, sex, and weight of animal(s)
- Overall health status, number of animals treated, and number of animals affected
- Write “CLiK Extra use for NWS under an EUA” in the section labeled “**Adverse Event/Product Problem/Product Use Error**.”
- Describe the signs you observed, when they started in relation to the medication, how long they lasted, any treatment given by you or your veterinarian, and whether/when the animal(s) recovered.
- Note any pre-existing health problems of the animal(s) and any other medications or treatments they are currently receiving.
- Provide details about the use of the product, including dose given, the route of administration, and lot number.

Contact Information

For technical assistance, contact Elanco Animal Health at 888-545-5973 or https://www.elanco.com/us/contact.

Justification for Emergency Use of Animal Drugs for NWS

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

- determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves NWS (*Cochliomyia hominivorax*); and

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

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

Criteria for issuing an EUA include:

- The biological agent(s) can cause a serious or life-threatening disease or condition;

- Based on the totality of available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that:

    - the product may be effective in diagnosing, preventing, or treating the serious or life-threatening disease or condition; and

    - the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and

- There is no adequate, approved,[4] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[5]

How Supplied

0.8 L and 2.2 L bottles

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

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

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

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

Dispensing Status

Over the counter (OTC)

Storage Conditions

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

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

Rev. 08/07/2026

August 07, 2026

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

Re: Emergency Use Authorization 006723

Dear Dr. Schofield:

This letter is in response to the request by Elanco US Inc. (Elanco) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of CLiK Extra (dicyclanil topical suspension) wound spray[1] for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured[2] wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

On August 18, 2025, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025, declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to Section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.[3]

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

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

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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 the scope of this authorization for such products.
[2] Definitions for "captive wildlife" and "captured wildlife" can be found in the last section of the USDA APHIS New World Screwworm Response Playbook, accessible at https://www.aphis.usda.gov/animal-emergencies/nws
[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

described in this authorization, the known and potential benefits of CLiK Extra outweigh the known and potential risks of such product, since NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the FD&C Act are met, I am authorizing the emergency use of CLiK Extra for application on or around wounds for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, as described in this authorization and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of CLiK Extra for application on or around wounds for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, when administered as described in this authorization, meets the criteria for issuance of an authorization under Section 564(c) of the FD&C Act, because:

1. NWS can cause a serious or life-threatening disease or condition to animals and humans;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that CLiK Extra may be effective in preventing NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of CLiK Extra when used to prevent NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved,[4] and available alternative to the emergency use of CLiK Extra for application on or around wounds for the prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn.[5]

II. Scope of Authorization

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

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

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

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

- The use of CLiK Extra covered by this authorization must be in accordance with the authorized Fact Sheet.

Product Description

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

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

CLiK Extra is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to all users:

- Fact Sheet: Emergency Use Authorization of CLiK Extra (dicyclanil topical suspension) Wound Spray for New World Screwworm (NWS)

I have concluded, pursuant to Section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of CLiK Extra, when used for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, and used in accordance with this authorization, outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the FD&C Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that CLiK Extra may be effective for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that CLiK Extra,

as described in this authorization, meets the criteria set forth in Section 564(c) of the FD&C Act concerning safety and potential effectiveness.

The emergency use of this product under an EUA must be consistent with, and may not exceed, the terms of this authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the FD&C Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the FD&C Act, CLiK Extra is authorized for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn, as described in this authorization, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the FD&C Act, I am establishing the following conditions on this authorization:

A. Elanco will ensure that the authorized CLiK Extra, accompanied with the authorized Fact Sheet, is distributed to authorized distributor(s)[6] consistent with the terms and conditions of this EUA, and that authorized distributor(s) will limit distribution to other authorized distributors and end users.

B. Elanco will ensure that if a sticker is used on the labeling, the sticker contains a website address and QR code that link to the authorized Fact Sheet and that the sticker is placed in a blank space or does not obscure any important use or safety information.

C. Elanco and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.

D. Elanco and authorized distributor(s) will provide to each authorized distributor immediately downstream in the supply chain a copy of this Letter of Authorization and promptly communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (e.g., its authorized Fact Sheet).

E. Elanco may request changes to this authorization, including to the authorized Fact Sheet for CLiK Extra. Requests for changes must be submitted to the Office of New

[6] 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).

Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.[7]

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

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

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

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

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

G. Through a process of inventory control, Elanco and authorized distributor(s) will maintain records regarding distribution of the authorized CLiK Extra (i.e., lot numbers, quantity, receiving site, receipt date).

H. Elanco and authorized distributor(s) will maintain records in connection with this EUA for at least two years following the termination of the declaration or the revocation of the authorization, or until notified by HHS or FDA, whichever is sooner, and will make such records available to FDA for inspection upon request.

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

[8] 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.

[9] 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.

[10] 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.

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)[11] unless such requirements are specifically waived or modified in this authorization. Sponsor and any person engaged in manufacturing, packing, or holding shall only manufacture CLiK Extra using the processes, facilities, controls, and equipment specified in the file for this EUA request at the time of authorization, and no changes may be implemented until accepted by FDA.[12]

Conditions of Authorization Related to Advertisements and other Promotional Descriptive Printed Matter

J. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of CLiK Extra, shall be consistent with the authorized Fact Sheet[13] and the terms set forth in this EUA, as well as comply with FD&C Act Section 502(a). Additionally, the sponsor and authorized distributor(s) shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.

K. Elanco and authorized distributor(s) may not imply that CLiK Extra is FDA approved, conditionally approved, or indexed for the authorized use. Elanco and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of CLiK Extra that provide accurate descriptions of safety and effectiveness information summarized in the authorized Fact Sheet. Such materials must include any limitations of information submitted to support this authorization.

L. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of CLiK Extra shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:

- CLiK Extra has not been approved for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn;

[11] Among other requirements, all expiration dates shall be established in accordance with 21 CFR 211.137.
[12] Any request submitted via an update to the file is considered accepted after 30 calendar days unless FDA provides notice to the contrary.
[13] If the authorized Fact Sheet references sections of a drug's FDA-approved labeling, the entirety of each section is considered part of the Fact Sheet, except as otherwise specified. Advertising and promotional materials may not use general references to approved labeling in lieu of summarizing or restating its contents when a summary or restatement is otherwise needed to comply with applicable requirements.

- CLiK Extra has been authorized by FDA under an EUA for application on or around wounds for the prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in sheep, cattle, goats, swine, camelids, and the following captive and captured wildlife species: cervids, American bison, bighorn sheep, and Sonoran pronghorn; and

- CLiK Extra is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of CLiK Extra under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revised or revoked sooner.

M. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter must be submitted to your Type VII Veterinary Master File as a G submission at the time of initial dissemination (publication or broadcast). When submitting, identify the submission as promotion and advertising material.

If FDA notifies Elanco or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Elanco or authorized distributor(s) must discontinue and/or cease distribution of such advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter in accordance with FDA's notification. Furthermore, as part of its notification, FDA may also require Elanco or authorized distributor(s) to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective as described herein until the declaration that circumstances exist justifying the authorization of the emergency use of animal drugs during the NWS public health emergency is terminated under Section 564(b)(2) of the FD&C Act or the EUA is revised or revoked under Section 564(g) of the FD&C Act.

Sincerely,

{see appended electronic signature page}
Timothy Schell, Ph.D.
Director
Center for Veterinary Medicine
U.S. Food and Drug Administration

Enclosures:
Freedom of Information Summary
Fact Sheet

Electronic Signature Addendum for Submission ID

V-006723-A-0000-OT

Signing Authority (Role)	Letter Date
Timothy Schell (Center Director)	8/7/2026

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