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

[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.

---

[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