U.S. FOOD & DRUG ADMINISTRATION

April 24, 2026

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

Re: Emergency Use Authorization 006677

Dear Dr. Khanna:

This letter is in response to the request you submitted on behalf of Health and Hygiene (Pty) Ltd (Health and Hygiene) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment)[1] for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, horses, minor species[2] of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

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

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

[1] Unless specified by name, products sold under separate distributor's labeling per 21 CFR 514.80(b)(5)(iii) are not subject to this EUA. A request must be made to change to the scope of this authorization for such products.
[2] Minor species are all animals, other than humans, that are not one of the major species. They include animals such as zoo animals, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, and game birds, among others. The term 'major species' means cattle, horses, swine, chickens, turkeys, dogs, and cats.
[3] See U.S. Department of Health and Human Services, Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm, August 20, 2025: https://www.federalregister.gov/documents/2025/08/20/2025-15918/declaration-of-emergency-pursuant-to-the-federal-food-drug-and-cosmetic-act-for-new-world-screwworm

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

Based on the totality of scientific evidence available to the FDA, including information submitted in support of MIF 900-011 and this EUA, as well as publicly available information, it is reasonable to believe that F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) may be effective for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of F10 Antiseptic Barrier Ointment with Insecticide outweigh the known and potential risks of such product, since NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the FD&C Act are met, I am authorizing the emergency use of F10 Antiseptic Barrier Ointment with Insecticide for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals, as described in this authorization and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of F10 Antiseptic Barrier Ointment with Insecticide for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals, when administered as described in this authorization, meets the criteria for issuance of an authorization under Section 564(c) of the FD&C Act, because:

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

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that F10 Antiseptic Barrier Ointment with Insecticide may be effective in preventing and treating NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of F10 Antiseptic Barrier Ointment with Insecticide when used to prevent and treat NWS outweigh the known and potential risks of such product; and

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

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

II. Scope of Authorization

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

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

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

Product Description

F10 Antiseptic Barrier Ointment with Insecticide is a synthetic pyrethroid ectoparasiticide with antiseptic. The authorized F10 Antiseptic Barrier Ointment with Insecticide jar label is clearly marked for NWS under Emergency Use Authorization, with a website address and QR code that links to the authorized Fact Sheet.

Store between 15° to 30°C (59° to 86°F) in dry conditions.

F10 Antiseptic Barrier Ointment with Insecticide is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to all users:

- Fact Sheet: Emergency Use Authorization of F10 Antiseptic Barrier Ointment with Insecticide (benzalkonium chloride, polyhexanide and cypermethrin topical ointment) for New World Screwworm (NWS)

I have concluded, pursuant to Section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of F10 Antiseptic Barrier Ointment with Insecticide, when used for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet

[5] "Approved" products include conditionally approved products for purposes of EUAs issued under Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.
[6] There are no approved products for horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals. Although there are conditionally approved products for the prevention and treatment of NWS in cattle, F10 Antiseptic Barrier Ointment with Insecticide provides an important option for treating and preventing NWS in cattle because it is a topical ointment product that is applied locally, directly to wounds. Cattle and other hoof stock are at particular risk of infestation by NWS, and a diverse and sufficient supply of products is needed to adequately address an incursion in the United States.
[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

birds, and captive wild, exotic, and zoo mammals and used in accordance with this authorization, outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the FD&C Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that F10 Antiseptic Barrier Ointment with Insecticide may be effective for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that F10 Antiseptic Barrier Ointment with Insecticide, as described in this authorization, meets the criteria set forth in Section 564(c) of the FD&C Act concerning safety and potential effectiveness.

The emergency use of this product under an EUA must be consistent with, and may not exceed, the terms of this authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the FD&C Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the FD&C Act, F10 Antiseptic Barrier Ointment with Insecticide is authorized for the prevention and treatment of infestations caused by NWS larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals as described in this authorization, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

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

A. Health and Hygiene will ensure that the authorized F10 Antiseptic Barrier Ointment with Insecticide, accompanied with the authorized Fact Sheet, is distributed to authorized distributor(s)[8] consistent with the terms and conditions of this EUA, and that authorized distributor(s) will limit distribution to other authorized distributors and end users.

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

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

[8] The term "distributors" includes all parties in the supply chain between the recipient of this authorization letter and the end user, excluding veterinary facilities and veterinarians who only provide product to veterinarians and end users at their facility. "Authorized distributors" are all distributors who otherwise lawfully obtain and distribute the product, unless Health and Hygiene places limits on distribution in writing (e.g., via contract or written notice accompanying the product).

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

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

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

Health and Hygiene will report to FDA all product/manufacturing defects[10] within 3 days, all serious adverse events[11] and medication errors[12] associated with the use of the authorized F10 Antiseptic Barrier Ointment with Insecticide that are reported to Health and Hygiene within 15 days, and all non-serious adverse drug events within 90 days. Submit the reports electronically using either of the following options which are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage (www.fda.gov/IndustryReportAnimalAE).

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

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

Submitted reports must state in the "Narrative of Adverse Event" field: "F10 Antiseptic Barrier Ointment with Insecticide use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at CVMAESupport@fda.hhs.gov for any questions related to electronic reporting or for assistance with setting up a Safety Reporting Portal account.

[9] Changes that do not necessitate revision to this letter (e.g., changes to the Fact Sheet, changes related to current good manufacturing practice requirements, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.
[10] Product defect/manufacturing defect is the deviation of a distributed product from the standards specified in the indexed file, or any significant chemical, physical, or other change, or deterioration in the distributed drug product, including any microbial or chemical contamination. A manufacturing defect is a product defect caused or aggravated by a manufacturing or related process. A manufacturing defect may occur from a single event or from deficiencies inherent to the manufacturing process. These defects are generally associated with product contamination, product deterioration, manufacturing error, defective packaging, damage from disaster, or labeling error. For example, a labeling error may include any incident that causes a distributed product to be mistaken for, or its labeling applied to, another product.
[11] Serious adverse event is an adverse event that is fatal, or life-threatening, or requires professional intervention, or causes an abortion, or stillbirth, or infertility, or congenital anomaly, or prolonged or permanent disability, or disfigurement.
[12] Medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

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

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

I. Health and Hygiene and any person engaged in manufacturing, packing, or holding will comply with all FD&C Act requirements for animal drugs, including, but not limited to, registration and listing and drug quality requirements (e.g., current good manufacturing practice requirements),[13] unless such requirements are specifically waived or modified for the authorized product in this authorization. Health and Hygiene and any person engaged in manufacturing, packing or holding shall only manufacture F10 Antiseptic Barrier Ointment with insecticide using the processes, facilities, controls, and equipment specified in the file for this EUA request at the time of authorization, and no changes may be implemented until accepted by FDA.[14]

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

J. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of F10 Antiseptic Barrier Ointment with Insecticide shall be consistent with the authorized Fact Sheet[15] and the terms set forth in this EUA, as well as comply with FD&C Act Section 502(a). Additionally, the sponsor and authorized distributor(s) shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.

K. Health and Hygiene and authorized distributor(s) may not imply that F10 Antiseptic Barrier Ointment with Insecticide is FDA approved, conditionally approved, or indexed for the authorized use by making statements such as “F10 Antiseptic Barrier Ointment with Insecticide is safe and effective for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cattle, horses, minor species of hoof stock, raptors and other wild birds, pet birds, and captive wild, exotic, and zoo mammals”. Health and Hygiene and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of F10 Antiseptic Barrier Ointment with Insecticide that provide accurate descriptions of safety and effectiveness information summarized in the authorized Fact Sheet. Such materials must include any limitations of information submitted to support this authorization.

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

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

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

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

- F10 Antiseptic Barrier Ointment with Insecticide is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of F10 Antiseptic Barrier Ointment with Insecticide under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revised or revoked sooner.

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

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

IV. Duration of Authorization

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

Sincerely,

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

Enclosures:
Freedom of Information Summary
Fact Sheet