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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0004]

Authorization of Emergency Use for Three Animal Drugs for the Prevention and Treatment of New World Screwworm; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the issuance of three Emergency Use Authorizations (EUA or Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for new animal products. FDA has issued one EUA for an animal product as requested by Zoetis Inc. for the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*; NWS) larvae (myiasis) in dairy cattle, horses, swine, sheep, and deer. FDA has issued one EUA for an animal product as requested by Felix Pharmaceuticals Pvt. Ltd. for the treatment of infestations caused by NWS myiasis in dogs, puppies, cats, and kittens. FDA has issued one EUA for an animal product as requested by Alberta Vet Labs Ltd for the short-term prevention of infestations caused by NWS myiasis in horses. The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the August 18, 2025, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves NWS. On the basis of such determination, the Secretary of HHS declared on August 18, 2025, that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorizations are effective on their dates of issuance: May 19, 2026, June 11, 2026, and July 15, 2026, respectively.

ADDRESSES: Submit written requests for single copies of the EUAs to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Crystal Groesbeck, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240-402-0819, Crystal.Groesbeck@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents

(CBRN); (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (i) a CBRN; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces;[1] (C) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents; or (D) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the *Federal Register* a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on FDA's website. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355,

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine, within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration (see section 564(b)(6) of the FD&C Act).

360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

Under section 564(c) of the FD&C Act, FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA[2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorizations

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

The Authorizations follow the August 18, 2025, determination by the Secretary of HHS that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves NWS. On the basis of such determination, the Secretary of HHS declared, on August 18, 2025, that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals. Notice of the Secretary's determination and declaration was provided in the *Federal Register* on August 20, 2025 (90 FR 40609). Having concluded that the criteria for the issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has issued three authorizations for the emergency use of animal products. On May 19, 2026, FDA issued an EUA to Zoetis Inc. for the animal product Dectomax/Dectomax-CA1 (doramectin injection), subject to the terms of its Authorization. On June 11, 2026, FDA issued an EUA to Felix Pharmaceuticals Pvt. Ltd. for the animal product Nitenpyram Tablets (nitenpyram), subject to the terms of its Authorization. On July 15, 2026, FDA issued an EUA to Alberta Vet Labs Ltd for the animal product Ivermectin Liquid for Horses (ivermectin oral solution), subject to the terms of its Authorization.

The initial Authorizations, included below in their entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provide explanations of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuance of the Authorizations can be found on FDA's web page at: https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians.

IV. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

U.S. FOOD & DRUG ADMINISTRATION

May 19, 2026

Zoetis Inc.
Attention: John Hallberg, DVM, PhD
Senior Director of Regulatory Affairs
333 Portage St.
Kalamazoo, MI 49007

Re: Emergency Use Authorization 006700

Dear Dr. Hallberg:

This letter is in response to the request by Zoetis Inc. (Zoetis) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of DECTOMAX/DECTOMAX-CA1 (doramectin injection)[1] for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

On August 18, 2025, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025, declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to Section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.[2]

DECTOMAX (doramectin injection) is an antiparasitic drug that is indicated under NADA 141-061 for the treatment and control of nematode and arthropod parasites in cattle and swine. DECTOMAX-CA1 (doramectin injection) is the same antiparasitic drug, is indicated under NADA 141-616, and conditionally approved for the prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and the prevention of reinfestation for 21 days in cattle.

Based on the totality of scientific evidence available to the FDA, including dose confirmation studies, pharmacokinetic studies, margin of safety studies, and published scientific literature, it

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[1] Unless specified by name, products sold under separate distributor's labeling per 21 CFR 514.80(b)(5)(iii) (i.e., with a different proprietary name) are not subject to this EUA. A request must be made to change to the scope of this authorization for such products.

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

is reasonable to believe that DECTOMAX/DECTOMAX-CA1 (doramectin injection) may be effective for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of DECTOMAX/DECTOMAX-CA1 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 DECTOMAX/DECTOMAX-CA1 (doramectin injection) for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, 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 DECTOMAX/DECTOMAX-CA1 for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, 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 DECTOMAX/DECTOMAX-CA1 may be effective in treating and/or preventing NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of DECTOMAX/DECTOMAX-CA1 when used to prevent and/or treat NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved,[3] and available alternative to the emergency use of DECTOMAX/DECTOMAX-CA1 for the prevention and treatment of infestations caused

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

by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer.[4]

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:

- DECTOMAX/DECTOMAX-CA1, as covered by this authorization, will be used only for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, over the counter. DECTOMAX/DECTOMAX-CA1 may be administered by subcutaneous injection only in dairy cattle and deer, by intramuscular injection only in swine and horses, and by subcutaneous or intramuscular injection in sheep.

- The use of DECTOMAX/DECTOMAX-CA1 covered by this authorization must be in accordance with the authorized Fact Sheets.

Product Description

DECTOMAX/DECTOMAX-CA1 is a highly active, broad-spectrum parasiticide. It contains doramectin, a fermentation-derived macrocyclic lactone. The authorized DECTOMAX/DECTOMAX-CA1 (doramectin injection) Fact Sheets/label are clearly marked for the approved indications and for NWS under Emergency Use Authorization with a website address and QR code that links to the authorized Fact Sheet(s).

Store below 30°C (86°F).

DECTOMAX/DECTOMAX-CA1 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 DECTOMAX/DECTOMAX-CA1 (doramectin injection) for New World Screwworm (NWS) Dairy Cattle, Swine, Sheep, and Deer

- Fact Sheet: Emergency Use Authorization of DECTOMAX/DECTOMAX-CA1

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

(doramectin injection) for New World Screwworm (NWS) Horses

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 DECTOMAX/DECTOMAX-CA1, when used for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, 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 DECTOMAX/DECTOMAX-CA1 may be effective for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, 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 DECTOMAX/DECTOMAX-CA1, 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, DECTOMAX/DECTOMAX-CA1 is authorized for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer, except for horses under one year of age and lactating sheep, 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. Zoetis will ensure that the authorized DECTOMAX/DECTOMAX-CA1, accompanied with the authorized Fact Sheets, is distributed to authorized distributor(s)[5] 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. Zoetis 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 Sheets and that the sticker is placed in a blank space or does not obscure any important use or safety information.

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

D. Zoetis 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 Sheets).

E. Zoetis may request changes to this authorization, including to the authorized Fact Sheets for DECTOMAX/DECTOMAX-CA1. Requests for changes must be submitted to the Office of New Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.[6]

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

   Zoetis will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Zoetis will attempt to determine whether the use of DECTOMAX/DECTOMAX-CA1 was related to the EUA and will put this categorization, as well as the reason for use, in the narrative description of the adverse event. Zoetis will submit the reports electronically using either of the options that are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage (www.fda.gov/IndustryReportAnimalAE).

   Submitted reports must state in the "Narrative of Adverse Event" field: "DECTOMAX/DECTOMAX-CA1 use for NWS under an EUA". Contact the Pharmacovigilance Liaison in CVM's Division of Pharmacovigilance and Surveillance at CVMAESupport@fda.hhs.gov for any questions related to electronic reporting or for assistance with setting up a Safety Reporting Portal account.

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[5] 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 Zoetis places limits on distribution in writing (e.g., via contract or written notice accompanying the product).
[6] Changes that do not necessitate revision to this letter (e.g., changes to the Fact Sheets, changes related to current good manufacturing practice requirements, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

G. Through a process of inventory control, Zoetis and authorized distributor(s) will maintain records regarding distribution of the authorized DECTOMAX/DECTOMAX-CA1 (i.e., lot numbers, quantity, receiving site, receipt date).

H. Zoetis 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. Zoetis (and any other person engaged in manufacturing, packing, or holding) will comply with all other FD&C Act requirements applicable to the approved product, DECTOMAX/DECTOMAX-CA1, including, but not limited to, requirements related to registration and listing, drug quality, and the requirement to manufacture using the processes, facilities, controls, and equipment specified in the approved application,[7] unless such requirements are specifically waived or modified in this authorization. Zoetis, and authorized distributor(s) who distribute EUA product under separate distributor labeling, if any, shall update their drug listing to reflect the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

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 DECTOMAX/DECTOMAX-CA1, shall be consistent with the authorized Fact Sheets[8] 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. Zoetis and authorized distributor(s) may not imply that DECTOMAX/DECTOMAX-CA1 is FDA approved or conditionally approved for the authorized use by making statements such as "DECTOMAX/DECTOMAX-CA1 is safe and effective for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer." Zoetis and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of DECTOMAX/DECTOMAX-CA1 that provide accurate descriptions of safety and effectiveness information summarized in the

[7] Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.
[8] 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.

authorized Fact Sheets. 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 DECTOMAX/DECTOMAX-CA1 shall be accompanied by the authorized Fact Sheets and the applicable approved labeling (e.g., package insert attached to the vial), and shall clearly and conspicuously state that:

- DECTOMAX/DECTOMAX-CA1 has not been approved for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal. DECTOMAX/DECTOMAX-CA1 has not been approved for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer.

- DECTOMAX/DECTOMAX-CA1 has been authorized by FDA under an EUA for the prevention and treatment of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal; and, for the prevention of infestations caused by *Cochliomyia hominivorax* larvae (myiasis) in horses one year and older, swine, sheep except for lactating sheep, and deer; and

- DECTOMAX/DECTOMAX-CA1 is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of DECTOMAX/DECTOMAX-CA1 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 the CVM OSC DER eSubmitter Program at the time of initial dissemination (publication or broadcast). Each submission of promotional labeling or advertisements must be accompanied by a completed Form FDA 2301.

If FDA notifies Zoetis or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Zoetis 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 Zoetis 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 Sheets (2)

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION

June 11, 2026

Felixvet Inc.
Attention: Sreejith Kurup
Vice President
U.S. Agent for Felix Pharmaceuticals Pvt. Ltd.
25-28 North Wall Quay
Dublin 1, Ireland

Re: Emergency Use Authorization 006661

Dear Mr. Kurup:

This letter is in response to the request on behalf of Felix Pharmaceuticals Pvt. Ltd. (Felix) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of Nitenpyram Tablets (nitenpyram)[1] for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

On August 18, 2025, pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025, declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to Section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.[2]

Nitenpyram Tablets are an oral antiparasitic that are indicated under ANADA 200-858 to kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older. Nitenpyram Tablets are not approved for the treatment of NWS myiasis.

Based on the totality of scientific evidence available to the FDA, including data from published literature, it is reasonable to believe that Nitenpyram Tablets may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Nitenpyram Tablets outweigh the known and potential risks of such product, since NWS infestations can have significant adverse health consequences and

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[1] Unless specified by name, products sold under separate distributor's labeling per 21 CFR 514.80(b)(5)(iii) (i.e., with a different proprietary name) are not subject to this EUA. A request must be made to change to the scope of this authorization for such products.

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

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 Nitenpyram Tablets for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, 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 Nitenpyram Tablets for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, 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 Nitenpyram Tablets may be effective in treating NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of Nitenpyram Tablets when used to treat NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved[3], and available alternative[4] to the emergency use of Nitenpyram Tablets for the treatment of infestations caused by NWS (*Cochliomyia*

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

[4] There are no approved alternatives for the treatment of NWS myiasis in cats and kittens.
There are no approved alternatives for the treatment of NWS myiasis in dogs and puppies between 4 and 8 weeks of age or weighing between 2 and 3.3 pounds because the conditionally approved product is indicated for the treatment of NWS in dogs and puppies at least 8 weeks of age and weighing at least 3.3 pounds.
Additionally, there are no adequate approved over the counter (OTC) products for dogs and puppies, and OTC marketing will allow the product to be available in circumstances where access to a veterinarian is limited.
Furthermore, there are no approved products with a single active ingredient for the treatment of NWS myiasis in dogs and puppies; Nitenpyram Tablets contain a single active pharmaceutical ingredient, whereas the conditionally approved product contains multiple active ingredients. The presence of multiple active ingredients in the conditionally approved product may increase the likelihood of adverse events in dogs and puppies that have recently been treated with a heartworm preventative or other antiparasitic drug in the same pharmacological class as one of the conditionally approved product's active ingredients. Because Nitenpyram Tablets contain only a single active ingredient that is not in that drug class, their use may minimize the potential for adverse events in these dogs.
Lastly, Nitenpyram Tablets act through a mechanism of action that is distinct from each of the active ingredients in the conditionally approved product. Because no approved alternative product works through the same mechanism of action as Nitenpyram Tablets, the conditionally approved product is not an adequate therapeutic substitute in circumstances where Nitenpyram Tablets distinct mechanism of action is clinically relevant.

hominivorax) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older.[5]

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:

- Nitenpyram Tablets, as covered by this authorization, will be used only for over the counter use in dogs and cats 2 pounds of body weight or greater and 4 weeks of age and older; and

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

Product Description

Nitenpyram Tablets are oral tablets for dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older. Nitenpyram Tablets belong to the chemical class of neonicotinoids and kill adult fleas. The authorized Nitenpyram Tablets carton labeling is clearly marked for the approved indications and for NWS under Emergency Use Authorization, with a website address and QR code that links to the authorized Fact Sheet.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).

Nitenpyram Tablets are 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 Nitenpyram Tablets (Nitenpyram) 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 Nitenpyram Tablets, when used for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older 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 Nitenpyram Tablets may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

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[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) 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 Nitenpyram Tablets, as described in this authorization, meet 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, Nitenpyram Tablets are authorized for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older 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. Felix will ensure that the authorized Nitenpyram Tablets, accompanied with the authorized Fact Sheet, are 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. Felix 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. Felix and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.

D. Felix 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).

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

E. Felix may request changes to this authorization, including to the authorized Fact Sheet for Nitenpyram Tablets. Requests for changes must be submitted to the Office of Generic Animal Drugs. Such changes require appropriate authorization prior to implementation.[7]

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

Felix will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Felix will attempt to determine whether the use of Nitenpyram Tablets was related to the EUA and will put this categorization, as well as the reason for use, in the narrative description of the adverse event. Felix will submit the reports electronically using either of the options that are described on FDA's Veterinary Adverse Event Reporting for Manufacturers webpage (www.fda.gov/IndustryReportAnimalAE).

Submitted reports must state in the "Narrative of Adverse Event" field: "Nitenpyram Tablets 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, Felix and authorized distributor(s) will maintain records regarding distribution of the authorized Nitenpyram Tablets (i.e., lot numbers, quantity, receiving site, receipt date).

H. Felix 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. Felix (and any other person engaged in manufacturing, packing, or holding) will comply with all other FD&C Act requirements applicable to the approved product, Nitenpyram Tablets, including, but not limited to, requirements related to registration and listing, drug quality, and the requirement to manufacture using the processes, facilities, controls, and equipment specified in the approved application,[8] unless such requirements are specifically waived or modified in this authorization. Felix, and authorized distributor(s) who distribute EUA product under separate distributor labeling, if any, shall update their drug listing to reflect the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

[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] Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.

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 Nitenpyram Tablets, shall be consistent with the authorized Fact Sheet[9] 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. Felix and authorized distributor(s) may not imply that Nitenpyram Tablets are FDA approved, conditionally approved, or indexed for the authorized use. Felix and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Nitenpyram Tablets 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 Nitenpyram Tablets shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:

- Nitenpyram Tablets have not been approved for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older;

- Nitenpyram Tablets have been authorized by FDA under an EUA for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older; and

- Nitenpyram Tablets are authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Nitenpyram Tablets 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 the CVM OSC DER eSubmitter Program at

[9] 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.

the time of initial dissemination (publication or broadcast). Each submission of promotional labeling or advertisements must be accompanied by a completed Form FDA 2301.

If FDA notifies Felix or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Felix 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 Felix 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

July 15, 2026

Argenta
Attention: Aaron Johnson, DVM, MS
Principal Regulatory Manager
U.S. Agent for Alberta Vet Labs Ltd
7226 107 Ave SE
Calgary, Alberta, T2C 5N6, Canada

Re: Emergency Use Authorization 006681

Dear Dr. Johnson:

This letter is in response to the request on behalf of Alberta Vet Labs Ltd (AVL) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of Ivermectin Liquid for Horses (ivermectin oral solution)[1] for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses, 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 significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025, declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to Section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.[2]

Ivermectin Liquid for Horses (ivermectin oral solution) is an antiparasitic. Ivermectin Liquid for Horses (ivermectin oral solution) is not FDA-approved for any indication.

Based on the totality of scientific evidence available to the FDA, including pharmacokinetic data from a bioequivalence study and information in published scientific literature, it is reasonable to believe that Ivermectin Liquid for Horses (ivermectin oral solution) may be effective for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Ivermectin Liquid for Horses (ivermectin oral

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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] 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

solution) 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 Ivermectin Liquid for Horses (ivermectin oral solution) for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses, 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 Ivermectin Liquid for Horses (ivermectin oral solution) for short-term prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses, 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 Ivermectin Liquid for Horses (ivermectin oral solution) 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 Ivermectin Liquid for Horses (ivermectin oral solution) when used to prevent NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved,[3] and available alternative to the emergency use of Ivermectin Liquid for Horses (ivermectin oral solution) for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses.[4]

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:

- Ivermectin Liquid for Horses (ivermectin oral solution), as covered by this authorization, will be used only for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses as ordered by veterinary prescription; and

[3] "Approved" products include conditionally approved products for purposes of EUAs issued under Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

- The use of Ivermectin Liquid for Horses (ivermectin oral solution) covered by this authorization must be in accordance with the authorized Fact Sheet.

Product Description

Ivermectin Liquid for Horses (ivermectin oral solution) is an oral antiparasitic for use in horses. The authorized Ivermectin Liquid for Horses (ivermectin oral solution) 120 mL bottle vial and carton labels and 15 mL syringe overwrap are clearly marked for NWS under Emergency Use Authorization, with a website address and QR code that links to the authorized Fact Sheet.

Ivermectin Liquid for Horses (ivermectin oral solution) should be stored tightly closed at or below 77°F (25°C) and protected from light.

Ivermectin Liquid for Horses (ivermectin oral solution) is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to veterinarians and others who may administer the product:

- Fact Sheet for Veterinarians: Emergency Use Authorization of Ivermectin Liquid for Horses (ivermectin oral solution) 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 Ivermectin Liquid for Horses (ivermectin oral solution), when used for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses 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 Ivermectin Liquid for Horses (ivermectin oral solution) may be effective for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses 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 Ivermectin Liquid for Horses (ivermectin oral solution), 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, Ivermectin Liquid for Horses (ivermectin oral solution) is

authorized for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses 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. AVL will ensure that the authorized Ivermectin Liquid for Horses (ivermectin oral solution), accompanied with the authorized Fact Sheet, is distributed to veterinary facilities[5] and veterinarians, or 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. AVL 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. AVL and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to veterinary facilities and veterinarians.

D. AVL and authorized distributor(s) will ensure that the terms and conditions of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, veterinary facilities, and veterinarians) involved in distributing or receiving authorized Ivermectin Liquid for Horses (ivermectin oral solution). AVL will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (e.g., its authorized Fact Sheet).

E. AVL may request changes to this authorization, including to the authorized Fact Sheet for Ivermectin Liquid for Horses (ivermectin oral solution). Requests for changes must be submitted to the Office of New Animal Product Evaluation. Such changes require appropriate authorization prior to implementation.[7]

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[5] Veterinary facilities include veterinary hospitals, veterinary clinics, and other establishments providing veterinary care. If a veterinarian is not associated with a veterinary facility, the veterinarian then assumes the obligations of the veterinary facility.

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

[7] 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.

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

AVL 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 Ivermectin Liquid for Horses (ivermectin oral solution) that are reported to AVL 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 should state in the "Narrative of Adverse Event" field: "Ivermectin Liquid for Horses (ivermectin oral solution) 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, AVL and authorized distributor(s) will maintain records regarding distribution of the authorized Ivermectin Liquid for Horses (ivermectin oral solution) (i.e., lot numbers, quantity, receiving site, receipt date).

H. AVL 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. AVL 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 Ivermectin

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[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.

[11] Among other requirements, all expiration dates shall be established in accordance with 21 CFR 211.137.

Liquid for Horses (ivermectin oral solution) 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 for Veterinary Facilities and Veterinarians

J. Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of this Letter of Authorization. Authorized Fact Sheets will be made available to veterinarians, and veterinary facilities and veterinarians will ensure that the client is aware that the drug is authorized for emergency use, but not approved, for the treatment of NWS myiasis and advise the client of the risks, benefits, and any alternatives.

K. Veterinary facilities and veterinarians receiving Ivermectin Liquid for Horses (ivermectin oral solution) will track serious adverse events potentially related to Ivermectin Liquid for Horses (ivermectin oral solution) use under this EUA and must report these to FDA in accordance with the Fact Sheet for Veterinarians. Report by (1) contacting AVL at 1-877-456-2755, (2) downloading and submitting Form FDA 1932a available at https://www.fda.gov/reportanimalae, or (3) contacting FDA at 1-888-FDA-VETS to request this form. Include the statement "Ivermectin Liquid for Horses (ivermectin oral solution) use for NWS under an EUA" under the "Describe Adverse Event/Product Problem/Product Use Error" heading, followed by a detailed account of the adverse event.

L. Veterinary facilities will maintain inventory records regarding the dispensing and administration of Ivermectin Liquid for Horses (ivermectin oral solution) for the use authorized in this Letter of Authorization. The records will include lot numbers, quantity, receiving site (if a multi-site clinic), and receipt date.

M. Veterinary facilities will maintain health records that include the following information: client name, patient name, patient age, disease manifestation, number of doses prescribed or administered per patient, lot number prescribed or administered, and other drugs coadministered. The records shall be maintained in a manner that allows veterinary facilities to identify in a reasonable time which patients received drugs subject to this EUA.

N. Veterinary facilities will maintain any records associated 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. Such records will be made available to AVL, HHS, and FDA for inspection upon request.

[12] Any request submitted via an update to the file is considered accepted after 30 calendar days unless FDA provides notice to the contrary.

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

O. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of Ivermectin Liquid for Horses (ivermectin oral solution) 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 Sections 502(a) and 502(n), and 21 CFR Part 202. 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.

P. AVL and authorized distributor(s) may not imply that Ivermectin Liquid for Horses (ivermectin oral solution) is FDA approved, conditionally approved, or indexed for the authorized use. AVL and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Ivermectin Liquid for Horses (ivermectin oral solution) 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.

Q. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of Ivermectin Liquid for Horses (ivermectin oral solution) shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:

- Ivermectin Liquid for Horses (ivermectin oral solution) has not been approved for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses;

- Ivermectin Liquid for Horses (ivermectin oral solution) has been authorized by FDA under an EUA for short-term prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth or at the time of initial wound care in horses; and

- Ivermectin Liquid for Horses (ivermectin oral solution) is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Ivermectin Liquid for Horses (ivermectin oral solution) 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.

R. 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

[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 authorized 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.

submission at the time of initial dissemination (publication or broadcast). When submitting, identify the submission as promotion and advertising material.

If FDA notifies AVL or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, AVL 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 AVL 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,

/S/

Timothy Schell, Ph.D.
Director
Center for Veterinary Medicine
U.S. Food and Drug Administration

Enclosures:
Freedom of Information Summary
Fact Sheet

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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