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

[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

[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