U.S. FOOD & DRUG ADMINISTRATION

February 5, 2026

Boehringer Ingelheim Animal Health USA, Inc.
Attention: Tracy Robertson
Regulatory Affairs, Operations
3239 Satellite Blvd.
Duluth, GA 30096

Re: Emergency Use Authorization 006689

Dear Ms. Robertson:

This letter is in response to the request by Boehringer Ingelheim Animal Health USA, Inc. (Boehringer) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of Ivomec (ivermectin) injection for prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal[1], 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]

Ivomec (ivermectin) injection is an antiparasitic drug that is indicated under NADA 128-409 for the treatment and control of a variety of internal and external parasites in cattle. Ivomec (ivermectin) injection is not approved or conditionally approved for prevention of NWS myiasis.

Based on the scientific evidence available to the FDA, including summaries of dose confirmation studies and published scientific literature, it is reasonable to believe that Ivomec (ivermectin) injection may be effective for prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Ivomec (ivermectin) injection

[1] Hereinafter, "cattle, except for female dairy cattle producing milk for human consumption and calves that will be processed for veal," will be referred to as "certain cattle."
[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

outweigh the known and potential risks of such product.

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 Ivomec (ivermectin) injection for prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle, 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 Ivomec (ivermectin) injection for prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle, 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 scientific evidence available to FDA, it is reasonable to believe that Ivomec (ivermectin) injection 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 Ivomec (ivermectin) injection when used to prevent NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative[3] to the emergency use of Ivomec (ivermectin) injection for prevention of infestations caused by NWS larvae (myiasis) in certain cattle for the authorized indications.[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:

- Ivomec (ivermectin) injection, as covered by this authorization, will be used only for prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle; and

[3] Other therapeutics are conditionally approved for prevention of infestations caused by NWS larvae (myiasis) in cattle. However, these products are not available alternatives because there are insufficient quantities to meet the demands of a widescale incursion of NWS into the United States. In addition, one conditionally approved product is not an adequate alternative because it requires a prescription, potentially delaying administration. There is a significant benefit to expedient administration of a preventative product, particularly if animals nearby are infested. Thus, FDA concluded that this additional OTC injectable macrocyclic lactone product indicated for prevention of NWS in cattle is needed to meet the demands of a widescale incursion of NWS into the United States.
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

- The use of Ivomec (ivermectin) injection covered by this authorization must be in accordance with the authorized Fact Sheet.

Product Description

Ivomec (ivermectin) injection is derived from the avermectins, a family of broad-spectrum antiparasitic agents. The authorized Ivomec (ivermectin) injection carton label 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 or below 25°C (77°F) with excursions permitted up to 30°C (86°F). Protect product from light.

Ivomec (ivermectin) injection 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 Ivomec (ivermectin) Injection 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 Ivomec (ivermectin) injection, when used for prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle 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 scientific evidence available to FDA, that it is reasonable to believe that Ivomec (ivermectin) injection may be effective for prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle 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 Ivomec (ivermectin) injection, 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, Ivomec (ivermectin) injection is authorized for prevention of infestations caused by NWS larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle 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. Boehringer will ensure that the authorized Ivomec (ivermectin) injection, accompanied with the authorized Fact Sheet, 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. Boehringer will ensure that if a sticker is used on the labeling, that 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. Boehringer and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.

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

E. Boehringer may request changes to this authorization, including to the authorized Fact Sheet for Ivomec (ivermectin) injection. 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:

   Boehringer will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Boehringer will attempt to determine whether the use of Ivomec (ivermectin) injection 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. Boehringer 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).

[5] The term "distributors" includes all parties in the supply chain between the recipient of this authorization letter and the end user. "Authorized distributors" are all distributors who otherwise lawfully obtain and distribute the product, unless Boehringer places limits on distribution in writing (e.g., via contract or written notice accompanying the product).
[6] Revisions that do not necessitate revision to this letter (e.g., changes to the Fact Sheet, specified cGMPs, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.

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

H. Boehringer and authorized distributor(s) will maintain records in connection with this EUA for at least two years following the termination of the declaration or 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. Boehringer will comply with all other FD&C Act requirements applicable to the approved product, Ivomec (ivermectin) injection, including, but not limited to, requirements related to registration and listing, drug quality, and manufacturing process, facilities, and equipment in accordance with the approved application[7] unless such requirement is specifically waived or modified for the authorized product in this authorization. Boehringer 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 Ivomec (ivermectin) injection, shall be consistent with the authorized Fact Sheet[8], and the terms set forth in this EUA, as well as comply with FD&C Act section 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.

K. Boehringer and authorized distributor(s) may not imply that Ivomec (ivermectin) injection is FDA approved or conditionally approved for the authorized use by making statements such as "Ivomec (ivermectin) injection is safe and effective for prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle". Boehringer and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Ivomec (ivermectin) injection that provide accurate descriptions of safety and

[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.

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 Ivomec (ivermectin) injection shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:

- Ivomec (ivermectin) injection has not been approved for prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle;

- Ivomec (ivermectin) injection has been authorized by FDA under an EUA for prevention of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle; and

- Ivomec (ivermectin) injection is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Ivomec (ivermectin) injection under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization 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 Boehringer that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Boehringer 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 Boehringer 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