August 27, 2026

Bimeda Inc.
Attention: Stephanie Batliner
VP R&D and Regulatory Affairs North America
U.S. Agent for Bimeda Animal Health Ltd.
1B The Herbert Building, The Park
Carrickmines, Dublin 18
Ireland

Re: Emergency Use Authorization 006729

Dear Ms. Batliner:

This letter is in response to the request on behalf of Bimeda Animal Health Ltd. (Bimeda) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of Bimectin (ivermectin) injection[1] for the 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,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3).

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

Bimectin (ivermectin) injection is an antiparasitic drug that is indicated under ANADA 200-447 for the treatment and control of a variety of internal and external parasites in cattle, swine, reindeer, and American bison. Bimectin injection is not approved for the prevention of NWS myiasis.

Based on the totality of scientific evidence available to the FDA, including summaries of data

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[1] Bimectin (ivermectin) injection is also distributed by Aspen Veterinary Resources, LTD; Durvet, Inc.; and MWI under the proprietary names IVERMAX; Ivermectin; and Vetrimec 1%, respectively. All references to Bimectin in this letter include each of the drugs sold under the aforementioned proprietary names. This authorization is limited to Bimectin, IVERMAX, Ivermectin, and Vetrimec 1%. Except those previously named, any other products sold under separate distributor's labeling per 21 CFR 514.80(b)(5)(iii) are not subject to this EUA. A request must be made to change the scope of this authorization for any additional products.

[2] 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".

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

from studies performed on ivermectin injection, it is reasonable to believe that Bimectin (ivermectin) injection may be effective for the prevention of NWS myiasis in certain cattle, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Bimectin injection 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 Bimectin injection for the 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, 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 Bimectin injection for the 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 totality of scientific evidence available to FDA, it is reasonable to believe that Bimectin 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 Bimectin injection when used to prevent NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved,[4] and available alternative[5] to the emergency use of Bimectin injection for the prevention of infestations caused by NWS larvae (myiasis)

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

[5] While there are therapeutics conditionally approved for prevention of infestations caused by NWS larvae (myiasis) in cattle, they are not considered adequate and available alternatives for the purpose of this analysis. The existing conditionally approved injectable product is not an available alternative because there are insufficient quantities to meet the demands of a widescale incursion of NWS into the United States. The conditionally approved topical product is not an adequate alternative because it is a different pharmacological class with a different route of administration, and its label restricts use to cattle two months of age and older. Furthermore, because this topical product requires a prescription, it is not a readily available alternative, as the requirement for veterinary intervention could delay 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 over-the-counter 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.

when administered within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle.[6]

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:

- Bimectin injection, as covered by this authorization, will be dispensed over the counter and used only for subcutaneous administration within 24 hours of birth, at the time of castration, or at the appearance of a wound in certain cattle; and

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

Product Description

Bimectin injection is derived from the avermectins, a family of broad-spectrum antiparasitic agents. The authorized Bimectin injection labeling (vial labels, carton labeling, and package insert) 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°C to 25°C (68°F to 77°F). Protect product from light.

Bimectin 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 Bimectin (ivermectin) Injection for New World Screwworm (NWS)[7]

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 Bimectin injection, when used for the 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 totality of scientific evidence available to FDA, that it is reasonable to believe that Bimectin injection may be effective for the 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.

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[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.
[7] IVERMAX, Ivermectin, and Vetrimec 1% will be accompanied by the IVERMAX Fact Sheet, Ivermectin Fact Sheet, and Vetrimec 1% Fact Sheet, respectively. Hereinafter, when we refer to the Bimectin Fact Sheet we are including all four Fact Sheets which differ only in the product name and distributor.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Bimectin 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, Bimectin injection is authorized for the 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. Bimeda will ensure that the authorized Bimectin injection, accompanied with the authorized Fact Sheet, is distributed to authorized distributor(s)[8] consistent with the terms and conditions of this EUA, and that authorized distributor(s) will limit distribution to other authorized distributors and end users.

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

D. Bimeda 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. Bimeda may request changes to this authorization, including to the authorized Fact Sheet for Bimectin injection. Requests for changes must be submitted to the Office of Generic Animal Drugs. Such changes require appropriate authorization prior to implementation.[9]

[8] The term "distributors" includes all parties in the supply chain between the recipient of this authorization letter and the end user, excluding veterinary facilities and veterinarians who only provide product to veterinarians and end users at their facility. "Authorized distributors" are all distributors who otherwise lawfully obtain and distribute the product, unless Bimeda places limits on distribution in writing (e.g., via contract or written notice accompanying the product).
[9] 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.

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

Bimeda will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Bimeda will attempt to determine whether the use of Bimectin 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. Bimeda 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: "Bimectin injection 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, Bimeda and authorized distributor(s) will maintain records regarding distribution of the authorized Bimectin injection (i.e., lot numbers, quantity, receiving site, receipt date).

H. Bimeda 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. Bimeda (and any other person engaged in manufacturing, packing, or holding) will comply with all other FD&C Act requirements applicable to the approved product, Bimectin injection, 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,[10] unless such requirements are specifically waived or modified in this authorization. Bimeda, 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 Bimectin injection, shall be consistent with the authorized Fact Sheet[11] and the terms set forth in this EUA, as well as

[10] Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.
[11] 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.

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. Bimeda and authorized distributor(s) may not imply that Bimectin injection is FDA approved, conditionally approved, or indexed for the authorized use. Bimeda and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Bimectin injection 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 Bimectin 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:

- Bimectin injection has not been approved for the 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;

- Bimectin injection has been authorized by FDA under an EUA for the 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

- Bimectin injection is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Bimectin 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 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 Bimeda or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Bimeda 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 Bimeda 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