U.S. FOOD & DRUG ADMINISTRATION

February 18, 2026

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

Re: Emergency Use Authorization 006686

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 NexGard COMBO (esafoxolaner, eprinomectin, and praziquantel topical solution) for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens, 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.[1]

NexGard COMBO is a topical antiparasitic that is indicated under NADA 141-570 for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (fourth stage larval and adult *Toxocara cati*), hookworm (fourth stage larval and adult *Ancylostoma tubaeforme*; adult *Ancylostoma braziliense*), and tapeworm (*Dipylidium caninum*) infections. NexGard COMBO kills adult fleas (*Ctenocephalides felis*) and is also indicated under NADA 141-570 for the treatment and prevention of flea infestations and the treatment and control of *Ixodes scapularis* (black-legged tick) and *Amblyomma americanum* (lone star tick) infestations for one month in cats and kittens 8 weeks of age and older, and weighing 1.8 lbs or greater. NexGard COMBO is not approved for the treatment of NWS larvae (myiasis).

Based on the totality of scientific evidence available to the FDA, including data from a laboratory effectiveness study, it is reasonable to believe that NexGard COMBO may be effective for the treatment of infestations caused NWS larvae (myiasis) in cats and kittens, as described in this

[1] 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

authorization, and when used under the conditions described in this authorization, the known and potential benefits of NexGard COMBO outweigh the known and potential risks of such product for cats of all ages and weights because NWS is potentially fatal in cats if left untreated, therefore justifying including cats less than 8 weeks of age and less than 1.8 lbs in this authorization.

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 NexGard COMBO for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens, 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 NexGard COMBO for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens, 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 NexGard COMBO 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 NexGard COMBO when used to treat NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative[2] to the emergency use of NexGard COMBO for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens.[3]

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:

- NexGard COMBO, as covered by this authorization, will be used only for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens by a veterinarian by prescription; and

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

[2] There are no approved products for the treatment of New World screwworm (myiasis) in cats and kittens.
[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the FD&C Act.

Product Description

NexGard COMBO is a topical antiparasitic. The authorized NexGard COMBO 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.

NexGard COMBO should be stored at 59° – 86°F (15° – 30°C). Brief periods up to 104°F (40°C) are permitted. Protect from light.

NexGard COMBO 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 NexGard COMBO (esafoxolaner, eprinomectin, and praziquantel topical 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 NexGard COMBO, when used for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens 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 NexGard COMBO may be effective for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens 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 NexGard COMBO, 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, NexGard COMBO is authorized for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens 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 NexGard COMBO, accompanied with the authorized Fact Sheet, is distributed to veterinary facilities[4] and veterinarians, or 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 is maintained until the product is delivered to veterinary facilities and veterinarians.

D. Boehringer 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 NexGard COMBO. Boehringer 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. Boehringer may request changes to this authorization, including to the authorized Fact Sheet for NexGard COMBO. Requests for changes should 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 NexGard COMBO 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).

   Submitted reports should state in the "Narrative of Adverse Event" field: "NexGard COMBO 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

[4] 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.
[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.

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 NexGard COMBO (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 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. Boehringer will comply with all other FD&C Act requirements applicable to the approved product, NexGard COMBO, 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 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 NexGard COMBO will track serious adverse events potentially related to NexGard COMBO use under this EUA and must report these to FDA in accordance with the Fact Sheet for Veterinarians. Report by (1) contacting Boehringer at 1-888-637-4251, (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 “NexGard COMBO 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 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.

M. 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

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

notified by HHS or FDA, whichever is sooner. Such records will be made available to Boehringer, HHS, and FDA for inspection upon request.

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

N. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of NexGard COMBO 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 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.

O. Boehringer and authorized distributor(s) may not imply that NexGard COMBO is FDA approved or conditionally approved for the authorized use by making statements such as "NexGard COMBO is safe and effective for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens". 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 NexGard COMBO 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.

P. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the authorized use of NexGard COMBO shall be accompanied by the authorized Fact Sheet and the applicable approved labeling (e.g., package insert), and shall clearly and conspicuously state that:

- NexGard COMBO has not been approved for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens;
- NexGard COMBO has been authorized by FDA under an EUA for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens; and
- NexGard COMBO is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of NexGard COMBO 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.

Q. 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.

[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 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.

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