November 21, 2025

Elanco US Inc
Attention: Brett McKusick, BA, DVM, MS, PhD
Senior Director, Global Regulatory Affairs
450 Elanco Circle
Indianapolis, IN 46221

Re: Emergency Use Authorization 006664

Dear Dr. McKusick:

This letter is in response to the request by Elanco US Inc. (Elanco) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of Credelio CAT (lotilaner) 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 hominovorax*) (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]

Credelio CAT is an antiparasitic that kills adult fleas and is indicated under NADA 141-528 for the treatment and prevention of flea infestations (*Ctenocephalides felis*) for one month in cats and kittens 8 weeks of age and older, and weighing 2.0 pounds or greater. Credelio CAT is also indicated under NADA 141-528 for the treatment and control of *Ixodes scapularis* (black-legged tick) infestations for one month in cats and kittens 6 months of age and older, and weighing 2.0 pounds or greater. Credelio CAT is not approved or conditionally approved for the treatment of NWS myiasis.

Based on the scientific evidence available to the FDA, including data from published scientific literature, it is reasonable to believe that Credelio CAT may be effective for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Credelio CAT outweigh the known and potential risks 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 or less than 2.0 lbs in this authorization.

[1] https://public-inspection.federalregister.gov/2025-15918.pdf.

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 Credelio CAT 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 Credelio CAT 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 scientific evidence available to FDA, it is reasonable to believe that Credelio CAT may be effective in treating NWS myiasis and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of Credelio CAT when used to treat NWS outweigh the known and potential risks of such product; and

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

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:

- The emergency use of Credelio CAT covered by this authorization will be used only for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens as prescribed by a veterinarian; and

- The emergency use of Credelio CAT covered by this authorization should be in accordance with the enclosed authorized Fact Sheet.

Product Description

Credelio CAT is an isoxazoline antiparasitic. The Credelio CAT carton label is clearly marked for 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 15-25°C (59-77°F), excursions permitted between 5 to 40°C (41 to 104°F).

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

Credelio CAT is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to veterinarians:

- Fact Sheet for Veterinarians: Emergency Use Authorization of Credelio™ CAT (lotilaner)

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 Credelio CAT, 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 scientific evidence available to FDA, that it is reasonable to believe that Credelio CAT 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 Credelio CAT (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, Credelio CAT is authorized for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens as described in this authorization under this EUA, 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. Elanco will ensure that the authorized Credelio CAT, accompanied with the authorized Fact Sheet, is distributed to veterinary facilities[3] and veterinarians consistent with the terms and conditions of this EUA.

B. Elanco will ensure that if a sticker is used on the carton, 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. Elanco and authorized distributor(s) will ensure that appropriate storage is maintained until the product is delivered to veterinary facilities and veterinarians.

[3] Veterinary facilities include veterinary hospitals, veterinary clinics and other establishments providing veterinary care.

D. Elanco 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 Credelio CAT. Elanco 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. Elanco may request changes to this authorization, including to the authorized Fact Sheet for Credelio CAT, and FDA may determine that such changes may be permitted without reissuing this Letter. Requests for changes should be submitted to the Office of New Animal Product Evaluation.

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

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

H. Elanco and authorized distributor(s) will maintain records in connection with this EUA for at least two years following the termination or revocation of the EUA, or until notified by HHS or FDA, whichever is sooner, and will make such records available to FDA for inspection upon request.

I. Elanco will comply with all other FD&C Act requirements applicable to the approved product, Credelio CAT (including, but not limited to, requirements related to registration and listing, drug quality, and manufacturing in accordance with the approved application) unless such requirement is specifically waived or modified in this authorization. Elanco should 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 Credelio CAT will track serious adverse events potentially related to Credelio CAT use under this EUA and must report these to FDA in accordance with the Fact Sheet for Veterinarians. Report by (1) contacting Elanco US at 1-888-545-5973, (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 "Credelio CAT use for the treatment of infestations of NWS under an EUA" under the "Describe Adverse Event/Product Problem/Event Use Error" heading, followed by a detailed account of the adverse event.

L. Veterinary facilities will maintain health records for the authorized use in this Letter of Authorization 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 health records for the authorized use in this Letter of Authorization for at least two years following the termination or revocation of this EUA, or until notified by HHS or FDA, whichever is sooner. Such records will be made available to Elanco, 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 Credelio CAT, shall be consistent with the authorized Fact Sheet,[4] as well as the terms set forth in this EUA, and comply with FD&C Act section(s) 502(a) and 502(n), and 21 CFR Part 202. Additionally, the sponsor shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.

[4] 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.

O. Elanco may not imply that Credelio CAT is FDA approved or conditionally approved for the authorized use by making statements such as "Credelio CAT is safe and effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens." Elanco may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Credelio CAT that provide accurate descriptions of safety and effectiveness information summarized in the authorized Fact Sheet. Such materials must include any limitations of the results and information as described in the authorized labeling.

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

- Credelio CAT has not been approved for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens;

- Credelio CAT has been authorized by FDA under an EUA for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in cats and kittens;

- Credelio CAT is authorized as described herein only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Credelio CAT under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless this authorization is revised, terminated, 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.

If the FDA notifies Elanco that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Elanco 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 Elanco 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

Enclosures:
Freedom of Information Summary
Fact Sheet