U.S. FOOD & DRUG ADMINISTRATION

October 24, 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 006662

Dear Dr. McKusick:

This letter is in response to the request by Elanco US Inc. (Elanco) that the Food and Drug Administration (FDA or Agency) issue an Emergency Use Authorization (EUA) for the emergency use of Credelio (lotilaner) for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies, 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 is an antiparasitic that kills adult fleas and is indicated under NADA 141-494 for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations [*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick)] for one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater. Credelio is indicated for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks; however, Credelio is not 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 may be effective for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Credelio outweigh the known and potential risks for dogs of all ages and weights because NWS is potentially fatal in dogs if left untreated, therefore justifying including dogs less than 8 weeks of age or less than 4.4 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 for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies, 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 for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies 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 may be effective in treating NWS myiasis, and that, when used under the conditions described in this authorization, the known and potential benefits of Credelio 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 for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies.[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 Credelio covered by this authorization will be used only for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies as prescribed by a veterinarian; and

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

Product Description

Credelio is an isoxazoline antiparasitic. The Credelio carton label is clearly marked for approved indications and “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 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™ (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, when used for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies 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 may be effective for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the 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 (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 your product under an EUA must be consistent with, and may not exceed, the terms of the Authorization, including this authorization 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 is authorized for the treatment of infestations caused by NWS larvae (myiasis) in dogs and puppies 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, accompanied with the authorized Fact Sheet, is distributed to 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 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 and cold chain is maintained until the product is delivered to the end user.

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 clinics, veterinarians and dog owners) involved in distributing or receiving authorized Credelio. 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, and FDA may determine that such changes may be permitted without amendment of this EUA, upon concurrence of 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 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 that: "use of Credelio was 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 (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 (including, but not limited to, requirements related to registration and listing, drug quality, manufacturing in accordance with the approved application, etc.) unless such requirement is specifically waived or modified in this authorization. Elanco should create a new drug listing that reflects the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

Veterinary Clinics and Other Similar Facilities to Whom the Authorized Credelio Is Distributed and Veterinarians Administering the Authorized Credelio

J. Veterinary Clinics and veterinarians will ensure that the end user is aware of the terms and scope of this Letter of Authorization; that the authorized Fact Sheet is made available to veterinarians, through appropriate means; and that they adhere to the terms of the authorization as set forth in the letter of authorization.

K. Veterinary Clinics and veterinarians receiving Credelio must track serious adverse events potentially attributable to Credelio use and must report these to FDA in accordance with the Fact Sheet for Veterinarians. Complete and submit a Form FDA 1932a available at FDA's "How to Report Animal Drug Side Effects" webpage (www.fda.gov/ReportAnimalAE). When completing the adverse event report form, begin the description in the "Adverse Event/Product Problem/Event Use Error (Long Narrative)" section with the statement: "Use of Credelio was under an EUA". This should be the first sentence of the narrative description, followed by a detailed account of the adverse event.

L. Veterinary Clinics will maintain records regarding the dispensed authorized Credelio (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain use information (e.g., client name, age, disease manifestation, number of doses administered per patient, other drugs administered).

M. Veterinary Clinics will ensure that any records associated with this EUA are maintained for at least two years following the termination or revocation of the 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 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 the Credelio, shall be consistent with the authorized Fact Sheet,[3] as well as the terms set forth in this EUA, and comply with FD&C Act section(s) 502(a), 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.

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

[3] 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.

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

- Credelio has not been approved for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.
- Credelio has been authorized by FDA under an EUA for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies.
- Credelio is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Credelio under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is amended, 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 Conditions N through Q of 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 Agency's notification. Furthermore, as part of its notification, the Agency 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