Fact Sheet for Veterinarians: Emergency Use Authorization of Credelio™ (lotilaner) Chewable Tablets for New World Screwworm (NWS)

Credelio™
(lotilaner)
Chewable Tablets
For oral use in dogs

Original EUA Authorized Date: 10/24/2025

Emergency Use Authorization of Credelio (lotilaner) Chewable Tablets for NWS
The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the approved product Credelio (lotilaner) chewable tablets for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies. Credelio is not approved for this use.
Credelio (lotilaner) (NADA 141-494) is approved for other uses in dogs and puppies.[1]

Limitations of Authorized Use
Credelio (lotilaner) chewable tablets is authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Credelio (lotilaner) chewable tablets under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

Justification for Emergency Use of Animal Drugs for NWS
The Secretary of the U.S. Department of Health and Human Services (HHS) has:

- 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 NWS (*Cochliomyia hominivorax*); and
- declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals.[2]

An EUA is an FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances declared by the Secretary of HHS to justify emergency use authorization, including, among others, a determination that there is a public health emergency or a significant potential for a public health emergency that may affect national security and that involves a biological agent.[3]
Criteria for issuing this EUA include:

- The biological agent(s) can cause a serious or life-threatening disease or condition;
- Based on the totality of available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that:
  - o the product may be effective in diagnosing, preventing, or treating the serious or life-threatening disease or condition; and
  - o the known and potential benefits of the product - when used to diagnose, prevent, or treat such disease or condition - outweigh the known and potential risks of the product; and
- There is no adequate, approved,[4] and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.[5]

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Product Description
Refer to the Credelio package insert for full **Product Description** information.

Dosage and Administration
Credelio is given orally at the minimum dosage of 9 mg/lb (20 mg/kg).

Dosage Schedule:

Body Weight	Lotilaner Per Chewable Tablet (mg)	Chewable Tablets Administered
4.4 to 6.0 lbs	56.25	One
6.1 to 12.0 lbs	112.5	One
12.1 to 25.0 lbs	225	One
25.1 to 50.0 lbs	450	One
50.1 to 100.0 lbs	900	One
Over 100.0 lbs	Administer the appropriate combination of chewable tablets	

Credelio must be administered with food.

Credelio is not available as scored tablets. The effectiveness of the administration of less than full tablets has not been evaluated.

Risk-Benefit Consideration for Dogs on Other Isoxazolines:

If a dog is currently receiving another isoxazoline product for routine ectoparasite control, veterinarians should consider administering Credelio to dogs diagnosed with NWS myiasis based on a risk-benefit assessment and the emergency nature of NWS myiasis treatment.

Information Supporting Emergency Use Authorization
Based on the totality of scientific evidence available to FDA, including data from published scientific literature, it is reasonable to believe that Credelio (lotilaner) chewable tablets may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs and puppies; and when used under the conditions described in the authorization, the known and potential benefits of Credelio (lotilaner) chewable tablets outweigh the known and potential risks.
A study conducted by do Vale et al.[6] evaluated the effectiveness of Credelio for the treatment of naturally acquired NWS myiasis in dogs in Brazil. Eleven client-owned dogs with active myiasis caused by *C. hominivorax* larvae were enrolled based on lesion severity and larval burden. The age of the enrolled dogs (5 males, 6 females) ranged from 1.5 to 10.0 years, weighing between 3.3 to 25.0 kg. All dogs received a single oral administration of Credelio at doses ranging from 23.9 to 40.9 mg/kg body weight, following the dose bands for the approved flea and tick indications. The study did not include a control group.
After treatment, the dogs were kept in individual kennels with a removable tray. The dogs were observed 2- and 6-hours post-treatment, at which times expelled larvae were collected and quantified. At 24 hours post-treatment, the remaining larvae were mechanically removed from the wound and counted.
The study demonstrated 100% overall effectiveness (number of expelled live and dead larvae and dead larvae mechanically removed) against *C. hominivorax* larvae at 24 hours post-treatment with expulsion of larvae of 80.5% and 93% at 2 and 6 hours after treatment, respectively. The mean larvicidal effectiveness was 41.1% at 24 hours. There were no adverse reactions during the study.
There are limitations of the data supporting the benefits of Credelio for the treatment of infestations caused by NWS larvae. The do Vale et al. study was conducted in a limited population of 11 naturally infested dogs in Brazil, and the inferential value to the United States population is unknown. The primary mechanism of action against *C. hominivorax* appears to be live larval expulsion. Additionally, the use of mechanical removal coupled with the lack of a control group confound the ability to define a pure treatment effect.
The available clinical data supporting the effectiveness of Credelio against *C. hominivorax* larvae, along with the established safety profile, support the potential benefit of Credelio in the authorized patient population for the treatment of infestations caused by NWS larvae.

Contraindications
There are no known contraindications for the use of Credelio.

Warnings

User Safety Warnings
Not for human use. Keep this and all drugs out of the reach of children. Keep Credelio in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.
To obtain a Safety Data Sheet (SDS), contact Elanco US Inc. at 1-888-545-5973 or https://www.elanco.com/us/elanco-safety-data-sheets.

Precautions
Lotilaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders.
The safe use of Credelio in breeding, pregnant, or lactating dogs has not been evaluated.
The safety of Credelio has not been evaluated in dogs less than 8 weeks of age or less than 4.4 lbs.

Adverse Reactions
Refer to the Credelio package insert for full prescribing information, including **Animal Safety**, **Adverse Reactions**, and **Post-Approval Experience**.
As described in the Letter of Authorization, veterinary facilities and veterinarians must report all **SERIOUS ADVERSE EVENTS*** potentially related to Credelio (lotilaner) use under this EUA (1) by contacting Elanco US Inc. at 1-888-545-5973, (2) by 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.

When reporting adverse events on Form FDA 1932a, include the following elements when applicable and/or available:

- Patient demographics (e.g., age, species and breed, sex, weight)
- The statement "Credelio (lotilaner) use for NWS under an EUA" under the "**Adverse Event/Product Problem/Product Use Error**" heading
- Information about the serious adverse event (e.g., signs and symptoms, test/laboratory data, timing of drug administration in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping/reducing the dosage, evidence of reappearance after reintroduction, clinical outcomes)
- Patient's pre-existing medical conditions and use of concomitant products
- Information about the product (e.g., dosage, route of administration, lot number)

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- An event that causes an abortion, stillbirth, or infertility
- A congenital anomaly or birth defect in offspring of treated animals
- A prolonged or permanent disability (e.g., persistent or significant incapacity or disruption of normal life functions)
- An event that requires professional intervention (e.g., important medical events that may require a medical/surgical intervention to prevent a death, life-threatening event, hospitalization, disability)

Reporting of lack of effectiveness, nonserious adverse events, or product quality defects is strongly encouraged via the mechanisms and including the information identified above for **SERIOUS ADVERSE EVENTS**.

Additional Information for Veterinarians
Veterinary facilities and veterinarians will ensure that they are aware of and adhere to the terms of the Letter of Authorization. Fact Sheets will be made available to veterinarians. 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.
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 co-administered. 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. Veterinary facilities will maintain any health records for the authorized use in the Letter of Authorization 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. Such records will be made available to Elanco US Inc., HHS, and FDA for inspection upon request.

Information for Client (e.g., Animal Owner or Caretaker)
The lifecycle for *C. hominivorax* is as short as 21 days and wounds can be rapidly infested. Proper wound care and management practices are essential for preventing NWS myiasis. Dogs may become reinfested following treatment.

Animal owners should be advised that:

- Gloves should be worn if cleaning the wound, or the dog's bedding, or disposing of larvae.
- Dogs should be housed to prevent exposure to NWS flies until wounds have fully healed.
- Live larvae may exit the wound and be deposited on bedding or areas where the dog sits or lies after treatment.
- If expelled larvae are seen, owners should place the larvae in a sealed container with rubbing alcohol.
- If there is worsening of the wound, the owner should contact the veterinarian.

How Supplied
Credelio is available in five chewable tablet sizes for use in dogs: 56.25, 112.5, 225, 450, and 900 mg lotilaner. Each chewable tablet size is available in color-coded packages of 1, 3, or 6 chewable tablets.

Storage Information
Store at 15-25°C (59-77°F), excursions permitted between 5 to 40°C (41 to 104°F).

Manufactured for:
Elanco US Inc
Greenfield, IN 46140 USA
Revised 03/27/2026

[1] On January 19, 2018, Credelio was approved to kill adult fleas and is indicated for the treatment 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) and *Rhipicephalus sanguineus* (brown dog tick)] for one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater. On September 3, 2019, Credelio received a supplemental approval for the prevention of flea infestations (*Ctenocephalides felis*) for one month in dogs and puppies 8 weeks of age and older, and weighing 4.4 pounds or greater. On October 24, 2025, Credelio received a supplemental approval for the treatment and control of *Haemaphysalis longicornis* (longhorned tick) tick infestations for one month in dogs and puppies 8 weeks of age and older, weighing 4.4 pounds or greater, and for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

[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

[3] Emergency Use Authorization of Medical Products and Related Authorities | FDA (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities)

[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] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

[6] do Vale TL, Costa AR, Miranda LM, Silva GF, Silva NCS, Lima TB, Chaves DP, Sager H, Lasmar PVF, Costa-Junior LM. Efficacy of lotilaner against myiasis caused by *Cochliomyia hominivorax* (Diptera: Calliphoridae) in naturally infested dogs. *Parasit Vectors*. 2023;16(1):86.

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

Electronic Signature Addendum for Submission ID

V-006662-A-0000-OT

Signing Authority (Role)	Letter Date
Timothy Schell (Center Director)	10/24/2025

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.