extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product.

Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, ZELSUVMI (berdazimer sodium), indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for ZELSUVMI (U.S. Patent No. 9,855,211) from LNHC, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZELSUVMI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ZELSUVMI is 4,144 days. Of this time, 3,778 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* September 2, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 2, 2012.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* January 5, 2023. FDA has verified the applicant's claim that the new drug application (NDA) for ZELSUVMI (NDA 217424) was initially submitted on January 5, 2023.

3. *The date the application was approved:* January 5, 2024. FDA has verified the applicant's claim that NDA 217424 was approved on January 5, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application(s) for patent extension, this applicant seeks 1,280 days of patent term extension.

## III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must

be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**Brian Fahey,**

*Associate Commissioner for Legislation.*

[FR Doc. 2025–23868 Filed 12–23–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2025–N–6971]**

### Authorization of Emergency Use for Two Animal Drugs for the Treatment of New World Screwworm; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the issuance of two Emergency Use Authorizations (EUA) (Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for new animal drug products. FDA has issued one EUA for a new animal drug product as requested by Elanco US Inc. for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) (NWS) larvae (myiasis) in dogs and puppies and one EUA for a new animal drug product as requested by Elanco US Inc. for the treatment of infestations caused by NWS larvae (myiasis) in cats and kittens. The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the August 18, 2025, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects or has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves NWS. On the basis of such determination, the Secretary of HHS declared on August 18, 2025, that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

**DATES:** The Authorizations are effective on their dates of issuance: October 24, 2025, and November 21, 2025, respectively.

**ADDRESSES:** Submit written requests for single copies of the EUAs to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

**FOR FURTHER INFORMATION CONTACT:** Steven Fleischer, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240–402–0809, *Steven.Fleischer@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

## II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents (''CBRN''); or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (C) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents; or (D) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on FDA's website. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

Under section 564(c) of the FD&C Act, FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) 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, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

## III. The Authorizations

The Authorizations follow the August 18, 2025, determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad and that involves NWS. On the basis of such determination, the Secretary of HHS declared, on August 18, 2025, that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals. Notice of the Secretary's determination and declaration was provided in the **Federal Register** on August 20, 2025 (90 FR 40609). Having concluded that the criteria for the issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has issued two authorizations for the emergency use of animal drug products. On October 24, 2025, FDA issued an EUA to Elanco US Inc. for the animal drug product Credelio (lotilaner), subject to the terms of its Authorization. On November 21, 2025, FDA issued an EUA to Elanco US Inc. for the animal drug product Credelio CAT (lotaliner), subject to the terms of its Authorization.

The initial Authorizations, included below in their entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provide

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine, within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration (see section 564(b)(6) of the FD&C Act).

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

explanations of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuance of the Authorizations can be found on FDA's web page at: *https://www.fda.gov/animal-veterinary/safety-health/animal-drugs-new-world-screwworm.*

## IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

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

U.S. FOOD & DRUG ADMINISTRATION

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

**Lowell M. Zeta,**
*Acting Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–23914 Filed 12–23–25; 8:45 am]
**BILLING CODE 4164–01–C**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2025–N–7022]**

### Roundtable on Premarket Tobacco Application Submissions for Electronic Nicotine Delivery Systems Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of roundtable discussion; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing a roundtable discussion with small tobacco product manufacturers to solicit input on premarket tobacco product application (PMTA) submissions for electronic nicotine delivery systems (ENDS) products. The topics to be discussed will include certain components of PMTAs such as product characterization, manufacturing controls, pharmacological profile (*e.g.,* pharmacokinetic studies), studies of adult benefit (*e.g.,* longitudinal cohort/randomized controlled trial (RCT) studies), and toxicological profile (*e.g.,* estimated lifetime cancer risk). The purpose of the roundtable is to provide manufacturers an opportunity to share their experience with, and other opinions about, the premarket application process. This notice provides information on meeting participation and selection. FDA is establishing a docket for public comments related to the roundtable meeting.

**DATES:** The roundtable meeting will be held on February 10, 2026, 9:00 a.m. to 5 p.m., Eastern Time. Electronic or written comments on the roundtable may be submitted beginning December 29, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The roundtable meeting will be held in the White Oak Great Room and virtually. Entrance for the roundtable panelists (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 3, 2026, to be considered for the roundtable discussion. All other electronic comments must be submitted on or before March 12, 2026. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 12, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before these dates.

The public can submit comments on the roundtable topics during the open comment period; the request for comments is not limited to small tobacco product manufacturers.

You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2025–N–7022 for ''Roundtable on Premarket Tobacco Application Submissions for Electronic Nicotine Delivery Systems Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received, timely comments (see **ADDRESSES**) will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.