U.S. FOOD & DRUG ADMINISTRATION

June 11, 2026

Felixvet Inc.
Attention: Sreejith Kurup
Vice President
U.S. Agent for Felix Pharmaceuticals Pvt. Ltd.
25-28 North Wall Quay
Dublin 1, Ireland

Re: Emergency Use Authorization 006661

Dear Mr. Kurup:

This letter is in response to the request on behalf of Felix Pharmaceuticals Pvt. Ltd. (Felix) that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of Nitenpyram Tablets (nitenpyram)[1] for the treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, 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 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 New World screwworm (*Cochliomyia hominivorax*) (hereinafter "NWS"). On the basis of such determination, the Secretary of HHS on August 18, 2025, declared that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals, pursuant to Section 564(b)(1) of the FD&C Act, subject to terms of any authorization issued under that section.[2]

Nitenpyram Tablets are an oral antiparasitic that are indicated under ANADA 200-858 to kill adult fleas and are indicated for the treatment of flea infestations on dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older. Nitenpyram Tablets are not approved for the treatment of NWS myiasis.

Based on the totality of scientific evidence available to the FDA, including data from published literature, it is reasonable to believe that Nitenpyram Tablets may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, as described in this authorization, and when used under the conditions described in this authorization, the known and potential benefits of Nitenpyram Tablets outweigh the known and potential risks of such product, since NWS infestations can have significant adverse health consequences and

[1] Unless specified by name, products sold under separate distributor's labeling per 21 CFR 514.80(b)(5)(iii) (i.e., with a different proprietary name) are not subject to this EUA. A request must be made to change to the scope of this authorization for such products.
[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

can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae.

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 Nitenpyram Tablets for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, 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 Nitenpyram Tablets for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older, when administered as described in this authorization, meets the criteria for issuance of an authorization under Section 564(c) of the FD&C Act, because:

1. NWS can cause a serious or life-threatening disease or condition to animals and humans;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Nitenpyram Tablets may be effective in treating NWS, and that, when used under the conditions and within the scope described in this authorization, the known and potential benefits of Nitenpyram Tablets when used to treat NWS outweigh the known and potential risks of such product; and

3. There is no adequate, approved[3], and available alternative[4] to the emergency use of Nitenpyram Tablets for the treatment of infestations caused by NWS (*Cochliomyia*

[3] "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.

[4] There are no approved alternatives for the treatment of NWS myiasis in cats and kittens.

There are no approved alternatives for the treatment of NWS myiasis in dogs and puppies between 4 and 8 weeks of age or weighing between 2 and 3.3 pounds because the conditionally approved product is indicated for the treatment of NWS in dogs and puppies at least 8 weeks of age and weighing at least 3.3 pounds.

Additionally, there are no adequate approved over the counter (OTC) products for dogs and puppies, and OTC marketing will allow the product to be available in circumstances where access to a veterinarian is limited.

Furthermore, there are no approved products with a single active ingredient for the treatment of NWS myiasis in dogs and puppies; Nitenpyram Tablets contain a single active pharmaceutical ingredient, whereas the conditionally approved product contains multiple active ingredients. The presence of multiple active ingredients in the conditionally approved product may increase the likelihood of adverse events in dogs and puppies that have recently been treated with a heartworm preventative or other antiparasitic drug in the same pharmacological class as one of the conditionally approved product's active ingredients. Because Nitenpyram Tablets contain only a single active ingredient that is not in that drug class, their use may minimize the potential for adverse events in these dogs.

Lastly, Nitenpyram Tablets act through a mechanism of action that is distinct from each of the active ingredients in the conditionally approved product. Because no approved alternative product works through the same mechanism of action as Nitenpyram Tablets, the conditionally approved product is not an adequate therapeutic substitute in circumstances where Nitenpyram Tablets distinct mechanism of action is clinically relevant.

hominivorax) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older.[5]

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:

- Nitenpyram Tablets, as covered by this authorization, will be used only for over the counter use in dogs and cats 2 pounds of body weight or greater and 4 weeks of age and older; and

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

Product Description

Nitenpyram Tablets are oral tablets for dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older. Nitenpyram Tablets belong to the chemical class of neonicotinoids and kill adult fleas. The authorized Nitenpyram Tablets carton labeling is clearly marked for the approved indications and for NWS under Emergency Use Authorization, with a website address and QR code that links to the authorized Fact Sheet.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).

Nitenpyram Tablets are authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to all users:

- Fact Sheet: Emergency Use Authorization of Nitenpyram Tablets (Nitenpyram) for New World Screwworm (NWS)

I have concluded, pursuant to Section 564(d)(2) of the FD&C Act, that it is reasonable to believe that the known and potential benefits of Nitenpyram Tablets, when used for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older and used in accordance with this authorization, outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the FD&C Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Nitenpyram Tablets may be effective for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older when used in accordance with this authorization, pursuant to Section 564(c)(2)(A) of the FD&C Act.

[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) 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 Nitenpyram Tablets, as described in this authorization, meet 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, Nitenpyram Tablets are authorized for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older as described in this authorization, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the FD&C Act, I am establishing the following conditions on this authorization:

A. Felix will ensure that the authorized Nitenpyram Tablets, accompanied with the authorized Fact Sheet, are distributed to authorized distributor(s)[6] consistent with the terms and conditions of this EUA, and that authorized distributor(s) will limit distribution to other authorized distributors and end users.

B. Felix will ensure that if a sticker is used on the labeling, 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. Felix and authorized distributor(s) will ensure that appropriate storage conditions are maintained until the product is delivered to the end user.

D. Felix and authorized distributor(s) will provide to each authorized distributor immediately downstream in the supply chain a copy of this Letter of Authorization and promptly communicate any subsequent amendments that might be made to this Letter of Authorization and its authorized accompanying materials (e.g., its authorized Fact Sheet).

[6] The term "distributors" includes all parties in the supply chain between the recipient of this authorization letter and the end user, excluding veterinary facilities and veterinarians who only provide product to veterinarians and end users at their facility. "Authorized distributors" are all distributors who otherwise lawfully obtain and distribute the product, unless Felix places limits on distribution in writing (e.g., via contract or written notice accompanying the product).

E. Felix may request changes to this authorization, including to the authorized Fact Sheet for Nitenpyram Tablets. Requests for changes must be submitted to the Office of Generic Animal Drugs. Such changes require appropriate authorization prior to implementation.[7]

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

Felix will fully comply with the reporting requirements under 21 CFR 514.80. When collecting adverse event information, Felix will attempt to determine whether the use of Nitenpyram Tablets 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. Felix 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 must state in the "Narrative of Adverse Event" field: "Nitenpyram Tablets 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, Felix and authorized distributor(s) will maintain records regarding distribution of the authorized Nitenpyram Tablets (i.e., lot numbers, quantity, receiving site, receipt date).

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

I. Felix (and any other person engaged in manufacturing, packing, or holding) will comply with all other FD&C Act requirements applicable to the approved product, Nitenpyram Tablets, including, but not limited to, requirements related to registration and listing, drug quality, and the requirement to manufacture using the processes, facilities, controls, and equipment specified in the approved application,[8] unless such requirements are specifically waived or modified in this authorization. Felix, and authorized distributor(s) who distribute EUA product under separate distributor labeling, if any, shall update their drug listing to reflect the EUA, including submission of updated labeling, before commercial distribution of the EUA product begins.

[7] Changes that do not necessitate revision to this letter (e.g., changes to the Fact Sheet(s), changes related to current good manufacturing practice requirements, expiration dating extensions) may be authorized through separate notification without reissuance of this letter.
[8] Changes shall be submitted and approved in accordance with 21 CFR 514.8, unless otherwise approved under Paragraph E of this letter.

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

J. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter, relating to the authorized use of Nitenpyram Tablets, shall be consistent with the authorized Fact Sheet[9] and the terms set forth in this EUA, as well as comply with FD&C Act Section 502(a). Additionally, the sponsor and authorized distributor(s) shall comply with any other applicable requirements in the FD&C Act and its implementing regulations regarding advertising and/or promotion.

K. Felix and authorized distributor(s) may not imply that Nitenpyram Tablets are FDA approved, conditionally approved, or indexed for the authorized use. Felix and authorized distributor(s) may disseminate advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter relating to the emergency use of Nitenpyram Tablets that provide accurate descriptions of safety and effectiveness information summarized in the authorized Fact Sheet. Such materials must include any limitations of information submitted to support this authorization.

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

- Nitenpyram Tablets have not been approved for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older;

- Nitenpyram Tablets have been authorized by FDA under an EUA for the treatment of infestations caused by NWS (*Cochliomyia hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens 2 pounds of body weight or greater and 4 weeks of age and older; and

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

M. All advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter must be submitted to the CVM OSC DER eSubmitter Program at

[9] 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.

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 FDA notifies Felix or authorized distributor(s) that any descriptive materials, advertising, or promotional materials do not meet the terms set forth in this EUA, Felix or authorized distributor(s) must discontinue and/or cease distribution of such advertisements (including printed and nonprinted communications) and other promotional descriptive printed matter in accordance with FDA's notification. Furthermore, as part of its notification, FDA may also require Felix or authorized distributor(s) to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective as described herein until the declaration that circumstances exist justifying the authorization of the emergency use of animal drugs during the NWS public health emergency is terminated under Section 564(b)(2) of the FD&C Act or the EUA is revised or revoked under Section 564(g) of the FD&C Act.

Sincerely,

{see appended electronic signature page}
Timothy Schell, Ph.D.
Director
Center for Veterinary Medicine
U.S. Food and Drug Administration

Enclosures:
Freedom of Information Summary
Fact Sheet