Date of Authorization: September 03, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

Revised Emergency Use Authorization (EUA)

EUA 006661

Nitenpyram Tablets

(nitenpyram)

Dogs and Cats

Scope of Authorization: For the treatment and prevention 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**.

Sponsored by:

Felix Pharmaceuticals Pvt. Ltd.

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I. GENERAL INFORMATION

A. File Number

EUA 006661

B. Sponsor

Felix Pharmaceuticals Pvt. Ltd.
25-28 North Wall Quay
Dublin 1, Ireland

Drug Labeler Code: 086101

U.S. Agent Name and Address:

Sreejith Kurup
Felixvet Inc.
1300 NW Briarcliff Parkway
Suite 100
Kansas City, MO 64150

C. Proprietary Name

Nitenpyram Tablets

D. Drug Product Established Name

nitenpyram

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Tablet

G. Amount of Active Ingredient

Each tablet contains 11.4 mg or 57.0 mg nitenpyram.

H. How Supplied

Nitenpyram Tablets are available in two tablet sizes: 11.4 and 57.0 mg. Each tablet size is available in packages of 6 or 60 tablets.

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

Weigh your pet prior to administration to ensure proper dosage. Do not administer to pets under 2 pounds.

Recommended Dosage Schedule

Species	Body Weight	Dose	Nitenpyram Per Tablet
Dog or Cat	2-25 lbs.	One tablet	11.4 mg
Dog	25.1-125 lbs.	One tablet	57.0 mg

Treatment:
Nitenpyram Tablets should be administered according to the Recommended Dosage Schedule above. **A second dose should be administered 6 hours after the first.**

Prevention:
Nitenpyram Tablets should be administered once daily according to the Recommended Dosage Schedule above. Nitenpyram Tablets must be administered daily to prevent NWS infestations.

K. Route of Administration

Oral

L. Species

Dogs and cats

M. Food and Drug Administration (FDA) Approved Indications

Nitenpyram Tablets (ANADA 200-858) 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.**

N. Emergency Authorized Use

For the treatment and prevention 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**.

O. Limitations of Authorized Use

Nitenpyram Tablets (nitenpyram) are not authorized for use in dogs, puppies, cats and kittens less than 2 pounds of body weight or 4 weeks of age.

Nitenpyram Tablets (nitenpyram) are authorized for this use only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Nitenpyram Tablets (nitenpyram) 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.

P. Effect of EUA Revision

This revision provides for an update to the indications to include the prevention of NWS. The updated indications are: "For the treatment and prevention 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**."

II. EFFECTIVENESS

A. Dosage Characterization

This Emergency Use Authorization does not change the previously approved 0.45 mg/lb (1 mg/kg) dose, given orally. The FOI Summary for the original approval of ANADA 200-858, dated June 8, 2026, contains dosage characterization information for dogs and cats.

B. Evidence Supporting Emergency Use Authorization

In accordance with Section 564 of the FD&C Act, the sponsor demonstrated that it is reasonable to believe that Nitenpyram Tablets may be effective for the treatment and prevention of infestations caused by New World screwworm (*Cochliomyia hominivorax*, NWS) larvae (myiasis) in dogs, puppies, cats and kittens based on data from published scientific literature. The evidence supporting effectiveness is based on published scientific literature and the mechanism of action of nitenpyram. Collectively, the data support that it is reasonable to believe that Nitenpyram Tablets may be effective for the treatment and prevention of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in dogs, puppies, cats and kittens.

1. Published Literature (Treatment)

   a. Correia, T. R., Scott, F. B., Verocai, G. G., Souza, C. P., Fernandes, J. I., Melo, R. M., Vieira, V. P., & Ribeiro, F. A. (2010). Larvicidal efficacy of nitenpyram on the treatment of myiasis caused by *Cochliomyia hominivorax* (Diptera: Calliphoridae) in dogs. *Veterinary Parasitology*, *173*(1-2), 169–172.

      The study, conducted in Brazil, evaluated seven laboratory beagles with naturally acquired *C. hominivorax* infestations. The infestations appeared during different seasons of the year. The dogs were 9 months to 6 years of age and weighed 7.9 to 13.2 kg. After diagnosis of myiasis by observation of larvae in a wound, all dogs were administered nitenpyram tablets orally at the recommended labeled dose for the approved flea indication (range 1.4 to 4.4 mg/kg). A second dose was administered 6 hours after the first dose. The study did not include a control group. Expelled larvae were collected in trays beneath the dogs' kennels for 18 hours after the first dose of nitenpyram (15, 30, and 45 minutes, and 1, 2, 3, 4, 6, and 18 hours). After the 18-hour expelled larvae observation period, the remaining larvae were mechanically removed. All expelled and mechanically removed larvae were counted (Table II.1). All larvae were morphologically identified as *C. hominivorax* second and third instar.

Table II.1. Correia et al. Total Number of Expelled Larvae, Mean Non-Cumulative and Mean Cumulative Percentage of Expelled Larvae (n = 7)

Time Post-Treatment*	Total Number of Larvae Expelled	Mean Non-Cumulative Percentage of Expelled Larvae	Mean Cumulative Percentage of Expelled Larvae
15 min	0	0	0
30 min	0	0	0
45 min	1	0.1	0.1
1 h	32	4.2	4.2
2 h	313	41.4	43.7
3 h	144	19.1	61.9
4 h	62	8.2	69.7
6 h†	129	17.1	86
18 h	74	9.8	95.3

*minutes (min), hours (h)
†second dose administered

After the 18-hour expelled larvae observation period and mechanical removal of the remaining larvae, the following parameters were evaluated:

- Larval Expulsion Percentage: ((number of expelled larvae of each animal) / (sum of expelled and mechanically collected larvae of each animal) x 100)

- Percentage of expelled larvae per observational period, considering all animals: ((total of expelled larvae by each time) / (sum of expelled and mechanically collected larvae))

A total of 792 larvae were collected (range 8 to 444). Seven hundred fifty-five of 792 (95.3%) larvae were expelled (individual expulsion rates ranged from 80 to 100%). Thirty-seven of 792 (4.7%) were removed (individual mechanical removal rates ranged from 0 to 20%).
The larval expulsion percentage was 86% and 95.3%, 6 and 18 hours after the first treatment, respectively. The remaining larvae mechanically removed were dead, demonstrating an overall larvicidal effectiveness of 100%.

No adverse events were reported for the study.

b. Han, H.S., Chen, C., Schievano, C., & Noli, C. (2018). The comparative efficacy of afoxolaner, spinosad, milbemycin, spinosad plus milbemycin, and nitenpyram for the treatment of canine cutaneous myiasis. *Veterinary Dermatology*, 10.1111/vde.12548.

The study evaluated 40 privately-owned dogs with naturally acquired cutaneous myiasis; 8 dogs were treated with nitenpyram tablets. All screwworms were assumed to be *Chrysomya bezziana* (Old World screwworm, OWS), but morphological confirmation was not performed to confirm the species. Dogs were randomized to five different treatment

groups, eight dogs per group, and dosed orally at doses recommended by the manufacturer for treatment of their approved target parasite species. Dogs were evaluated hourly for 7 hours and again 24 hours post-treatment. Observations were recorded as no observed effect, partial paresis/death of some larvae and their expulsion, and complete death of all larvae. Dogs with live larvae present at 24 hours were then treated with topical organophosphates. All dogs in the nitenpyram treatment group had complete resolution of their infestation by 6 hours post-treatment. The mean speed of onset was 2.4 hours and the mean time for complete resolution of larvae infestation was 5.4 hours.

No adverse events were reported for the study.

c. de Souza, C. P., Verocai, G. G., & Ramadinha, R. H. (2010). Myiasis caused by the New World screwworm fly *Cochliomyia hominivorax* (Diptera: Calliphoridae) in cats from Brazil: report of five cases. *Journal of feline medicine and surgery, 12*(2), 166–168.

The series case report briefly describes the treatment and outcome of five cats in Brazil with naturally acquired *C. hominivorax* infestations. Three unowned cats presented with massive larval infestations in extensive lesions, including a left humeral fracture, a serious wound on the right front leg and a large wound on the left neck extending to the face. Two client-owned cats, previously treated with cryosurgery, presented with larval infestations in their surgical wounds 18 to 36 days post-surgery. In all cats, debridement of necrotic tissue and mechanical removal of accessible larvae were promptly performed, and nitenpyram tablets were administered following the recommended labeled dose for the approved flea indication. A few hours after administration, larvae actively left the wound in all cats. Larvae that penetrated deeper into the lesion and were not expelled required mechanical removal. Larvae were classified as third instar *C. hominivorax*. The case reports do not quantify the number of dead or alive, expelled or mechanically removed larvae, and do not provide an effectiveness assessment at any specific time point.

The three unowned cats died 1 to 4 days after treatment. Death of the cats was attributed to the severity of the wounds and massive larval infestations. The client-owned cats were successfully treated.

There are limitations of the data supporting the benefits of nitenpyram for treatment of infestations caused by NWS in dogs. The Correia et al. study was conducted in a limited population of seven naturally infested laboratory dogs in Brazil and the lack of a control group confounds the ability to define a pure treatment effect. The Han et al. study was conducted with presumptive OWS infestations. The comparability of OWS and NWS is unknown.

The de Souza et al. publication of case reports provides circumstantial support that nitenpyram may be effective for the treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in cats and kittens. The mechanism of action of nitenpyram is to bind to nicotinic acetylcholine receptors in the postsynaptic membranes and blocks acetylcholine-mediated neuronal transmission causing

paralysis and death of the parasite.[1] Based on the de Souza et al. publication, the scientific evidence available to FDA demonstrating effectiveness against C. *hominivorax* myiasis in dogs and puppies treated with nitenpyram,[2] the mechanism of action of nitenpyram, and the established safety profile in cats, it is reasonable to believe that Nitenpyram Tablets may be effective for the treatment of infestations caused by NWS (*C. hominivorax*) larvae (myiasis) in cats and kittens.

2. Prevention

   The lifecycle of the *C. hominivorax* fly can be as short as 21 days. NWS infestations begin when a female fly lays eggs on open wounds or other parts of the body in live, warm-blooded animals. One adult female fly can lay 200 to 300 eggs at a time and up to 3,000 eggs during her 10- to 30-day lifespan. The eggs hatch in 12 to 24 hours depending on environmental conditions. Once hatched, the larvae burrow into the wound to feed on living tissue. The larvae progress through three larval stages (L-1 through L-3) over 5 to 7 days. Once larvae reach the L-3 stage, the larvae fall from the wound and burrow into the ground to pupate, emerging as adult flies in 7 to 54 days depending on temperature and humidity.

   Nitenpyram Tablets do not kill or repel adult flies, prevent adult flies from laying eggs, prevent eggs from hatching, or prevent newly hatched larvae from feeding. Daily administration of Nitenpyram Tablets prevents establishment of NWS infestations by killing newly hatched larvae (L1) within 24 hours of dose administration.

III. TARGET ANIMAL SAFETY

FDA did not require target animal safety studies for this authorization. The FOI Summary for the original approval of ANADA 200-858 dated June 8, 2026, contains a summary of bioequivalence studies conducted in dogs and cats. Nitenpyram Tablets were demonstrated to be bioequivalent to the Reference Listed New Animal Drug, which was shown to be safe and effective, as referenced in the original approval (ANADA 200-858).

IV. HUMAN FOOD SAFETY

This drug is intended for use in dogs and cats. Because this new animal drug is not intended for use in food-producing animals, FDA did not require data pertaining to drug residues in food (i.e., human food safety) for this authorization.

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[1] https://pubchem.ncbi.nlm.nih.gov/compound/3034287

[2] Correia, T. R., Scott, F. B., Verocai, G. G., Souza, C. P., Fernandes, J. I., Melo, R. M., Vieira, V. P., & Ribeiro, F. A. (2010). Larvicidal efficacy of nitenpyram on the treatment of myiasis caused by *Cochliomyia hominivorax* (Diptera: Calliphoridae) in dogs. *Veterinary Parasitology*, *173*(1-2), 169-172.

V. USER SAFETY

The product Fact Sheet contains the following information regarding safety to humans handling, administering, or exposed to Nitenpyram Tablets:

Not for human use. Keep this and all drugs out of the reach of children.

VI. AGENCY CONCLUSIONS

Based on the totality of scientific evidence available to FDA, including data from published literature, it is reasonable to believe that Nitenpyram Tablets, when used as authorized, may be effective for the treatment and prevention 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 that the known and potential benefits of Nitenpyram Tablets outweigh the known and potential risks, since NWS infestations can have significant adverse health consequences and can be fatal if left untreated due to the extensive tissue damage caused by *Cochliomyia hominivorax* larvae.

There is no adequate, approved,[3] and available alternative to the product for the treatment and prevention of NWS myiasis in dogs and cats. There are no approved alternatives for the treatment and prevention of NWS myiasis in cats and kittens. There are no adequate, approved, available alternatives for the treatment and prevention of NWS myiasis in dogs and puppies due to the weight and age ranges for dogs, the prescription marketing status, multiple active ingredients, and mechanism of action of the conditionally approved product.

There are no approved alternatives for the treatment and prevention 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 and prevention 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 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 and prevention 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.

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[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.

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 the Nitenpyram Tablets distinct mechanism of action is clinically relevant.

For additional information on all products authorized or conditionally approved for use to treat and/or prevent New World screwworm, please see FDA's "New World Screwworm: Information for Veterinarians" webpage at https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians.

A. Duration of Authorization: Revision and Revocation

This EUA will be effective until revoked under Section 564(g) of the FD&C Act or until the Secretary's declaration of emergency or threat justifying emergency authorized use is terminated (Section 564(f)(1)), with exception for continued use permissible under Section 564(f)(2). FDA may revoke or revise this authorization if emergency use of this animal drug for NWS myiasis is no longer justified, if the product no longer meets the criteria for issuance of an EUA under Section 564(c) of the FD&C Act, or other circumstances make such revocation or revision of the authorization appropriate to protect the public health or safety (Section 564(g)(2) of the FD&C Act).

B. Marketing Status

This product is authorized to be marketed OTC because the authorized labeling contains adequate directions for use by laypersons and the conditions of use prescribed on the label are reasonably certain to be followed in practice.