Date of Approval: June 8, 2026

# FREEDOM OF INFORMATION (FOI) SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-858

Nitenpyram Tablets

(nitenpyram)

Dogs and Cats

Nitenpyram Tablets 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.**

Sponsored by:

Felix Pharmaceuticals Pvt. Ltd.

## Executive Summary

Nitenpyram Tablets (nitenpyram) are approved 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**. The reference listed new animal drug (RLNAD) is CAPSTAR® (nitenpyram) tablets, sponsored by Sergeant's Pet Care Products LLC under NADA 141-175. This is the first generic nitenpyram tablets for dogs and cats.

## Bioequivalence

The sponsor conducted one *in vivo* blood-level study in dogs to show that the 11.4 mg Nitenpyram Tablets are bioequivalent to the 11.4 mg CAPSTAR® tablets. No serious adverse events were reported during the study. The sponsor also conducted one *in vivo* blood-level study in cats to show that the 11.4 mg Nitenpyram Tablets are bioequivalent to the 11.4 mg CAPSTAR® tablets. No serious adverse events were reported during the study.

The sponsor conducted a comparative *in vitro* dissolution study for the additional product strength. Based on the dissolution data, the 57.0 mg tablet for use in dogs qualified for a waiver from the requirement to perform separate *in vivo* bioequivalence studies (a biowaiver). The Food and Drug Administration (FDA) granted a biowaiver for this strength.

## Conclusions

Based on the data submitted by the sponsor for the approval of Nitenpyram Tablets, FDA determined that the drug is safe and effective when used according to the label.

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# I. GENERAL INFORMATION

## A. File Number

ANADA 200-858

## 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

Nitenpyram Tablets should be administered according to the following schedule. **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 |

### K. Route of Administration

Oral

### L. Species

Dogs and cats

### M. Indications

Nitenpyram Tablets 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. Reference Listed New Animal Drug (RLNAD)

CAPSTAR®; nitenpyram; NADA 141-175; Sergeant's Pet Care Products LLC

## II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required.

For this ANADA, two *in vivo* blood-level studies were conducted to demonstrate product bioequivalence in cats and dogs using the generic and RLNAD nitenpyram 11.4 mg tablet. The RLNAD is available in 11.4 mg and 57.0 mg tablet sizes. The cat *in vivo* blood-level study was conducted in 28 healthy, fasted cats. The pivotal parameters to evaluate bioequivalence are the observed maximum plasma drug concentration ($C_{MAX}$) and area under the concentration-time curve (AUC) from time 0 to the last sampling time before the first unquantifiable concentration after $C_{MAX}$. Bioequivalence was demonstrated between the 11.4 mg RLNAD nitenpyram tablets and the 11.4 mg generic nitenpyram tablets by the average bioequivalence approach as described in the Statistical Methods section below.

The dog *in vivo* blood-level study was conducted in 28 healthy, fasted dogs. The pivotal parameters to evaluate bioequivalence are the observed maximum plasma drug concentration ($C_{MAX}$) and area under the concentration-time curve (AUC) from time 0 to the last sampling time before the first unquantifiable concentration after $C_{MAX}$. Bioequivalence was demonstrated between the 11.4 mg RLNAD nitenpyram tablets and the 11.4 mg generic nitenpyram tablets by the average bioequivalence approach as described in the Statistical Methods section below.

A waiver from the requirement to demonstrate *in vivo* bioequivalence (biowaiver) for the generic 57.0 mg tablet for use in dogs was requested. Dissolution data was used to demonstrate that the generic 11.4 mg and 57.0 mg nitenpyram tablets are comparable to the RLNAD 11.4 mg and 57.0 mg tablet strengths. Therefore, a biowaiver for the generic 57.0 mg nitenpyram tablets was granted. The study information is summarized below.

**A. Blood-level Bioequivalence Study in Cats**

**Title**: Pivotal Bioequivalence Study of Generic Nitenpyram Tablets and CAPSTAR® Tablets when Administered Orally to Cats in a Fasted State. (Study No. 080-BF-2224)

**Study Dates:** February 18, 2025 to August 1, 2025

**Study Locations:**

In-life phase: Ontario, Canada

Bioanalytical testing: Ontario, Canada

**Study Design:**

Objective: The objective of this study was to determine the comparative *in vivo* blood-level bioequivalence data for the generic 11.4 mg nitenpyram tablets and the RLNAD 11.4 mg CAPSTAR® (nitenpyram) tablets in fasted cats.

Study Animals: 28 male and female neutered cats aged 6 months to 3 years.

Experimental Design: A randomized, masked, two-period, two-sequence, single-dose crossover study conducted according to Organization for Economic Cooperation and Development Principles of Good Laboratory Practice.

Drug Administration: Each animal received 11.4 mg of either the generic or RLNAD nitenpyram tablet according to their randomized treatment sequence (generic/RLNAD or RLNAD/generic).

Measurements and Observations: The plasma concentrations of nitenpyram were measured using a validated bioanalytical method. Pharmacokinetic parameters were determined for each animal individually in each period. Animal observations were made throughout the study for assessment of general health and adverse events.

**Statistical Methods:**

The laboratory study was conducted as a randomized, masked, two-period, two-sequence, two-treatment, single-dose crossover design using 28 cats with a 14-day washout between periods. Appropriate randomization of animal to sequence and pen/treatment order was performed. Primary variables evaluated were $C_{MAX}$ and AUC. Time to maximum concentration ($T_{MAX}$) was summarized and evaluated clinically.

A mixed-effect model was used to evaluate bioequivalence. The model included fixed effects of treatment, sequence and period, and a random effect of subject nested within sequence. Prior to the analysis, $C_{MAX}$ and AUC were natural logarithm transformed. Bioequivalence is established because the back-transformed estimated upper and lower bounds of the 90% confidence interval for geometric mean ratios (generic:RLNAD) of both $C_{MAX}$ and AUC are contained within the acceptance limits of 0.80 to 1.25.

**Results:**

As seen in the table below, $C_{MAX}$ and AUC fall within the prescribed bounds (Table II.1). The mean values of $T_{MAX}$ obtained for the generic article and RLNAD were summarized.

**Table II.1. Bioequivalence Evaluation**

| Parameter | Generic Mean | RLNAD Mean | Ratio[◊] | Lower 90% CI | Upper 90% CI |
|---|---|---|---|---|---|
| AUC (ng/mL)*hour | 49455[†] | 48031[†] | 1.03 | 1.01 | 1.05 |
| $C_{MAX}$ (ng/mL) | 4085[†] | 3741[†] | 1.09 | 1.05 | 1.14 |
| $T_{MAX}$ (hours) (SD)[‡] | 0.76 (0.78)[‡] | 1.01 (0.76)[‡] | NE | NE | NE |

[†] Geometric mean
[‡] Arithmetic mean and standard deviation (SD)
[◊] Ratio = Test/Reference
CI = confidence interval
NE = not estimated

**Adverse Reactions:**

There were no serious adverse events related to the test or reference article reported during the study.

**Conclusion:**

The *in vivo* bioequivalence study demonstrated that the generic 11.4 mg nitenpyram tablet and the RLNAD 11.4 mg CAPSTAR® (nitenpyram) tablet are bioequivalent in cats.

## B. Blood-level Bioequivalence Study in Dogs

**Title**: Pivotal (GLP) Two Period Bioequivalence Study of Capstar® (11.4 mg nitenpyram) Tablet and a Generic Tablet (11.4 nitenpyram) in Fasted Dogs. (Study No. 024-01986)

**Study Dates:** February 13, 2025 to August 11, 2025

**Study Locations:**

In-life phase: Las Cruces, NM

Bioanalytical testing: Ontario, Canada

**Study Design:**

Objective: The objective of this study was to determine the comparative *in vivo* blood-level bioequivalence data for the generic 11.4 mg nitenpyram tablets and the RLNAD 11.4 mg CAPSTAR® (nitenpyram) tablets in fasted dogs.

Study Animals: 28 intact male and female dogs, approximately 2 to 9 years of age

Experimental Design: A randomized, masked, two-period, two-sequence, single-dose crossover study conducted according to Good Laboratory Practice for Nonclinical Laboratory Studies.

Drug Administration: Each animal received 11.4 mg of either the generic or RLNAD nitenpyram tablet according to their randomized treatment sequence (generic/RLNAD or RLNAD/generic).

Measurements and Observations: The plasma concentrations of nitenpyram were measured using a validated bioanalytical method. Pharmacokinetic parameters were determined for each animal individually in each period. Animal observations were made throughout the study for assessment of general health and adverse events.

**Statistical Methods:**

The laboratory study was conducted as a randomized, masked, two-period, two-sequence, two-treatment, single-dose crossover design using 28 dogs with a 14-day washout between periods. Appropriate randomization of animal to sequence and pen/treatment order was performed. Primary variables evaluated were $C_{MAX}$ and AUC. Time to maximum concentration ($T_{MAX}$) was summarized and evaluated clinically.

A mixed-effect model was used to evaluate bioequivalence. The model included fixed effects of treatment, sequence and period, and a random effect of subject nested within sequence. Prior to the analysis, $C_{MAX}$ and AUC were natural logarithm transformed. Bioequivalence is established because the back-transformed estimated upper and lower bounds of the 90% confidence interval for geometric mean ratios (generic:RLNAD) of both $C_{MAX}$ and AUC are contained within the acceptance limits of 0.80 to 1.25.

**Results:**

As seen in the table below, $C_{MAX}$ and AUC fall within the prescribed bounds (Table II.2). The mean values of $T_{MAX}$ obtained for the generic article and RLNAD were summarized.

**Table II.2. Bioequivalence Evaluation**

| Parameter | Generic Mean | RLNAD Mean | Ratio◊ | Lower 90% CI | Upper 90% CI |
|---|---|---|---|---|---|
| AUC (ng/mL)*hour | 5116.00† | 5166.00† | 0.99 | 0.95 | 1.03 |
| $C_{MAX}$ (ng/mL) | 1466.74† | 1499.71† | 0.98 | 0.94 | 1.02 |
| $T_{MAX}$ (hours) (SD)‡ | 0.77 (0.35)‡ | 0.73 (0.43)‡ | NE | NE | NE |

† Geometric mean
‡ Arithmetic mean and standard deviation (SD)
◊ Ratio = Test/Reference
CI = confidence interval
NE = not estimated

**Adverse Reactions:**

There were no serious adverse events related to the test or reference article reported during the study.

**Conclusion:**

The *in vivo* bioequivalence study demonstrated that the generic 11.4 mg nitenpyram tablet and the RLNAD 11.4 mg CAPSTAR® (nitenpyram) tablet are bioequivalent in dogs.

## C. Bioequivalence Waiver

A pivotal *in vivo* blood bioequivalence study was conducted using the 11.4 mg nitenpyram tablet strength in dogs and cats. A waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) for the generic 57.0 mg tablet strength for use in dogs was requested. To qualify for a biowaiver for the 57.0 mg tablet strength for use in dogs, *in vitro* dissolution studies were conducted to determine the dissolution profiles of the generic and RLNAD 11.4 mg and 57.0 mg nitenpyram tablets. Comparisons were made between the following tablets:

- Generic 11.4 mg and RLNAD 11.4 mg tablets
- Generic 57.0 mg and RLNAD 57.0 mg tablets

Test conditions were as follows:

- Dissolution apparatus: USP Apparatus II
- Dissolution medium: Purified degassed water
- Dissolution medium volume: 900 mL
- Temperature: 37 °C
- Paddle speed: 100 rpm

- Number of vessels: 12
- Data points: 5, 10, 15, 20. 30, and 45 minutes

The generic drug lot number used in the *in vivo* bioequivalence study was the same lot used to support the *in vitro* profile comparisons. Analytical method validation was required to ensure that the quantification of drug concentrations in all samples was accurate and precise.

The use of mean data was not necessary if dissolution profiles were rapidly dissolving and $f_2$ (similarity factor) calculations were not applicable.

A summary of the results is presented in Table II.3. below:

**Table II.3. Similarity Results**

| Dissolution Comparison | Similarity Results |
|---|---|
| Dog: 11.4 mg generic to the 11.4 mg RLNAD | $f_2 = 55$ |
| Dog: 57.0 mg generic to the 57.0 mg RLNAD | > 85% dissolved in 15 minutes |

Study results demonstrate similar dissolution profiles for all comparisons. However, because of rapid dissolving characteristics (>85% in 15 minutes) in the 57.0 mg strength, a dissolution profile comparison using the $f_2$ test is unnecessary. When comparative profiles between tablets do not require an $f_2$ test because of rapid dissolution or when the $f_2$ value is ≥50, the product strengths used in the comparison qualify for a biowaiver. Therefore, a biowaiver for the generic 57.0 mg nitenpyram tablets is granted.

## III. 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 approval of this ANADA.

## IV. USER SAFETY

The product labeling 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.

## V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Nitenpyram Tablets, when used according to the label, are safe and effective for the conditions of use in the General Information Section above.