Date of Approval: December 22, 2025

# FREEDOM OF INFORMATION (FOI) SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-829

Klentz™

(florfenicol, terbinafine, mometasone furoate)

Solution

Dogs

Klentz™ is indicated for the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

Sponsored by:

Aurora Pharmaceutical, Inc.

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## I. GENERAL INFORMATION

### A. File Number

ANADA 200-829

### B. Sponsor

Aurora Pharmaceutical, Inc.
1196 Highway 3 South
Northfield, MN 55057-3009

Drug Labeler Code: 051072

### C. Proprietary Name

Klentz™

### D. Drug Product Established Name

florfenicol, terbinafine, mometasone furoate

### E. Pharmacological Category

Antibacterial, antifungal, and anti-inflammatory

### F. Dosage Form

Solution

### G. Amount of Active Ingredient

16.6 mg/mL florfenicol, 14.8 mg/mL terbinafine (equivalent to 16.6 mg/mL terbinafine hydrochloride) and 2.2 mg/mL mometasone furoate

### H. How Supplied

Supplied in a single-use dropperette in a blister. Each dropperette contains one 1 mL dose. Available in cartons of two, twelve, and twenty-four dropperettes.

### I. Dispensing Status

Prescription (Rx)

### J. Dosage Regimen

Administer one dose (1 dropperette) per affected ear.

### K. Route of Administration

Otic

### L. Species

Dogs

### M. Indications

Klentz™ is indicated for the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

### N. Reference Listed New Animal Drug (RLNAD)

CLARO™; florfenicol, terbinafine, mometasone furoate; NADA 141-440; Elanco US Inc.

## 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 certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Aurora Pharmaceutical, Inc., was granted a biowaiver for the generic product Klentz™ (florfenicol, terbinafine, mometasone furoate) otic solution. The generic drug product is a solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is CLARO™ (florfenicol, terbinafine, mometasone furoate) otic solution, sponsored by Elanco US Inc., under NADA 141-440, and was approved for use in Dogs on September 20, 2015.

## III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, CVM 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 Klentz™:

**Klentz™ should be administered by veterinary personnel.**

**Wear eye protection when administering Klentz™.**

Splatter may occur if the dog shakes its head following administration. Persons near the dog during administration should also take steps to avoid ocular exposure.

**Klentz™ may cause eye injury and irritation**.

If contact with eyes occurs, flush copiously with water for at least 15 minutes. If irritation persists, contact a physician.

Humans with known hypersensitivity to any of the active ingredients in Klentz™ should not handle this product.

Not for use in humans. Keep this and all drugs out of reach of children. Avoid skin contact. In case of accidental ingestion by humans, contact a physician immediately.

**Wear eye protection when administering Klentz™ and restrain the dog** to minimize post application head shaking. Reducing the potential for splatter of product will help prevent accidental eye exposure in people and dogs and help to prevent ocular injury.

## 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 Klentz™, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.