Date of Approval: December 19, 2025

CORRECTED FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-823

Zygolide®

(pergolide tablets)

Horses

For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease) in horses.

Sponsored by:

Dechra Veterinary Products LLC

Executive Summary

Zygolide® (pergolide tablets) is approved for the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease) in horses. The reference listed new animal drug (RLNAD) is Prascend® (pergolide tablets) sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-331. This is the first generic pergolide tablets for horses.

Bioequivalence

The sponsor conducted one *in vivo* blood-level study in horses to show that the 1 mg Zygolide® (pergolide tablets) is bioequivalent to the 1 mg Prascend® (pergolide tablets). No serious adverse events were reported during the study.

Conclusions

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

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-823

B. Sponsor

Dechra Veterinary Products LLC
7015 College Blvd.
Suite 525
Overland Park, KS 66211

Drug Labeler Code: 017033

C. Proprietary Name

Zygolide®

D. Drug Product Established Name

pergolide tablets

E. Pharmacological Category

Dopamine receptor agonist

F. Dosage Form

Tablet

G. Amount of Active Ingredient

1 mg of pergolide (as pergolide mesylate) per tablet

H. How Supplied

1 mg tablets packaged 10 tablets per blister card in 60 or 160 tablets per carton.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Administer orally at a starting dose of 2 mcg/kg once daily. Dosage may be adjusted to effect, not to exceed 4 mcg/kg daily.

K. Route of Administration

Oral

L. Species/Class

Horses

M. Indication

For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease) in horses.

N. Reference Listed New Animal Drug

Prascend®; pergolide tablets; NADA 141-331; Boehringer Ingelheim Animal Health USA, 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 (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, one *in vivo* blood-level study was conducted to demonstrate product bioequivalence using the generic and RLNAD 1 mg pergolide tablets. The RLNAD is available in 1 mg tablets. The *in vivo* blood-level study was conducted in 24 healthy, fasted horses. 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 1 mg Prascend® (pergolide tablets) and the 1 mg Zygolide® (pergolide tablets) by the mixed reference-scaled average bioequivalence approach as described in the Statistical Methods section below. The study information is summarized below.

A. Blood Level Bioequivalence Study in Horses

Title: A Four-Period, Two-Sequence, Crossover Pivotal Bioequivalence Study Comparing a Generic Pergolide Tablet to Prascend® Following Oral Administration to Healthy Horses. (Study No. D21001)

Study Dates: January 26, 2023 to August 2, 2023

Study Locations:

In-life phase: Oakland, NE

Bioanalytical testing: Drenthe, Netherlands

Study Design:

Objective: The objective of this study was to determine the comparative *in vivo* blood-level bioequivalence data for the generic 1 mg Zygolide® (pergolide tablets) and the RLNAD 1 mg Prascend® (pergolide tablets) in fasted horses.

Study Animals: 24 horses (12 geldings and 12 non-pregnant, non-lactating mares), ages 4 to 12 years and weighing 368.5 kg to 487 kg.

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

Drug Administration: Each animal received 2 mg (two, 1 mg tablets) of either the generic or RLNAD pergolide tablets according to their randomized treatment sequence (generic/RLNAD/generic/RLNAD or RLNAD/generic/RLNAD/generic).

Measurements and Observations: The plasma concentrations of pergolide 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 four-period, two-sequence, two-treatment, single-dose crossover design using 24 horses with a 7-day washout between periods. Appropriate randomization of animal to sequence and stall/treatment order was performed. Primary variables evaluated were C_{MAX} and AUC. Time to maximum concentration (T_{MAX}) was summarized and evaluated clinically.

The reference-scaled average bioequivalence (RSABE) was used as appropriate to evaluate bioequivalence through the mixed scaling approach. Prior to analysis, C_{MAX} and AUC values were natural logarithm transformed. The estimated within-subject standard deviation (S_{WR}) of the RLNAD was calculated separately for transformed C_{MAX} and AUC to select the appropriate analysis approach based on FDA Guidances.

The S_{WR} was less than 0.294 for C_{MAX} and AUC, so the average bioequivalence method was used to evaluate bioequivalence. The statistical model included fixed effects of treatment, sequence, period, and gender, and the random effects of cohort and subject nested within sequence by gender by cohort. Period was modeled as a repeated factor. Bioequivalence was established because the back-transformed estimated upper and lower bounds of the pertinent 90% confidence interval for geometric mean ratios (generic/RLNAD) were 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 (pg/mL)*hour	15178.7†	16210.7†	0.94	0.87	1.01
C_{MAX} (pg/mL)	9316.4†	9519.6†	0.98	0.89	1.08
T_{MAX} (hour) (SD)‡	0.41 (0.12)‡	0.44 (0.13)‡	NE	NE	NE

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

Adverse Reactions:

There were no serious adverse events reported during the study.

Conclusion:

The *in vivo* bioequivalence study demonstrated that the generic 1 mg Zygolide® (pergolide tablets) and the RLNAD 1 mg Prascend® (pergolide tablets) are bioequivalent in horses.

III. HUMAN FOOD SAFETY

This drug is intended for use in horses. 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.

The product labeling contains the following Warning statement: Do not use in horses intended for human consumption.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Zygolide®:

Not for use in humans. Do not ingest the product. Keep this and all medications out of the reach of children. Zygolide should not be administered by persons who have had adverse reactions to ergotamine or other ergot derivatives.

Pergolide, like other ergot derivatives, may cause emesis, dizziness, lethargy or low blood pressure.

Pregnant or lactating women should wear gloves when administering this product. It has been reported that pergolide tablets may cause eye irritation, an irritating smell, or headache when pergolide tablets are split or crushed. Zygolide tablets should not be crushed due to the potential for increased human exposure and care should be taken to minimize exposure when splitting tablets. Store this product separately away from human medicinal products and handle this product with care to avoid accidental ingestion.

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

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

VI. APPENDIX

The following correction was made to the Study Design in Section II.A on January 8, 2026:

Original text:

Drug Administration: Each animal received 1 mg of either the generic or RLNAD pergolide tablets according to their randomized treatment sequence (generic/RLNAD/generic/RLNAD or RLNAD/generic/RLNAD/generic).

Revised text:

Drug Administration: Each animal received 2 mg (two, 1 mg tablets) of either the generic or RLNAD pergolide tablets according to their randomized treatment sequence (generic/RLNAD/generic/RLNAD or RLNAD/generic/RLNAD/generic).