Date of Approval: August 28, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-821

Isoflurane

Liquid

Horses and Dogs

Isoflurane is used for induction and maintenance of general anesthesia in horses and dogs.

Sponsored by:

Parnell Technologies Pty. Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-821

B. Sponsor

Parnell Technologies Pty. Ltd.,
Unit 4,
476 Gardeners Rd.,
Alexandria, New South Wales 2015,
Australia

Drug Labeler Code: 068504

C. Proprietary Name

Isoflurane

D. Drug Product Established Name

isoflurane

E. Pharmacological Category

Inhalation anesthetic

F. Dosage Form

Liquid

G. Amount of Active Ingredient

Each mL contains 99.9% isoflurane

H. How Supplied

250 mL amber-colored bottles

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Inspired Concentration: The delivered concentration of Isoflurane should be known. Isoflurane may be vaporized using a flow-through vaporizer specifically calibrated for isoflurane. Vaporizers delivering a saturated vapor which then is diluted (e.g., Vernitrol® vaporizer) also may be used. The delivered concentration from such a vaporizer may be calculated using the formula:

$$\% \text{ isoflurane} = \frac{100 P_v F_v}{F_T (P_A - P_v)}$$

Where: P_A = Pressure of atmosphere
P_v = Vapor pressure of isoflurane
F_v = Flow of gas through vaporizer (mL/min)
F_T = Total gas flow used (mL/min)

Horses:

Induction: Inspired concentrations of 3.0 to 5.0% isoflurane alone with oxygen following a barbiturate anesthetic induction are usually employed to induce surgical anesthesia in the horse.

These concentrations can be expected to produce surgical anesthesia in 5 to 10 minutes.

Maintenance: The concentration of vapor necessary to maintain anesthesia is much less than that required to induce it.

Surgical levels of anesthesia in the horse may be sustained with a 1.5 to 1.8% concentration of isoflurane in oxygen.

Dogs:

Induction: Inspired concentrations of 2.0 to 2.5% isoflurane alone with oxygen following a barbiturate anesthetic induction are usually employed to induce surgical anesthesia in the dog.

These concentrations can be expected to produce surgical anesthesia in 5 to 10 minutes.

Maintenance: The concentration of vapor necessary to maintain anesthesia is much less than that required to induce it.

Surgical levels of anesthesia in the dog may be sustained with a 1.5 to 1.8% concentration of isoflurane in oxygen.

K. Route of Administration

Inhalation

L. Species/Class

Horses and Dogs

M. Indication

Isoflurane is used for induction and maintenance of general anesthesia in horses and dogs.

N. Reference Listed New Animal Drug (RLNAD)

AErrane®; isoflurane; NADA 135-773; Baxter Healthcare Corporation

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, Parnell Technologies Pty. Ltd., was granted a biowaiver for the generic product Isoflurane inhalation anesthetic. 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 AErrane® (isoflurane) inhalation anesthetic, sponsored by Baxter Healthcare Corporation, under NADA 135-773, and was originally approved for use in horses on January 7, 1986, and dogs on June 1, 1989.

III. HUMAN FOOD SAFETY

This drug is intended for use in horses and 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.

The product labeling contains the following Warning statement: Not for 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 Isoflurane:

Caution: Operating rooms and animal recovery areas should be provided with adequate ventilation to prevent the accumulation of anesthetic vapors.

Not for use in Humans. Keep Out of 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 Isoflurane, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.