Date of Approval: January 30, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-830

Sevoflurane

Liquid

Dogs

Sevoflurane is indicated for induction and maintenance of general anesthesia in dogs.

Sponsored by:

Parnell Technologies Pty. Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-830

B. Sponsor

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

Drug Labeler Code: 068504

C. Proprietary Name

Sevoflurane

D. Drug Product Established Name

sevoflurane

E. Pharmacological Category

Inhalation anesthetic

F. Dosage Form

Liquid

G. Amount of Active Ingredient

250 mL sevoflurane

H. How Supplied

250 mL amber colored bottles

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Induction: For mask induction using sevoflurane alone, inspired concentrations of **up to 7%** sevoflurane with oxygen are employed to induce surgical anesthesia in the healthy dog. These concentrations can be expected to produce surgical anesthesia in 3 to 14 minutes.

Maintenance: Surgical levels of anesthesia in the healthy dog may be maintained with inhaled concentrations of **3.7 - 4.0%** sevoflurane in oxygen in the absence of premedication and **3.3 - 3.6%** in the presence of premedication.

K. Route of Administration

Inhalation

L. Species/Class

Dogs

M. Indication

Sevoflurane is indicated for induction and maintenance of general anesthesia in dogs.

N. Reference Listed New Animal Drug (RLNAD)

SevoFlo®; sevoflurane; NADA 141-103; Zoetis 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, Parnell Technologies Pty. Ltd. was granted a biowaiver for the generic product Sevoflurane inhalation anesthetic. The generic drug product is a liquid, 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 SevoFlo® (sevoflurane) inhalation anesthetic, sponsored by Zoetis Inc., under NADA 141-103, and was approved for use in dogs on November 17, 1999.

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, 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 Sevoflurane:

HUMAN SAFETY:
Not for human use. Keep out of reach of children.

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

There is no specific work exposure limit established for sevoflurane. However, the National Institute for Occupational Safety and Health has recommended an 8 hour time-weighted average limit of 2 ppm for halogenated anesthetic agents in general.

Direct exposure to eyes may result in mild irritation. If eye exposure occurs, flush with plenty of water for 15 minutes. Seek medical attention if irritation persists.

Symptoms of human overexposure (inhalation) to sevoflurane vapors include respiratory depression, hypotension, bradycardia, shivering, nausea and headache. If these symptoms occur, remove the individual from the source of exposure and seek medical attention.

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet(s), contact Parnell at 1-800-887-2763 or visit www.parnell.com.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

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