Approval Date: April 3, 2008

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-438

PETREM
(sevoflurane)

Indications for use: For induction and maintenance of general anesthesia in dogs

Sponsored by:

Minrad, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-438
b. Sponsor:	Minrad, Inc. 846 Main St., 2d floor Buffalo, NY 14202 Drug Labeler Code: 060307
c. Established Name:	Sevoflurane
d. Proprietary Name:	PETREM
e. Dosage Form:	Solution
f. How Supplied:	250 mL amber colored bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	250 mL sevoflurane
i. Route of Administration:	Inhalation
j. Species/Class:	Dogs
k. Recommended Dosage:	**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. **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.
l. Pharmacological Category:	Anesthesia
m. Indications:	PETREM is indicated for induction and maintenance of general anesthesia in dogs.

n. Pioneer Product: SEVOFLO; sevoflurane; NADA 141-103; Abbott Laboratories

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Minrad, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product PETREM (sevoflurane). The generic product is administered as an inhalant, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, SEVOFLO (sevoflurane), the subject of Abbott Laboratories, NADA 141-103, was approved on November 17, 1999.

3. HUMAN SAFETY:

This drug is intended for use in dogs which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that the inhaled product PETREM, when used under their proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-438:
PETREM (sevoflurane) – Container and Carton labels – 250 mL, Package insert

Pioneer Labeling for NADA 141-103:
SEVOFLO (sevoflurane) – Container and Carton labels – 250 mL, Package insert