Approval Date: December 19, 1997

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-237

B. Sponsor

Rhone-Poulenc Chemicals Ltd.
P.O. Box 46, St. Andrew's Road
Avonmouth, Bristol BS11 9YF
England

C. Proprietary Name

Isoflurane, USP

D. Established Name

isoflurane, USP

E. Dosage Form

Isoflurane, USP is a clear, colorless, stable liquid containing no additives or chemical stabilizers.

F. Dispensing Status

Rx

G. Dosing Regimen

Horses:

- For induction of surgical anesthesia: Inspired concentrations of 3.0 to 5.0% isoflurane with oxygen, following a barbiturate anesthetic induction, are used to induce surgical anesthesia in the horse.

- For maintenance of surgical anesthesia: Surgical levels of anesthesia may be sustained using a 1.5 to 1.8% concentration of isoflurane in oxygen.

Dogs:

- For induction of surgical anesthesia: Inspired concentrations of 2.0 to 2.5% isoflurane with oxygen, following a barbiturate anesthetic induction, are used to induce surgical anesthesia in the dog.

- For maintenance of surgical anesthesia: Surgical levels of anesthesia may be sustained using a 1.5 to 1.8% concentration of isoflurane in oxygen.

H. Route of Administration

Inhalation

I. Indication

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

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA is approved based on a demonstration of bioequivalence to the pioneer product. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1996).

Based on the formulation characteristics of the generic product, Rhone-Poulenc Chemicals Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Isoflurane, USP. The generic product is administered as an inhalation and contains the same active and inactive ingredients in the same concentration as the pioneer product.

III. HUMAN FOOD SAFETY

Human Safety Relative to Food Consumption
Regarding consumption of drug residues in food, human safety data were not required for approval of this ANADA. This drug is for use in dogs, which are non-food animals, and for horses that are not to be used for food, and is labeled: "Warning: Not for use in horses intended for food."

Human Safety Relative to Possession, Handling and Administration
A cautionary statement which pertains to the safety of this drug product for humans is included in the labeling of the drug product, as follows: "Caution: Operating room should be provided with adequate ventilation to prevent the accumulation of anesthetic vapors."

IV. AGENCY CONCLUSIONS

This is an abbreviated new animal drug application (ANADA) filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Isoflurane, USP, were established by demonstration of chemical equivalence to the pioneer product, Ohmeda Pharmaceutical Products Division, Inc.'s AErrane (Isoflurane, USP, NADA 135-773).

This generic product and the pioneer product have identical labeling indications for use. The route and method of administration of the two drugs are identical. Both drugs are administered by inhalation. The generic and pioneer products are both liquid anesthetics that contain the same active and inactive ingredients in the same concentrations. Therefore, consistent with FDA policy implementing section 512(b)(2) of the FFD&C Act, *in vivo* bioequivalency studies were not necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Isoflurane, USP is safe and effective for its labeled indications when used under its proposed conditions of use.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.