

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-129

B. Sponsor

Halocarbon Laboratories (Division of Halocarbon Products Corporation)
P.O. Box 6369
North Augusta, SC 29841

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. Dosage Regimen

Horses For induction of anesthesia: 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.

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

Dogs For induction of anesthesia: 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.

For maintenance of 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 dogs and horses.

II. EFFECTIVENESS & 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). For certain dosage forms, the Agency grants a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; fifth GADPTRA Policy Letter). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based on the formulation characteristics of the generic product, Halocarbon Laboratories was granted a waiver January 24, 1994 (photocopy attached) from conducting an *in vivo* bioequivalence study with Isoflurane, USP. The generic and pioneer products are liquid anesthetics with the same inactive ingredients and the same concentrations of the active ingredient.

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 rooms 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, Anaquest, 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, in compliance with FDA policy promulgated to implement Section 512(b)(2) of the FFD&C Act, no additional safety, efficacy, or *in vivo* bioequivalency studies were 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.

ANADA 200-129 A0000 Copy of waiver letter

Kenneth J. McDowell, Director
Environment, Health and Safety
Halocarbon Products Corporation
1100 Dittman Court
N. Augusta, SC 29841

Dear Mr. McDowell:

We refer to your Abbreviated New Animal Drug Application (ANADA) dated July 14, 1993 (A0000) for Isoflurane, USP liquid), an inhalant anesthetic proposed for the induction and maintenance of general anesthesia in horses and dogs. The application was submitted based on the generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988. The approved pioneer product is AErrane®, manufactured by Anaquest, Inc. (NADA 135-773). For administrative purposes, we have assigned number 200-129 to your ANADA.

The A0000 submission requested a waiver of the requirement for *in vivo* bioequivalency testing and provided information to establish the equivalence of the generic and pioneer products. It also provided information on the components and composition of the drug; the manufacturing methods, facilities and controls; pioneer and generic labeling; an Environmental Assessment (EA); and a Freedom of Information (FOI) Summary.

After reviewing the submission, we have concluded that the application is incomplete and have the following comments:

DEBARMENT STATEMENT: Complete

SAFETY AND EFFICACY: Complete

We have reviewed your submission requesting a waiver of *in vivo* bioequivalence testing for the proposed generic product of isoflurane, USP. Your request is granted.

Your product contains the same active ingredient in the same concentration as the pioneer product. The physicochemical characteristics of your proposed generic product conform to the USP XXII specifications for isoflurane. On the basis of the formulation and physicochemical characteristics of your proposed generic product, you have demonstrated the equivalence of the generic and pioneer products. Safety and efficacy of the generic product are based on the demonstration of chemical equivalence to the pioneer product.

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.