

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-200

B. Sponsor

Halocarbon Products Corporation
for Halocarbon Laboratories
P.O. Box 661
887 Kinderkamack Road
River Edge, NJ 07661

C. Proprietary Name

Halothane, USP

D. Established Name

halothane, USP

E. Dosage Form

Halothane, USP is a clear, colorless, stable liquid containing 0.01% Thymol as a preservative.

F. Amount of Active Ingredient

Each mL contains 99.99% halothane

G. How Supplied

HALOTHANE, USP is available in 250 mL amber-colored bottles.

H. Dispensing Status

Rx

I. Dosage Regimen

For induction of anesthesia: The concentration of Halothane, USP required to induce anesthesia will vary from patient to patient but will usually be between 2% and 5%. Use of an oxygen/nitrous oxide mixture will normally require a slightly lower concentration of halothane to achieve the same plane of anesthesia as opposed to use of oxygen alone. Use of a tranquilizer as a pre-anesthetic agent will also normally require a slightly lower concentration of Halothane, USP.

For maintenance of anesthesia: The maintenance dose of Halothane, USP usually will vary between 0.5% to 2% in the inhaled atmosphere. While under the effects of barbiturates the required maintenance concentration will normally be lower than after the effect of the barbiturate has terminated

J. Route of Administration

Inhalation

K. Species/Class

Dogs, cats, and other non-food animals.

L. Indication

HALOTHANE, USP (Halothane, USP) is used for induction and maintenance of general anesthesia in dogs cats, and other non-food animals.

M. Pioneer Product

HALOTHANE, USP, FORT DODGE LABORATORIES, Inc., Fort Dodge, Iowa 50501, NADA 14-170

II. 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 and the Center's first policy letter (53 FR 50460, December 15, 1988), an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). The sponsor of the generic product must demonstrate that the generic is bioequivalent to the pioneer. For certain dosage forms, the Agency may grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; fifth GADPTRA Policy Letter). In lieu of *in vivo* bioequivalence testing, the bioequivalence of the generic product is based on the demonstrated chemical equivalence.

Based on the formulation characteristics of the generic product, Halocarbon Products Corporation was granted a waiver (see attached approval letter) from conducting an *in vivo* bioequivalence study with Halothane, USP. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations of the active ingredient.

III. HUMAN FOOD SAFETY

A. Human Safety Relative to Food Consumption

Regarding consumption of drug residues in food, human safety data were not required for approval of this ANADA. The drug is to be labeled for use in dogs, cats and other non-food animals. "Warning: Halothane, USP should not be used in animals for use as food."

B. 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.

Bioequivalence of this generic animal drug, Halothane, USP, to the pioneer product, FORT DODGE LABORATORIES HALOTHANE, USP (Halothane, USP, NADA 14-170). was established by demonstration of chemical equivalence.

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 solutions that contain the same active and inactive ingredients in the same concentrations. Both products have the same pH. Therefore, consistent with FDA policy implementing Section 512(b)(2) of the FFD&C Act, no in vivo bioequivalency studies were necessary or required.

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

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.