Approval Date: July 26, 1994

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-141

B. Sponsor

Inhalon Pharmaceuticals, Inc.
P.O. Box 21170
Lehigh Valley, PA 18002-1170

C. Proprietary Name

Isoflurane, USP

D. Established Name

isoflurane, USP

E. Pharmacological Category

Anticoccidial, antimicrobial, antiparasitic, etc.

F. Dosage Form

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

G. Amount of Active Ingredient

X mg/ml, g/lb, etc.

H. How Supplied

Size and Description of container

I. Dispensing Status

Rx

J. Dosage Regimen

Horses:

For induction of 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 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.

Dogs:

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

K. Route of Administration

Inhalation

L. 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). 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, Inhalon Pharmaceuticals, Inc. was granted a waiver on April 4, 1994 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.

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.