Approval Date: March 11, 1993

# FREEDOM OF INFORMATION SUMMARY

## I. GENERAL INFORMATION

### A. File Number

ANADA 200-070

### B. Sponsor

Abbott Laboratories
Chemical and Agricultural Products Division
1401 Sheridan Road
North Chicago, IL 60064

### C. Proprietary Name

IsoFlo™

### D. Established Name

Isoflurane, USP

### E. Dosage Form

clear, colorless, stable liquid containing no additives or chemical stabilizers

### F. Dispensing Status

Rx

### G. Route of Administration

Inhalation

### H. Indication

IsoFlo (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 and drug effectiveness data werenot required for approval of this ANADA. This ANADA relies on the target animal safety and drug effectiveness data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to thepioneer. Bioequivalence is usually demonstrated through a clinical end-point study.

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 1990). Based upon the formulation characteristics of the

generic product, Abbott Laboratories was granted a waiver from conducting an in vivo bioequivalence study for IsoFlo(TM). The generic and pioneer products are liquid anesthetics with the same active and inactive ingredients. The generic and pioneer products also contain the same concentration of active ingredient. This ANADA was granted a waiver October 5, 1992 (see section 5).

## III. HUMAN FOOD SAFETY

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this ANADA. The drug is to be labeled for use in dogs, which are non-food animals, and only for use in horses that are not to be used for food, and is to be 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 ANADA satisfies the requirements of section 512 of the Act and demonstrates that IsoFlo (isoflurane, USP), when used under its proposed conditions of use, is safe and effective for 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.