Approval Date: July 21, 1994

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-073

B. Sponsor

American Veterinary Products, Inc.
749 S. Lemay, Suite A3-231
Fort Collins, Colorado 80524

C. Proprietary Name

ketamine hydrochloride injection, USP

D. Established Name

ketamine hydrochloride injection, USP

E. Dosage Form

Solution

F. Amount of Active Ingredient

Each mL contains ketamine hydrochloride equivalent to 100 mg ketamine base

G. Route of Administration

Intramuscular injection

H. Dispensing Status

Rx

I. Dosage Regimen

Cats:
A dose of 11 mg/kg (5 mg/lb) is recommended to produce restraint. Dosages from 22 to 33 mg/kg (10 to 15 mg/lb) produce anesthesia that is suitable for diagnostic or minor surgical procedures that do not require skeletal muscle relaxation.

Subhuman primates:
The recommended restraint dosages for the following species are: *Cercocebus torquatus* (whitecollared mangabey), *Papio cynocephalus* (yellow baboon), *Pan troglodytes verus* (chimpanzee), *Papio anubis* (olive baboon), *Pongo pygmaeus* (orangutan), *Macaca nemestrina* (pig-tailed macaque), 5 to 7.5 mg/kg; *Presbytis entellus* (entellus langur), 3 to 5 mg/kg; *Gorilla gorilla gorilla* (gorilla), 7 to 10 mg/kg; *Aotus trivirgatus* (night monkey), 10 to 12 mg/kg; *Macaca mulatta* (rhesus monkey), 5 to 10 mg/kg; *Cebus capucinus* (white-throated capuchin), 13 to 15 mg/kg; *Macaca fascicularis* (crab-eating macaque), *Macaca radiata* (bonnet macaque), and *Saimiri sciureus* (squirrel monkey), 12 to 15 mg/kg.

J. Indications for Use:

Ketamine hydrochloride injection, USP may be used in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. It may be used in subhuman primates for restraint.

K. Route of Administration

Intramuscular injection

L. Indication

Exactly from labeling

M. Reference Listed New Animal Drug

Ketaset® [Vetalar®] (ketamine hydrochloride, 100 mg/mL), NADA 045-290 by Fort Dodge Laboratories, Inc.

II. TARGET ANIMAL SAFETY AND EFFECTIVENESS

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, American Veterinary Products, Inc. was granted a waiver on June 4, 1992 (see section 4) from conducting an in vivo bioequivalence study with ketamine hydrochloride injection, 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

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 labeled for use in cats and subhuman primates not intended for food.

Human Safety Relative to Possession, Handling and Administration:
Labeling contains adequate caution/warning statements.

IV. WAIVER LETTER

INAD 8257 (C001)
Gene Komer, PhD Director of Research and Development American Veterinary Products, Inc. 749 S. LeMay, Suite A3-231 Fort Collins, CO 80524

Dear Dr. Komer:

We refer to your submission dated March 18, 1992 to the Investigational New Animal Drug (INAD) file for a generic copy of Fort Dodge's Vetalar® (ketamine hydrochloride, 100 mg/ml, NADA 045-290). The pioneer product is approved as a restraining agent in cats and subhuman primates. It can also be used as the sole anesthitic agent for diagnostic or minor, brief surgical procedures that do not requires skeletal muscle relaxation in cats. You requested a waiver of the requirement for an in vivo bioequivalence study to support the filing of an Abbreviated New Animal Drug Application (ANADA) based on the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988.

The submission contains the following:

1. Copies of previous correspondence regarding the proposed product.
2. Copies of the carton and illegible container labels and the package insert for the pioneer product.
3. A list of the pH of the pioneer product, the proposed generic product, and the pH range from USP XXII.
4. An itemized list of the active and inactive ingredients and their concentrations in the proposed product.
5. Comparative ultra-violet spectrophotometric scans of the pioneer product and your proposed generic product.

Your proposed generic product contains the same active and inactive ingredients in the same concentration as the pioneer product, Vetalar®.

The final pH of your product conforms to that of the pioneer and to current USP specifications.

Your request for a waiver of in vivo bioequivalence testing is granted on the condition that the information in your ANADA continues to show that your proposed generic product is equivalent to the pioneer, Vetalar®.

Granting of this waiver does not assure approval of your ANADA. All necessary requirements must be fulfilled, including certification that your product or its proposed uses do not violate or infringe upon any patent or exclusivity for the pioneer product or its uses.

We have reviewed your request for waiver of bioequivalency tests under the National Environmental Policy Act. Since there are no investigations planned under this INAD, no wastes are expected to enter the environment. Therefore, we have determined that this action qualifies under 21 CFR 25.24(d)(4) for categorical exclusion from the requirement to prepare an environmental assessment (EA). If any studies are planned under the INAD, please file either a claim for exclusion or an EA.

Future correspondence to your INAD file regarding this submission should be identified by the date of this letter and our file number, INAD 8257 (C001).

In submitting your ANADA, please refer to this number and include a copy of this correspondence in your original submission.

Should you have any questions or if we may be of further assistance, please contact Dr. Marcia K. Larkins, Chief, Companion and Wildlife Drugs Branch. The telephone number is (301) 295-8614.

Sincerely yours,

Bob G. Griffith, DVM Division of Drugs for Non-Food Animals New Animal Drug Evaluation Center for Veterinary Medicine

V. 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, ketamine hydrochloride injection, USP, 100 mg/mL, were established by demonstration of chemical equivalence to the pioneer product, Fort Dodge Laboratories Vetalar®/Ketaset® (ketamine hydrochloride injection, USP, 100 mg/mL, NADA 045-290). Therefore, this ANADA satisfies the requirements of section 512 of the Act.

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 intramuscular injection. 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, 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.

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.