Date of Approval: November 9, 2001

FREEDOM OF INFORMATION (FOI) SUMMARY

Ketamine Hydrochloride injection for cats and subhuman primates

ANADA 200-257

Vetrepharm Research, Inc.

119 Rowe Road

Athens, Georgia 30601

1. GENERAL INFORMATION

ANADA #: 200-257

Sponsor:
Vetrepharm Research, Inc.
119 Rowe Road
Athens, GA, U.S.A.
30601
DLC # 064847

Trade Name: Ketamine HCl

Generic Name: Ketamine hydrochloride injection USP

Dosage Form: Sterile Solution

How Supplied: 10 ml multiple doses vials

How Dispensed: Prescription

Amount of Active Ingredients: Each ml contains ketamine hydrochloride equivalent to 100-mg ketamine base.

Route of Administration: Intramuscular Injection

Species: Cats and subhuman primates

Labeled Dosage:

- **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* (white-collared 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.

A single intramuscular injection produces restraint suitable for TB testing, radiography, physical examination or blood collection.

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.

Pioneer Product:
Vetalar®, (ketamine hydrochloride, 100 mg/mL), NADA 045-290 by Fort Dodge Animal Health.

2. 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 (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, Vetrepharm Research, Inc. was granted a waiver February 6, 1998, from conducting an in vivo bioequivalence study with Ketamine Hydrochloride Injection. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations of the active ingredient.

3. HUMAN SAFETY:

Human Safety Relative to Food Consumption:
Regarding consumption of drug residues in food, human safety data are not required since 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.

4. 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 (100 mg/ml), were established by demonstration of chemical equivalence to the pioneer product, Fort Dodge Animal Health's Vetalar® (ketamine hydrochloride, USP, 100 mg/ml, NADA 045-290).

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.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Ketamine HCl is safe and effective for its labeled indications when used under its proposed conditions of use.