

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-029

B. Sponsor

Fermenta Animal Health Company
P.O. Box 338
15th and Oak St.
Elwood, KS 66024

C. Proprietary Name

Ketamine Hydrochloride Injection

D. Established Name

ketamine hydrochloride injection

E. Dosage Form

Solution

F. Amount of Active Ingredient

Each mL contains ketamine hydrochloride equivalent to 100 mg ketamine base

G. Dispensing Status

Rx

H. Dosage Regimen

Cats:

A dose of 11 mg/kg (5mg/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; *Maccaca mulatta* (rhesus monkey), 5 to 10 mg/kg; *Cebus capucinus* (white-throated capuchin), 13 to 15 mg/kg; *Macaca fascicularis* (crab-eating macaque), *Macaque 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.

I. Route of Administration

Injection

J. Species/Class

Cats and subhuman primates

K. Indication

Ketamine Hydrochloride Injection 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.

L. Pioneer Product

Fort Dodge Laboratories Vetalar®/Ketaset® (ketamine hydrochloride, 100 mg/mL, NADA 045- 290)

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 (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, Fermenta Animal Health Company was granted a waiver July 26, 1995, 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.

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. 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 Laboratories' Vetalar[®]/Ketaset[®] (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 Hydrochloride Injection 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.