Date of Approval: June 13 2000

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-279

Ketaflo™ (ketamine hydrochloride injection, USP) Sterile Solution

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.

Sponsored by:

Abbott Laboratories
Chemical and Agricultural Products Division
1401 Sheridan Road
North Chicago, Il 60064-6316

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA: 200-279

Sponsor: Abbott Laboratories
Chemical and Agricultural Products Division
1401 Sheridan Road
North Chicago, IL 60064-6316

Trade Name: KetaFlo®

Established Name: Ketamine Hydrochloride Injection

Dosage Form: Sterile Solution

How Supplied: 10 mL multiple dose vials

How Dispensed: Rx

Amount of Active Ingredients: 100 mg ketamine base equivalent/mL solution

Route of Administration: Intramuscular injection

Species: Cats and subhuman primates

Labeled Dosage:

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 pygamaeus* (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.

Indications for Use:

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.

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

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, Abbott Laboratories was granted a waiver June 4, 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 were not required for approval of this ANADA. This drug is labeled for use in cats and subhuman primates.

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 Laboratories' Vetalar® (ketamine hydrochloride, USP, 100mg/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.

5. ATTACHMENTS:

    1. Generic Labeling:

        Package Insert

        Vial label

        Carton label

    2. Pioneer Labeling:

        Package Insert

        Vial Label

Copies of these labels may be obtained by writing to the:

Freedom of Information Office
Center for Veterinary Medicine, FDA
7500 Standish Place
Rockville, MD 20855