

## FREEDOM OF INFORMATION SUMMARY

### I. GENERAL INFORMATION

#### A. File Number

ANADA 200-042

#### B. Sponsor

Phoenix Pharmaceutical Inc.  
3336 Pear Street  
P.O. Box 7 Farleigh Station  
St. Joseph, MO 64506

#### C. Proprietary Name

Ketaject®

#### D. Established Name

ketamine hydrochloride injection, USP

#### E. Dosage Form

Intramuscular injection

#### 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; *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.

### **I. Route of Administration**

Injection

### **J. Species/Class**

Cats and subhuman primates

### **K. Indication**

Ketaject® (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.

## **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). 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, Phoenix Pharmaceutical, Inc. was granted a waiver July 19, 1990 (see Section 4) from conducting an *in vivo* bioequivalence study with Ketaject®. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations of the active ingredient.

## **III. HUMAN FOOD SAFETY**

### **A. 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.

### **B. Human Safety Relative to Possession, Handling and Administration:**

Labeling contains adequate caution/warning statements.

## **IV. WAIVER LETTER**

INAD 6752 (A000)  
James H. Schafer, D.V.M.  
Consultant to the Veterinary  
Pharmaceutical Industry  
800 Helena Ct.  
Ft. Collins, Colorado 80524

Dear Dr. Schafer,

We refer to your submission dated April 9, 1990, requesting an Investigational Exemption for a generic copy of Ketaset (ketamine hydrochloride injection) for intramuscular use in cats as an anesthetic and restraining agent and in subhuman primates as a restraining agent. The Submission also contained a request for a waiver of *in vivo* bioequivalence testing required for an Abbreviated New Animal Drug Application (ANADA).

Based on the information you provided, your proposed product is a solution containing the same active and inactive ingredients as the pioneer product. It is intended solely for intramuscular injection. It is, therefore, eligible for waiver from *in vivo* bioequivalence testing under our current policy.

Your request for a waiver is granted on the condition that the full information presented in your ANADA continues to show that your proposed generic product is chemically equivalent to the pioneer product. If it is not shown to be chemically equivalent, *in vivo* bioequivalence testing could be required.

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.

For administrative purposes, we have assigned you Investigational New Animal Drug (INAD) number 6752 for the above referenced use of ketamine hydrochloride. In submitting your ANADA, please refer to this number and include a copy of this correspondence in your original submission. All future correspondence pertaining to this drug should be sent to the following:

Dr. Marcia K. Larkins  
Division of Drugs for Non-Food Animals  
HFV-112, Room 6B-24  
Center for Veterinary Medicine  
Food and Drug Administration  
5600 Fishers Lane Rockville, MD 20857

Should you have questions or need further assistance, please contact Dr. Marcia K. Larkins, Chief for Companion & Wildlife Drugs Branch. The telephone number is (301) 443-3430.

Sincerely yours,

Bob G. Griffith, DVM  
Director, 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, Ketaject® (ketamine hydrochloride, USP, 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 Ketaject® 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.