Approval Date: June 1, 2006

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-391

Griseofulvin Powder Microsize (Griseofulvin)

For the treatment of ringworm infection in horses

Sponsored by:

IVX Animal Health, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number	ANADA 200-391
b. Sponsor:	IVX Animal Health, Inc. 3915 South 48th Street Ter. St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Name:	Griseofulvin
d. Proprietary Name:	Griseofulvin Powder Microsize
e. Dosage Form:	Powder
f. How Supplied:	15-gram tubes and 15-gram pouches
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	2.5 grams Griseofulvin (microsize)
i. Route of Administration:	Oral
j. Species/Class:	Horses
k. Recommended Dosage:	Adults – 2 packet or bottle per day (2.5 grams). Yearlings – ½ to 1 packet or bottle per Day (1.25-2.5 grams). Foals - ½ packet or bottle per day.
l. Pharmacological Category:	Antifungal, antibiotic
m. Indications:	Equine – Ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum*.
n. Pioneer Product:	FULVICIN U/F (Griseofulvin microsize) Powder; NADA 39-792; Schering-Plough Animal Health Corp.

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 (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).
http://www.fda.gov/cvm/guidance/published.htm#documents

Based on the formulation characteristics of the generic product, IVX Animal Health, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Griseofulvin Powder Microsize. The generic product is administered as an oral solution, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, FULVICIN U/F (Griseofulvin microsize) Powder, the subject of Schering-Plough Animal Health Corp. NADA 39-792, was approved on May 19, 1970.

3. HUMAN SAFETY:

This drug is intended for use in horses, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human Warnings are not provided on the product label.

4. AGENCY CONCLUSIONS:

This supplemental ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Griseofulvin Powder Microsize, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-391:
Label 15 gram bottle
Label 15 gram pouch
Package Insert

Pioneer Labeling for NADA 39-792:
15 gram pouch
Carton of 50 15-gram packets
Package Insert