Date of Approval: January 22, 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-347

Indications for use: Treatment of erysipelas in turkeys.

Sponsored by:
Phoenix Scientific, Inc.
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. ANADA Number	200-347
b. Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th St. Terrace St. Joseph, MO 64503 21 CFR 510.600: Labeler Code: 059130
c. Established Name:	Penicillin G Potassium USP Soluble Powder
d. Trade/Proprietary Name:	Penicillin G Potassium USP Soluble Powder
e. Dosage Form:	Soluble Powder for drinking water
f. How Supplied:	48 oz HDPE jugs
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each jug contains Penicillin G Potassium equivalent to 0.5 billion I.U.
i. Route of Administration:	Oral
j. Species:	Turkeys
k. Labeled Dosage and Administration:	Administer orally at a dosage of 1,500,000 units of penicillin per gallon (3.8L) of drinking water for 5 consecutive days.
l. Indications for Use:	Penicillin G Potassium Soluble Powder is indicated in turkeys for the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.

m. Pharmacological Category: Antibacterial

n. Pioneer Product: Penicillin G Potassium Soluble Powder manufactured by Fort Dodge Animal Health (NADA 55-060)

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 drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA Sponsor shows 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 conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on July 3, 2001, from the requirement of an *in vivo* bioequivalence study for Penicillin G Potassium USP Soluble Powder. The generic and pioneer products contain the same active and inactive ingredients in nearly the same concentration as the pioneer and are oral solutions. The pioneer product, Penicillin G Potassium USP, the subject of Fort Dodge Animal Health's NADA 55-060 was approved on December 18, 1973.

3. HUMAN SAFETY:

Tolerance:

The tolerances established for the pioneer apply to the generic product.
Under section §556.510, Penicillin, a tolerance of 0.01 ppm is established for residues of penicillin in the uncooked edible tissues of turkeys.

Withdrawal Time:

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for Penicillin is established under 21 CFR 520.1696b. There is a one-day withdrawal period for turkeys.

Regulatory Methods for Residues:

The analytical method for the determination of penicillin in tissues uses a microbiological assay procedure using *Sarcina lutea*. This method is found in the Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Methods, Reports, and Protocols, revised October 1968, reprinted December 1974, National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204. The methods are on file at the Center for Veterinary Medicine, Food and Drug Administration, HFV-199, 7500 Standish Place, Rockville, Maryland 20855.

Human Safety Relative to Possession, Handling, and Administration:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed 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 Penicillin G Potassium Soluble Powder is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

ATTACHMENTS: Pioneer Labeling for NADA 55-060:

48 ounce wide mouth jar labeling

Generic Labeling:

AmTech Penicillin G Potassium USP
48 ounce wide mouth jar labeling

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

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.