Approval Date: April 17, 1995

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-122

B. Sponsor

Wade Jones Company
Highway 71 North
Lowell, Arkansas 72745

C. Proprietary Name

Penicillin G Potassium

D. Established Name

Solu-Pen

E. Pharmacological Category

Antibiotic

F. Dosage Form

Soluble powder

G. Amount of Active Ingredient

0.384 billion units penicillin G potassium

H. How Supplied

PENICILLIN G POTASSIUM USP SOLUBLE POWDER is supplied in 8.4 ounce (241 g) glass bottles or polyfoil packet.

I. Dispensing Status

OTC

J. Route of Administration

Oral

K. Species/Class

Turkeys

L. Indication

PENICILLIN G POTASSIUM USP SOLUBLE POWDER is indicated for treatment of erysipelas in turkeys (caused by *Erysipelothrix rhusiopathiae*).

II. TARGET ANIMAL SAFETY AND 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). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If point study, then a tissue bioequivalence is demonstrated through a clinical end-residue study to establish the withdrawal time for the generic product is also required. 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, April 1990).

Based upon the formulation characteristics of the generic product, Wade Jones in vivo bioequivalence study for Company was granted a waiver from conducting an PENICILLIN G POTASSIUM USP. The generic and pioneer products contain the sameactive ingredient and are administered as drinking water solutions.

III. HUMAN FOOD SAFETY

A. Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.01 ppm is already established for uncooked edible tissues of turkeys [21 CFR 556.510(c)].

B. 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.

For penicillin G potassium soluble powder [21 CFR 520.1696b], discontinue treatment at least 1 day prior to slaughter. Not for use in turkeys producing eggs for human consumption.

C. Regulatory Method

The analytical method for the determination of penicillin G potassium in tissues uses a microbiological assay procedure. This method is found in the Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols, revised October 1968, National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204.

IV. AGENCY CONCLUSIONS

This 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 penicillin G potassium when used under the proposed conditions of use, is safe and effective for its labeled indications.

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.