Date of Approval: January 29, 2004

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-307

Penicillin G Potassium, USP (penicillin)

Soluble Powder

For the treatment of erysipelas in turkeys caused by *Erysipelothrix rhusiopathiae.*

Sponsored by:

Vétoquinol N.-A., Inc.
Lavaltrie (PQ), Canada J0K 1H0

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-307
b. Sponsor:	Vétoquinol N.-A., Inc. 2000 chemin Georges Lavaltrie (PQ), Canada J0K 1H0 Drug Labeler Code: 059320
c. Established Name:	Penicillin G Potassium
d. Proprietary Name:	Penicillin G Potassium, USP
e. Dosage Form:	Soluble powder
f. How Supplied:	11.4 oz (324 g) jar
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	0.500 billion units of Penicillin G Potassium, USP
i. Route of Administration:	Oral
j. Species/Class:	Turkeys
k. Recommended Dosage:	Administer orally at a dosage of 1,500,000 units of penicillin per gallon of drinking water for 5 consecutive days.
l. Pharmacological Category:	Antibacterial
m Indications:	For the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae* in turkeys.
n. Pioneer Product:	Penicillin G Potassium, USP; (penicillin G potassium) NADA 55-060; Fort Dodge Animal Health.

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) 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).

Based on the formulation characteristics of the generic product, Vétoquinol N.-A., Inc. was granted a waiver on January 28, 2000, from the requirement for an *in vivo* bioequivalence study for the generic product Penicillin G Potassium, USP. The generic product is administered as an oral solution, contains the same active ingredient 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 Penicillin G Potassium, USP, manufactured by Fort Dodge Animal Health (NADA 55-060), was approved on December 18, 1973.

3. HUMAN SAFETY:

· **Tolerance**
The tolerance established for the pioneer product applies to the generic product.

A tolerance of 0.01 ppm is established for penicillin and the salts of penicillin residues in the uncooked tissues of turkeys under 21 CFR 556.510.

· Withdrawal Time:
Under the CVM Bioequivalence Guidelines, when a generic product is granted a waiver of *in vivo* bioequivalence testing, the withdrawal period established for the pioneer is also assigned to the generic product.

For this reason, a withdrawal period of 1 day has been established for Penicillin G Potassium, USP, (penicillin G potassium) in turkeys (21 CFR § 520.1696b (c)(3)).

· Regulatory Method for Residues:

The analytical method for the determination of penicillin 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, Reprinted December, 1974 National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204.

4. 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, USP, 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 indicated below:

Generic Labeling for ANADA 200-307:
Jar – 324 grams (11.4 oz)

Pioneer Labeling for NADA 55-060:
Pouch – 313 grams (11 oz)