

HFA-305

Date of Approval: \_\_\_\_\_

**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**

200-307

F0151

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. File Number: ANADA 200-307
- b. Sponsor: Vétquinol 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 (GADPTR) 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)

Label - Jar - PENICILLIN G POTASSIUM (USA)

**DOSAGE AND ADMINISTRATION:** Administer orally at a dosage of 1,500,000 units of penicillin per gallon (3.8 liters) of drinking water for 5 consecutive days.

**DIRECTIONS:** Add enough water (approx 2 pints - 946 mL) to fill bottle two-thirds full. Shake to dissolve. Allow the concentrated solution to stand until foam disappears. The concentrated solution should be used up or discarded within one hour of preparation.

**Automatic Watering Systems:** Pour the concentrated solution into a glass or plastic container then add enough water to make 2.6 gallons (9.9 liters) of stock solution. {This amount of solution will medicate 333 gallons (1260 liters) of drinking water}. The automatic waterer should be adjusted to deliver 1 ounce (30 mL) of stock solution per gallon (3.8 liters) of drinking water. Prepare fresh stock solutions and medicated drinking water solutions every twelve (12) hours. All solutions in contact with galvanized metal should be changed every three (3) hours.

**Gravity Flow Watering Systems:** Pour the concentrated solution into enough water to make 333 gallons (1260 liters) of drinking water. In gravity flow watering systems, prepare fresh solution every 12 hours. All solutions in contact with galvanized metal should be changed every three (3) hours.

Drinking water prepared as directed above will contain 1,500,000 units of Penicillin G Potassium per gallon (3.8 liters).

Lot Number :

Manufactured for:  
Vétoquinol N.-A. Inc.  
2000 ch. Georges  
Lavaltrie, Qc. Canada, J0K 1H0



**PENICILLIN G POTASSIUM  
USP**

**Antibiotic for drinking water**

**For Oral Use in Turkeys Only**

**ACTIVE INGREDIENT:**  
0.500 billion units Penicillin G Potassium

Non sterile

**FOR ANIMAL USE ONLY  
NOT FOR HUMAN USE**

**KEEP OUT OF REACH OF CHILDREN**

ANADA 200-307, Approved by FDA

Net Contents: 11.4 oz (324 g) jars

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

**WARNING:** Treated turkeys must not be slaughtered for food during treatment and for one day after last treatment.

Do not use in turkeys producing eggs for human consumption.

**PRECAUTIONS:** For best results, the treatment should be started at the first sign of infection. If improvement is not noted after 3 to 4 days of treatment, consult a poultry pathologist or veterinarian. Keep this and all medication out of reach of children.

Restricted drug under California law. Use only as directed. Store at or below 25°C (77°F). Protect from excessive heat, 40°C (104°F), and moisture. Label recommendations for storage and replacement of stock and medicated water solutions must be followed to assure the performance of this drug product.

Made in Canada

Exp. Date :

NDC 53501-059-02

**Penicillin G  
Potassium  
USP**

**Antibiotic for drinking water**

**FORT DODGE**®

For oral use in turkeys only

For veterinary use only

Store at room temperature; avoid excessive heat (104°F or 40°C).

Keep out of the reach of children.

Restricted drug (under California law) – Use only as directed

**Active ingredient:**

0.500 billion units penicillin G potassium

Nonsterile

**Net Weight: 313 grams (11 Ounces)**

NADA 55-060, Approved by FDA

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**Indications**

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

**Dosage and administration**

Administer orally at a dosage of 1,500,000 units of penicillin per gallon (3.8 liters) of drinking water for 5 consecutive days.

**Directions**

Combine contents and approximately 1 1/2 pints (710 mL) of water in a glass or plastic container. Stir to dissolve. Allow concentrated solution to stand until the foam disappears. The concentrated solution should be used up or discarded within one hour after preparation.

**Automatic Watering Systems** – Pour the concentrated solution into a glass or plastic container then add enough water to make 2.6 gallons (9.9 liters) of stock solution. [This amount of solution will medicate 333 gallons (1260 liters) of drinking water]. The automatic waterer should be adjusted to deliver 1 ounce (30 mL) of stock solution per gallon (3.8 liters) of drinking water. In automatic watering systems, prepare fresh solutions daily.

**Gravity Flow Watering Systems** – Pour the concentrated solution into enough water to make 333 gallons (1260 liters) of drinking water. In gravity flow watering systems, prepare fresh solutions every 12 hours.

Drinking water prepared as directed above will contain 1,500,000 units of penicillin G per gallon (3.8 liters).

**Warnings**

Treated turkeys must not be slaughtered for food during treatment and for one day after last treatment.

Do not use in turkeys producing eggs for human consumption.

**Precautions**

For best results, the treatment should be started at the first sign of infection. If improvement is not noted after 3 to 4 days of treatment, consult a poultry pathologist or veterinarian.

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12431B

SAMPLE

Manufactured for  
**Fort Dodge Animal Health**  
Fort Dodge, Iowa 50501 USA  
by G.C. Hanford Manufacturing Co.  
Syracuse, NY 13201

