

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-180

B. Sponsor

G.C. Hanford Mfg. Co.
304 Oneida St.
Syracuse, NY 13201

C. Proprietary Name

Ampicillin Trihydrate

D. Established Name

Ampicillin Trihydrate

E. Pharmacological Category

Antibiotic

F. Dosage Form

Sterile powder for suspension

G. How Supplied

10g/100mL vial
25g/250mL vial

H. Dispensing Status

Rx

I. Amount of Active Ingredients

10g of ampicillin activity per 100mL vial
25g of ampicillin activity per 250mL vial

J. Route of Administration

Subcutaneous or Intramuscular Injection

K. Species

Dogs, cats, cattle, calves

L. Dosage Regimen

Dogs and cats is 3 mg/lb. body weight twice daily by subcutaneous or IM injection.

Cattle and calves including non-ruminating (veal calves) is 2-5 mg/lb. body weight once daily by IM injection.

Dermal, immersion, injection, oral, topical, etc.

M. Indication

For the treatment of respiratory tract, urinary tract, gastrointestinal infections and skin, soft-tissue and post-surgical infection in dogs and cats. Respiratory tract infections in cattle and calves including non-ruminating (veal calves).

N. Pioneer

Fort Dodge Animal Health POLYFLEX[®] (NADA 55-030)

II. TARGET ANIMAL SAFETY AND EFFECTIVENESS

In accordance with the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Restoration Act and the Center's first policy letter (53 FR 50460, December 15, 1988) and the Center's fifth policy letter (June 18, 1990, 55 FR 24645), G. C. Hanford Mfg. Co. is entitled to the approval of the generic Ampicillin Trihydrate Suspension injectable product. In vivo bioequivalence studies were not required for the approval of this generic ampicillin trihydrate because both active and inactive ingredients, and the entire manufacturing process are identical to methods of the pioneer.

III. HUMAN FOOD SAFETY

A. Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.01ppm is established for negligible residues of ampicillin in the uncooked edible tissues of cattle and in milk (21 CFR 556.40).

B. Withdrawal Period

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 times for ampicillin trihydrate for sterile suspension are established under 21 CFR 522.90b: 6 days for the edible tissues of cattle and 48 hours for milk.

C. Regulatory Method for Residues

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Staphylococcus epidermidis* published by the Food and Drug Administration, "Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Methods, Reports, and Protocols", revised October 1968, reprinted December, 1974.

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 Ampicillin Trihydrate sterile powder for suspension when used under its proposed conditions of use, is safe and effective for the 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.