Date of Approval: June 24, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-812

Cefovecin Sodium for Injection

(cefovecin sodium)

Lyophilized powder for injection

Dogs and Cats

Dogs

Cefovecin Sodium for Injection is indicated for the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

Cats

Cefovecin Sodium for Injection is indicated for the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida*.

Sponsored by:

Qilu Animal Health Products Co., Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-812

B. Sponsor

Qilu Animal Health Products Co., Ltd.
No. 10688, Wenliang Road, Dongjia Town, Licheng District
Jinan, Shandong, 250100, China

Drug Labeler Code: 086163

U.S. Agent Name and Address:

Yang Liu
QILU PHARMA INC.
101 Lindenwood Drive, Suite 255
Malvern, PA 19355

C. Proprietary Name

Cefovecin Sodium for Injection

D. Drug Product Established Name

cefovecin sodium

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Lyophilized powder for injection

G. Amount of Active Ingredient

Each mL of reconstituted lyophile contains 80 mg of cefovecin as the sodium salt.

H. How Supplied

Cefovecin Sodium for Injection is available as a 10 mL multi-use vial containing 800 milligrams of cefovecin as a lyophilized cake.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Dogs: Administered as a single subcutaneous injection of 3.6 mg/lb (8 mg/kg) body weight. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete. The decision for a second injection for any individual dog should take into consideration such factors as progress toward clinical resolution, the susceptibility of the causative organisms, and the integrity of the dog's host-defense mechanisms. Therapeutic drug concentrations after the first injection are maintained for 7 days for *S. intermedius* infections and for 14 days for *S. canis* (Group G) infections. Maximum treatment should not exceed 2 injections.

Cats: Administered as a single, one-time subcutaneous injection at a dose of 3.6 mg/lb (8 mg/kg) body weight. After an injection of Cefovecin Sodium for Injection, therapeutic concentrations are maintained for approximately 7 days for *Pasteurella multocida* infections.

K. Route of Administration

Subcutaneous injection

L. Species/Class

Dogs and cats

M. Indications

Dogs

Cefovecin Sodium for Injection is indicated for the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

Cats

Cefovecin Sodium for Injection is indicated for the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida.*

N. Reference Listed New Animal Drug (RLNAD)

convenia®; cefovecin sodium; NADA 141-285; Zoetis Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required.

For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Qilu Animal Health Products Co., Ltd., was granted a biowaiver for the generic product Cefovecin Sodium for Injection (cefovecin sodium). The generic drug product is a lyophilized powder for injection, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is convenia® (cefovecin sodium), sponsored by Zoetis Inc., under NADA 141-285, and was approved for use in cats and dogs on April 25, 2008.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs and cats. Because this new animal drug is not intended for use in food-producing animals, the Center for Veterinary Medicine did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Cefovecin Sodium for Injection:

WARNINGS: Not for use in humans. Keep this and all drugs out of reach of children.

Consult a physician in case of accidental human exposure. For subcutaneous use in dogs and cats only. Antimicrobial drugs, including penicillins and cephalosporins, can cause allergic reactions in sensitized individuals. To minimize the possibility of allergic reactions, those handling such antimicrobials, including cefovecin, are advised to avoid direct contact of the product with the skin and mucous membranes.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Cefovecin Sodium for Injection, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.