Date of Approval: December 19, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-523

SULFAMED

(sulfadimethoxine)

Injection 40%

Cattle

For the treatment of bovine respiratory disease complex (shipping fever complex) and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

Sponsored by:

Cross Vetpharm Group Ltd.

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-523

B. Sponsor

Cross Vetpharm Group Ltd.
Broomhill Rd.
Tallaght, Dublin 24
Ireland

Drug Labeler Code: 061623

US Agent:
Linda M. Duple
Bimeda Inc.
2836 Dolliver Park Avenue
Lehigh, IA 50557

C. Proprietary Name

SULFAMED

D. Established Name

Sulfadimethoxine

E. Pharmacological Category

Antibiotic

F. Dosage Form

Injection 40%

G. Amount of Active Ingredient

400 mg/mL

H. How Supplied

250 mL bottles

I. Dispensing Status

OTC

J. Dosage Regimen

Intravenous injection at an initial dose of 25 milligrams per pound of body weight followed by 12.5 milligrams per pound of body weight every 24 hours until the animal is asymptomatic for 48 hours.

K. Route of Administration

Intravenous injection

L. Species/Class

Cattle

M. Indication

For the treatment of bovine respiratory disease complex (shipping fever complex) and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

N. Reference Listed New Animal Drug

ALBON; sulfadimethoxine; NADA 041-245; Zoetis Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). 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 reference listed new animal drug (RLNAD), 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 demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product SULFAMED (sulfadimethoxine) Injection 40%. The generic product is administered as an intravenous 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 ALBON (sulfadimethoxine) Injection 40% (250 mL), sponsored by Zoetis Inc. under NADA 041-245, and was approved for use in cattle on September 10, 1975.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

The following are assigned to this product for cattle:

A. Tolerances for Residues:

The tolerances established for the RLNAD apply to the generic product. A tolerance of 0.1 part per million (ppm) is established for negligible residues of sulfadimethoxine in uncooked edible tissues of cattle under 21 CFR 556.640. A tolerance of 0.01 ppm is established for negligible residues of sulfadimethoxine in milk under 21 CFR 556.640.

B. Withdrawal Periods:

Because a waiver from the requirement to demonstrate *in vivo* bioequivalence was granted, the withdrawal periods are those previously assigned to the RLNAD product.

Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not administer within 5 days of slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

C. Regulatory Method for Residues:

The validated regulatory method for the determination and confirmation of residues of sulfadimethoxine is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to SULFAMED:

Not for human use.

Keep out of reach of children.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that SULFAMED, when used according to the label, is safe and effective.