Date of Approval: September 29, 2022

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-694

SpectoGard®

(spectinomycin sulfate)

Injectable solution

Cattle

SpectoGard Sterile Solution is indicated for the treatment of bovine respiratory disease (pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*

Sponsored by:

Bimeda Animal Health Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-694

B. Sponsor

Bimeda Animal Health Ltd.
1B The Herbert Building
The Park, Carrickmines
Dublin 18, Ireland

Drug Labeler Code: 061133

U.S. Agent Name and Address:
Deb Ann Voss
Bimeda Inc.
291 Forest Prairie Road
Le Sueur, MN 56058

C. Proprietary Name

SpectoGard®

D. Drug Product Established Name

spectinomycin sulfate

E. Pharmacological Category

Antimicrobial

F. Dosage Form

injectable solution

G. Amount of Active Ingredient

100 mg per mL

H. How Supplied

500 mL multi-dose vial

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

SpectoGard Sterile Solution is to be administered to cattle at a daily dose of 10 to 15 mg spectinomycin per kg of body weight (4.5 to 6.8 mL per 100 lb body weight). Treatment should be administered at 24-hour intervals for 3 to 5 consecutive days. Selection of dose (10 to 15 mg/kg/day) and duration of

treatment (3 to 5 days) should be based on an assessment of the severity of disease, pathogen susceptibility, and clinical response.

K. Route of Administration

Injection

L. Species/Class

Cattle

M. Indication

SpectoGard Sterile Solution is indicated for the treatment of bovine respiratory disease (pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

N. Reference Listed New Animal Drug (RLNAD)

Adspec®; spectinomycin sulfate; NADA 141-077; 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, Bimeda Animal Health Ltd., was granted a biowaiver for the generic product SpectoGard® (spectinomycin sulfate) injectable solution. The generic drug product is an injectable solution, 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 Adspec® (spectinomycin sulfate), sponsored by Zoetis Inc., under NADA 141-077, and was approved for use in cattle on January 28, 1998.

III. HUMAN FOOD SAFETY

The tolerances for residues and withdrawal period established for the RLNAD apply to the generic product. The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of spectinomycin is 25 micrograms *per* kilogram of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 4 parts *per* million (ppm) is established for spectinomycin (the marker residue) in kidney (the target tissue), and 0.25 ppm in muscle under 21 CFR 556.600.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 11 days has been established for spectinomycin sulfate in cattle.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of spectinomycin is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, please submit a Freedom of Information request to:
https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

IV. USER SAFETY

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

- Not for human use.
- Keep out of reach of children.
- As with other antibiotics, allergic reactions may occur in previously sensitized individuals. Repeated or prolonged exposure may lead to sensitization. Avoid direct contact with skin, eyes, mouth, and clothing. Persons with a known hypersensitivity to spectinomycin should avoid exposure to this product. In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Seek medical attention if allergic reactions occur.

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 SpectoGard®, when used according to the label, is safe and effective for the indications listed in Section I.M. above.

Additionally, data demonstrate that residues in food products derived from cattle treated with SpectoGard® will not represent a public health concern when the product is used according to the label.