Date of Approval: August 28, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-819

GAMROZYNE™

(gamithromycin)

Injectable solution

Beef and non-lactating dairy cattle

GAMROZYNE™ is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle. GAMROZYNE™ is also indicated for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *Mannheimia haemolytica* and *Pasteurella multocida.*

Sponsored by:

Bimeda Animal Health Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-819

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

GAMROZYNE™

D. Drug Product Established Name

gamithromycin

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

150 mg/mL of gamithromycin

H. How Supplied

100 mL, 250 mL, and 500 mL vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Administer GAMROZYNE™ one time as a subcutaneous injection in the neck at 6 mg/kg (2 mL/110 lb) body weight (BW). If the total dose exceeds 10 mL, divide the dose so that no more than 10 mL is administered at each injection site.

K. Route of Administration

Subcutaneous injection in the neck

L. Species/Class

Beef and non-lactating dairy cattle

M. Indication

GAMROZYNE™ is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Mycoplasma bovis* in beef and non-lactating dairy cattle. GAMROZYNE™ is also indicated for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

N. Reference Listed New Animal Drug (RLNAD)

ZACTRAN®; gamithromycin; NADA 141-328; Boehringer Ingelheim Animal Health USA, 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 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 GAMROZYNE™ (gamithromycin) 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 ZACTRAN® (gamithromycin) injectable solution, sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 141-328, and was approved for use in beef and non-lactating dairy cattle on June 16, 2011.

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 gamithromycin is 10 µg/kg of body weight per day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 500 parts per billion (ppb) is established for gamithromycin (the marker residue) in liver (the target tissue), and 150 ppb in muscle, under 21 CFR 556.292.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 35 days has been established for gamithromycin in beef and non-lactating dairy cattle.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of gamithromycin 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 GAMROZYNE™:

NOT FOR USE IN HUMANS.
KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

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 GAMROZYNE™, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from beef and non-lactating dairy cattle treated with GAMROZYNE™ will not represent a public health concern when the product is used according to the label.