

Date of Approval: December 15, 2022

**FREEDOM OF INFORMATION SUMMARY**  
**SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION**

ANADA 200-455

BiloVet®

(tylosin tartrate)

Soluble Powder

Broiler Chickens

Provides for the addition of the indications and dosage and administration for the control of mortality caused by necrotic enteritis (**NE**) associated with *Clostridium perfringens* in broiler chickens.

Sponsored by:

Bimeda Animal Health Ltd.

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**I. GENERAL INFORMATION**

**A. File Number**

ANADA 200-455

**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:  
Debb Ann Voss  
Bimeda Inc.  
291 Forest Prairie Road  
Le Suer, MN 56058

**C. Proprietary Name**

BiloVet®

**D. Drug Product Established Name**

tylosin tartrate

**E. Pharmacological Category**

Antimicrobial

**F. Dosage Form**

Soluble Powder

**G. Amount of Active Ingredient**

100 g tylosin base per pouch or jar

**H. How Supplied**

100 g pouch and 100 g jar

**I. Dispensing Status**

Prescription (Rx)

**J. Dosage Regimen**

851 to 1, 419 mg/gallon (225 to 375 ppm) in drinking water for five consecutive days

**K. Route of Administration**

Oral

**L. Species/Class**

Broiler chickens

**M. Indication**

For the control of mortality caused by necrotic enteritis (**NE**) associated with *Clostridium perfringens* in broiler chickens.

**N. Reference Listed New Animal Drug**

Tylan™ Soluble; tylosin tartrate; NADA 013-076; Elanco US Inc.

**O. Effect of Supplement**

This supplement provides for the addition of the indications and dosage and administration for the control of mortality caused by necrotic enteritis (**NE**) associated with *Clostridium perfringens* in broiler chickens.

**II. BIOEQUIVALENCE**

CVM did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-455, dated July 5, 2011, contains a summary of data that demonstrates bioequivalence of the drug for broiler chickens.

**III. HUMAN FOOD SAFETY**

CVM did not require human food safety studies for this supplemental approval.

**IV. USER SAFETY**

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

**User Safety Warnings:** Not for Human Use. Keep Out of Reach of Children. Avoid contact with human skin. Exposure to tylosin may cause a rash.

**V. AGENCY CONCLUSIONS**

The information submitted in support of this supplemental ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that Bilovet®, 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 broiler chickens treated with Bilovet® will not represent a public health concern when the product is used according to the label.