Date of Approval: April 24, 2025

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-802

Pennitracin MD® and Coxidin®

(bacitracin Type A medicated article) and (monensin Type A medicated article)

Type A medicated articles to be used in the manufacture of Type C medicated feeds

Growing turkeys

Original abbreviated new animal drug approval of a medicated feed combination for the indications listed in Section I.L.

Sponsored by:

Huvepharma EOOD

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I. GENERAL INFORMATION

A. File Number

ANADA 200-802

B. Sponsor

Huvepharma EOOD
5th Floor
3A Nikolay Haytov Str.
1113 Sofia, Bulgaria

Drug Labeler Code: 016592

U.S. Agent Name and Address:

Kelly Beers, Ph.D.
Huvepharma, Inc.
525 West Park Drive
Peachtree City, GA 30269

C. Proprietary Name

Pennitracin MD® and Coxidin®

D. Drug Product Established Name

bacitracin Type A medicated article and monensin Type A medicated article

E. Pharmacological Categories

Pennitracin MD®: Antimicrobial
Coxidin®: Anticoccidial

F. Dosage Form

Type A medicated articles to be used in the manufacture of Type C medicated feeds.

G. Amount of Active Ingredients in Currently Marketed Products[1]

Pennitracin MD®: 50 g/lb of bacitracin (as feed grade bacitracin methylenedisalicylate)
Coxidin®: 90.7 g/lb of monensin

H. How Supplied

Pennitracin MD®: 50 lb (22.68 kg) bag
Coxidin®: 55.12 lb (25 kg) bag

[1] The sponsors of these individual currently marketed Type A medicated articles may have approvals for other strengths that are for use in the same species and class, for the same indications, and at the same dosages, but are not currently marketing those strengths of these Type A medicated articles. Such strengths, when legally marketed, are also approved for use in the manufacture of Type C medicated feeds that are the subject of this approval.

I. Dispensing Status

Over-the-counter (OTC)

J. Route of Administration

Oral

K. Species/Class

Growing turkeys

L. Indications and Dosage Regimens

1. For increased rate of weight gain and improved feed efficiency, and for the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis* and *E. gallopavonis* in growing turkeys.

   a. 4 to 50 g/ton of bacitracin (as Pennitracin MD®) for increased weight gain and improved feed efficiency

   b. 54 to 90 g/ton of monensin (as Coxidin®) for the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis* and *E. gallopavonis*

   Feed continuously as the sole ration. The optimum level depends upon the severity of coccidiosis exposure.

M. Reference Listed New Animal Drug (RLNAD) Combination

Pennitracin MD® and Coban™ (bacitracin Type A medicated article and monensin Type A medicated article); NADA 141-540; Pharmgate Inc.

N. Approved Original Generic Type A Medicated Article

Coxidin® (monensin Type A medicated article); ANADA 200-783; Huvepharma EOOD

O. Individual Type A medicated articles approved for use in the manufacture of the Type C combination medicated feeds in this application

Pennitracin MD® (bacitracin Type A medicated article); NADA 141-137; Pharmgate Inc.
Coxidin® (monensin Type A medicated article); ANADA 200-783; Huvepharma EOOD

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). Target animal safety and effectiveness data are not required for approval of an ANADA.

Following the approval of an ANADA for a generic Type A medicated article, Center of Veterinary Medicine's (CVM's) fourth policy letter issued on November 2, 1989, with regard to the implementation of GADPTRA, entitles the generic sponsor to submit an ANADA for each feed use combination (Type B or C medicated feed) for which the RLNAD is approved, without additional bioequivalence. CVM's fourth policy letter reaffirms that bioequivalence and tissue residues for each generic drug in the combination were adequately established in the ANADA at the time of its approval. Bacitracin methylenedisalicylate is codified under 21 CFR 558.76*,* monensin is codified under 21 CFR 558.355. The combination of bacitracin methylenedisalicylate and monensin is codified under 21 CFR 558.355.

III. HUMAN FOOD SAFETY

The following are assigned to this product for turkeys:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of bacitracin is 0.05 mg/kg of body weight per day. The tolerances established for the feed use RLNAD apply to the generic feed use combination new animal drug product. A tolerance of 0.5 parts per million is established for bacitracin in the edible tissues of turkeys under 21 CFR 556.70.

The ADI for total residues of monensin is 12.5 µg/kg of body weight per day. The tolerances established for the feed use RLNAD apply to the generic feed use combination new animal drug product. A tolerance is not required for monensin in edible tissues (excluding eggs) of turkeys under 21 CFR 556.420.

B. Withdrawal Period

Consistent with CVM's fourth policy letter issued on November 2, 1989, with regard to the implementation of GADPTRA, after the approval of an ANADA for a generic Type A medicated article, the generic sponsor is entitled to approval for all the feed mixed combinations for which the RLNAD is approved. Tissue residue studies are not required for the approval of the generic feed use combinations (Type B or Type C medicated feeds).

To this end, the withdrawal period for the generic combination Type B and Type C medicated feeds are those previously assigned to the RLNAD feed use combination. When used together, Pennitracin MD® (bacitracin Type A medicated article) and Coxidin® (monensin Type A medicated article) are approved with a zero-day withdrawal period.

C. Analytical Method for Residues

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

IV. USER SAFETY

CVM did not require user safety studies for this original approval.

The labeling does not contain user safety information.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(n) of the FD&C Act and demonstrate that Pennitracin MD® and Coxidin®, when they are used according to the label, are safe and effective for the conditions of use in the General Information Section above. Additionally, data demonstrate that residues in food products derived from growing turkeys administered Pennitracin MD® and Coxidin® will not represent a public health concern when the combination medicated feed is used according to the label.