Date of Approval: October 21, 2025

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-574

Pennitracin MD 50G® and Monteban™

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

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

Broiler chickens

Original approval of an Animal Drug Availability Act of 1996 (ADAA) feed combination for the indications listed in Section I.L.

Sponsored by:

Pharmgate Inc.

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I. GENERAL INFORMATION

A. File Number

NADA 141-574

B. Sponsor

Pharmgate Inc.
1800 Sir Tyler Dr.
Wilmington, NC 28405

Drug Labeler Code: 069254

C. Proprietary Names

Pennitracin MD 50G® and Monteban™

D. Drug Product Established Names

bacitracin Type A medicated article and narasin Type A medicated article

E. Pharmacological Categories

Pennitracin MD 50G®: Antimicrobial

Monteban™: Anticoccidial

F. Dosage Form

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

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

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

Monteban™: 45 g/lb of narasin

H. How Supplied

Pennitracin MD 50G®: 50 lb bag
Monteban™: 55.12 lb bag

I. Dispensing Status

Over-the-counter (OTC)

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[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.

J. Route of Administration

Oral

K. Species/Class

Broiler chickens

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 necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima* in broiler chickens.

    a. 4 to 50 g/ton of bacitracin (as feed grade bacitracin methylenedisalicylate) for increased rate of weight gain and improved feed efficiency

    b. 54 to 90 g/ton of narasin for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*

    Feed as the sole ration throughout the feeding period. The narasin concentration should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions.

2. For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens,* and for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima* in broiler chickens.

    a. 50 g/ton of bacitracin (as feed grade bacitracin methylenedisalicylate) for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*

    b. 54 to 90 g/ton of narasin for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*

    Feed as the sole ration for 28 to 35 days, starting from the time chicks are placed for brooding. The narasin concentration should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the ADAA of 1996, allows for drugs to be fed in combination in or on medicated feed without additional demonstration of their effectiveness or target animal safety when certain conditions are met. In those cases, the FD&C Act provides that effectiveness and target animal safety of each drug, demonstrated in its NADA at the time of the approval, are adequate. The Agency has based its determination of the effectiveness and target animal safety of the combination of bacitracin Type A medicated article and narasin Type A medicated article on the effectiveness and target animal safety of the previously separately approved conditions of use for Pennitracin MD 50G® and Monteban™ for use

in broiler chickens, respectively, as these drugs or their active ingredients intended for use in combination in animal feeds have met the following criteria:

- there is substantial evidence to indicate that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the proposed combination makes a contribution to the labeled effectiveness;
- each of the active ingredients or animal drugs intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population;
- where the combination contains more than one nontopical antibacterial active ingredient or animal drug, there is substantial evidence that each of the nontopical antibacterial active ingredients or animal drugs makes a contribution to the labeled effectiveness;
- there was not a substantiated scientific issue specific to an active ingredient or animal drug used in the combination that was not adequately evaluated based on the information contained in the application for the combination, and no data presented in the application raised a safety concern with the Agency; and
- there was not a scientific issue raised by target animal observations contained in the studies submitted to the NADA for the combination, and no data presented in the application raised a safety concern with the Agency.

Effectiveness and target animal safety of the individual drugs in this combination has been established by data in the following NADAs (refer to Table II.1):

Table II.1. Summary of effectiveness and target animal safety for the individual drugs subject to this combination approval.

Drug Product	Indications	Approval Information
Pennitracin MD 50G® Sponsored by Pharmgate Inc.	1. For use in feeds for broiler and replacement chickens for increased rate of weight gain and improved feed efficiency. 2. For use in feeds for broiler and replacement chickens for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*.	NADA 141-137 (refer to the FOI Summaries, dated October 6, 2015, and April 28, 2022)
Monteban™* Sponsored by Elanco US Inc.	1. For use in feeds for broiler chickens for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati*, and *E. maxima.*	NADA 118-980 (21 CFR 558.363)

*Elanco US Inc. has provided Pharmgate Inc. right of reference to use Monteban™ in this combination.

III. HUMAN FOOD SAFETY

With respect to the human food safety evaluation for these types of combination new animal drug approvals, the Agency evaluates whether any active ingredient or drug intended for use in the combination exceeds its established tolerance at the longest withdrawal time of any of the active ingredients or drugs in the combination, and whether any of the active ingredients or drugs of the combination interferes with the methods of analysis of another active ingredient or drug in the combination (Section 512(d)(4)(A) of the FD&C Act). Therefore, only additional residue chemistry data and assay noninterference information were needed to support approval of this ADAA feed-use combination. The Agency has based its determination of the human food safety of the combination of bacitracin Type A medicated article and narasin Type A medicated article on the human food safety of the previously separately approved conditions of use for Pennitracin MD 50G® and Monteban™ for use in broiler chickens, respectively, as these drugs or their active ingredients intended for use in combination in animal feeds have met the following criteria:

- none of the active ingredients or animal drugs used in combination at the longest withdrawal for any of the active ingredients or animal drugs in the combination exceeds the established tolerance, and
- none of the active ingredients or animal drugs in combination interferes with the method of analysis for another active ingredient or animal drug in the combination.

A. Microbial Food Safety

As noted, Section 512(d)(4)(A) of the FD&C Act, limits the Center for Veterinary Medicine's (CVM) human food safety evaluation for these types of ADAA feed-use combination new animal drug approvals; therefore, microbial food safety was not assessed.

B. Toxicology

As noted, Section 512(d)(4)(A) of the FD&C Act, limits CVM's human food safety evaluation for these types of ADAA feed-use combination new animal drug approvals; therefore, toxicology assessment of these types of combination new animal drugs was not performed. Safety of the individual drugs in this combination has been established by data in the following NADAs (refer to Table III.1.).

Table III.1. Toxicology assessment of the individual drugs in this combination.

Drug Product	Approval Information
Pennitracin MD 50G® Sponsored by Pharmgate LLC	NADA 141-437 (as published in the FEDERAL REGISTER (80 FR 79474) on December 22, 2015)
Monteban™* Sponsored by Elanco US Inc.	NADA 118-980 (refer to the FOI Summaries, dated August 14, 1986 and April 11, 2001)

*Elanco US Inc. has provided Pharmgate Inc. right of reference to use Monteban™ in this combination.

C. Residue Chemistry

1. Summary of Residue Chemistry Studies

   a. Residue Depletion Study

   Title: Narasin Residue Levels in Chicken Abdominal Fat of Broilers Fed Feed Containing 50 grams *per* ton Bacitracin Methylenedisalicylate and 90 grams *per* ton Narasin (Study No. HB002-21-0421)

   Study Dates: September 3, 2021, to November 8, 2022

   Study Locations: Wellington, Colorado, and Indianapolis, Indiana

   Objective: The objective of this study was to demonstrate that the concentration of narasin in the abdominal fat of broiler chickens does not exceed the codified tolerance of 480 parts *per* billion (ppb) (21 CFR 556.428) after feeding broiler chickens feed containing 50 g/ton bacitracin methylenedisalicylate and 90 g/ton narasin.

   Study Animals: Twenty Cobb 500 commercial broiler chicks (10 male and 10 female) were used.

   Experimental Design: In this Good Laboratory Practice study, birds were administered medicated feed containing 50 g/ton bacitracin methylenedisalicylate and 90 g/ton narasin *ad libitum* for 21 days. Medicated feed levels were monitored daily to ensure no unintended withdrawals from feed occurred during the course of the study. Three male and three female birds were slaughtered at 6-hour practical zero withdrawal. Abdominal fat samples were collected from each bird. Narasin residues were measured for each individual sample using a liquid chromatography-mass spectrometry (LC-MS/MS) method that has been bridged to the official thin-layer chromatography bioautographic method.

Results: All individual narasin concentrations from the LC-MS/MS analysis were below the codified tolerance for narasin. Because the narasin tolerance was based on data generated by the bioautography method, the LC-MS/MS values from the current study were converted to bioautography-equivalent values using a regression equation. Regression-estimated bioautography equivalent narasin concentrations in chicken abdominal fat were 117.93, 213.98, 290.27, 242.48, 199.73, and 288.59 ppb.

CVM calculated the 99th percentile with 95% confidence upper tolerance limit (99/95 UTL) for the method performance-adjusted narasin concentrations. The 99/95 UTL value was determined to be 472 ppb. Because the 99/95 UTL value is less than the codified narasin tolerance, a 0-day withdrawal period was confirmed for the combination of Pennitracin MD 50G® (bacitracin Type A medicated article) and Monteban™ (narasin Type A medicated article) for the manufacture of Type C medicated feeds containing 4 to 50 g/ton bacitracin methylenedisalicylate and 54 to 90 g/ton narasin.

In lieu of conducting studies to address assay noninterference, the sponsor obtained a right of reference to data and information in the NADA 140-926 file (approved combination of BMD® and Maxiban™ for use in the manufacture of Type C medicated feed in broiler chickens). CVM relied on the tissue residue depletion study No. AAC8721 in NADA 140-926 file to demonstrate assay noninterference for this approval, and to reach the conclusion that the combination Pennitracin MD 50G® and Monteban™ for use in the manufacture of Type C medicated feed in broiler chickens (4 to 50 g/ton bacitracin methylenedisalicylate and 54 to 90 g/ton narasin) qualifies for a zero-day withdrawal period assignment.

2. Target Tissues and Marker Residues

   a. Bacitracin

      A target tissue and a marker residue have not been established for bacitracin in chickens (refer to NADA 141-137, 80 FR 79474, dated December 22, 2015).

   b. Narasin

      The target tissue for narasin is abdominal fat. The marker residue is parent narasin (refer to the FOI Summary for NADA 118-980, dated April 11, 2001).

3. Tolerances

   a. Bacitracin

      The codified tolerance for bacitracin in edible tissues of chickens is 0.5 ppm (21 CFR 556.70).

   b. Narasin

The codified tolerance for parent narasin in chicken abdominal fat is 480 ppb (refer to the FOI Summary for NADA 118-980, dated April 11, 2001; 21 CFR 556.428).

4. Withdrawal Period

A zero-day withdrawal period is confirmed for the combination of Pennitracin MD 50G® (4 to 50 g/ton) and Monteban™ (54 to 90 g/ton) in Type C medicated feeds for use in broiler chickens.

D. Analytical Method for Residues

1. Determinative Method

Official methods for the individual drugs in this combination are described in NADA 140-926 for narasin and bacitracin methylenedisalicylate (FOI Summary, dated January 4, 1999).

In addition, an analytical method for narasin in chicken tissues has been published, based on LC-MS/MS in the following reference:
Lombardi, K.R., Burnett, T.J., Brunelle, S.L., Ulrey, W.D., and Coleman, M.R. (2013). Determination and confirmation of narasin and monensin in chicken, swine, and bovine tissues by LC/MS/MS: Final Action 2011.24. *Journal of AOAC International* 96(4).

2. Availability of Method

The validated analytical methods for analysis of residues of bacitracin and narasin are on file at the Center for Veterinary Medicine, 5001 Campus Drive, College Park, MD 20740. To obtain a copy of these 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 approval.

V. AGENCY CONCLUSIONS

The data submitted in support of this NADA satisfy the requirements of Section 512 of the FD&C Act and 21 CFR part 514. The data contained in the previously approved NADAs for Pennitracin MD 50G® and Monteban™ demonstrate that, when they are used according to the label, they 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 broiler chickens administered Pennitracin MD 50G® and Monteban™ will not represent a public health concern when the combination medicated feed is used according to the label.

A. Marketing Status

This product can be marketed over-the-counter (OTC) because the approved labeling contains adequate directions for use by laypersons and the conditions of use prescribed on the labeling are reasonably certain to be followed in practice.

B. Exclusivity

This approval does not qualify for marketing exclusivity under Section 512(c)(2)(F)(ii) of the FD&C Act.

C. Patent Information

For current information on patents, see the Green Book Reports in the Animal Drugs @ FDA database or the Green Book on the FDA CVM internet website.