Date of Approval: December 10, 2021

# FREEDOM OF INFORMATION SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-705

ZoaShield™ and BMD®

(zoalene Type A medicated article and bacitracin methylenedisalicylate Type A medicated article)

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

Broiler chickens, replacement chickens, and growing turkeys

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

Sponsored by:

Elanco US Inc.

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# I. GENERAL INFORMATION

## A. File Number

ANADA 200-705

## B. Sponsor

Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

Drug Labeler Code: 058198

## C. Proprietary Name

ZoaShield™ and BMD®

## D. Drug Product Established Name

zoalene Type A medicated article and bacitracin methylenedisalicylate Type A medicated article

## E. Pharmacological Categories

ZoaShield™: Anticoccidial
BMD®: Antibacterial

## 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]

ZoaShield™: 25% zoalene (3,5-dinitro-o-toluamide)
BMD®: 50 g/lb of bacitracin

## H. How Supplied

ZoaShield™: 50 lb (22.68 kg) bag
BMD®: 50 lb (22.68 kg) bag

## I. Dispensing Status

Over-the-counter (OTC)

[1] The sponsors of these individual currently marketed Type A medicated articles may have approvals for other strengths of these products 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, replacement chickens, and growing turkeys

## L. Indications

**Broiler Chickens:**

1. For prevention and control of coccidiosis and as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    a. 113.5 g/ton of zoalene (as ZoaShield™) for prevention and control of coccidiosis.

    b. 50 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    Feed continuously as the sole ration.

2. For prevention and control of coccidiosis and as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    a. 113.5 g/ton of zoalene (as ZoaShield™) for prevention and control of coccidiosis.

    b. 100 to 200 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    Feed continuously as the sole ration. To control necrotic enteritis, start this feed at first clinical sign of disease; vary bacitracin dosage based on severity of infection; administer continuously for 5-7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton).

**Replacement Chickens:**

1. Development of active immunity to coccidiosis and as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    a. 75.4 to 113.5 g/ton of zoalene (as ZoaShield™) for development of active immunity to coccidiosis.

    b. 50 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

Feed continuously as the sole ration where light to moderate exposure to coccidiosis is expected.

2. Development of active immunity to coccidiosis and as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    a. 75.4 to 113.5 g/ton of zoalene (as ZoaShield™) for development of active immunity to coccidiosis.

    b. 100 to 200 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    Feed continuously as the sole ration where light to moderate exposure to coccidiosis is expected. To control necrotic enteritis, start this feed at first clinical signs of disease; vary bacitracin dosage based on severity of infection; administer continuously for 5-7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton).

3. Development of active immunity to coccidiosis and as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    a. 113.5 g/ton of zoalene (as ZoaShield™) for development of active immunity to coccidiosis.

    b. 50 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    Feed continuously as the sole ration where severe exposure to coccidiosis is expected.

4. Development of active immunity to coccidiosis and as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    a. 113.5 g/ton of zoalene (as ZoaShield™) for development of active immunity to coccidiosis.

    b. 100 to 200 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    Feed continuously as the sole ration where severe exposure to coccidiosis is expected. To control necrotic enteritis, start this feed at first clinical signs of disease; vary bacitracin dosage based on severity of infection; administer continuously for 5-7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton).

5. Development of active immunity to coccidiosis and as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    a. 36.3 to 75.4 g/ton of zoalene (as ZoaShield™) for development of active immunity to coccidiosis.

    b. 50 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    Feed continuously as the sole ration where light to moderate exposure to coccidiosis is expected.

6. Development of active immunity to coccidiosis and as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin**.**

    a. 36.3 to 75.4 g/ton of zoalene (as ZoaShield™) for development of active immunity to coccidiosis.

    b. 100 to 200 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    Feed continuously as the sole ration where light to moderate exposure to coccidiosis is expected. To control necrotic enteritis, start this feed at first clinical signs of disease; vary bacitracin dosage based on severity of infection; administer continuously for 5-7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton).

7. Development of active immunity to coccidiosis and as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    a. 75.4 to 113.5 g/ton of zoalene (as ZoaShield™) for development of active immunity to coccidiosis.

    b. 50 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the prevention of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    Feed continuously as the sole ration where severe exposure to coccidiosis is expected.

8. Development of active immunity to coccidiosis and as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

    a. 75.4 to 113.5 g/ton of zoalene (as ZoaShield™) for development of active immunity to coccidiosis.

b. 100 to 200 g/ton of bacitracin methylenedisalicylate (as BMD®) as an aid in the control of necrotic enteritis caused by or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

Feed continuously as the sole ration where severe exposure to coccidiosis is expected. To control necrotic enteritis, start this feed at first clinical signs of disease; vary bacitracin dosage based on severity of infection; administer continuously for 5-7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton).

**Growing Turkeys:**

1. For prevention and control of coccidiosis, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

   a. 113.5 to 170.3 g/ton of zoalene (as ZoaShield™) for prevention and control of coccidiosis.

   b. 4 to 50 g/ton of bacitracin methylenedisalicylate (as BMD®) for increased rate of weight gain and improved feed efficiency in growing turkeys.

   Feed continuously until turkeys are 14 to 16 weeks of age.

**M. Reference Listed New Animal Drug Combination (RLNAD)**

Zoamix™ and BMD® (zoalene Type A medicated article and bacitracin methylenedisalicylate Type A medicated article); NADA 141-085; Zoetis Inc.

**N. Approved Original Generic Type A Medicated Article**

ZoaShield™; zoalene Type A medicated article; ANADA 200-690; Elanco US Inc.

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

ZoaShield™ (zoalene Type A medicated article); ANADA 200-690; Elanco US Inc.
BMD® (bacitracin methylenedisalicylate Type A medicated article); NADA 046-592; 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). Target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Following the approval of an ANADA for a generic Type A medicated article, 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 and tissue residue studies. 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. Zoalene is codified under 21 CFR 558.680, bacitracin methylenedisalicylate is codified under 21 CFR 558.76. The combination of zoalene and bacitracin methylenedisalicylate is codified under 21 CFR 558.680.

## III. HUMAN FOOD SAFETY

The following are assigned to this product for broiler chickens, replacement chickens, and growing turkeys:

### A. Acceptable Daily Intake and Tolerances for Residues

An acceptable daily intake (ADI) is not cited for zoalene. The tolerances established for the feed-use RLNAD apply to the generic feed use combination new animal drug product. A tolerance of 6 ppm is established for zoalene and its metabolite 3-amino-5-nitro-*o*-toluamide (the marker residue) in chicken liver and kidney, 3 ppm in chicken muscle, 2 ppm in chicken fat, and 3 ppm in turkey liver and muscle, under 21 CFR 556.770.

The ADI for total residue 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 ppm is established for bacitracin (the marker residue) in edible chicken and turkey tissues, under 21 CFR 556.70.

### 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-use 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, ZoaShield™ (zoalene Type A medicated article) and BMD® (bacitracin methylenedisalicylate Type A medicated article) are approved with a 0-day withdrawal period.

### C. Analytical Method for Residues

The validated analytical method for analysis of residues of zoalene and bacitracin methylenedisalicylate 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

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

## V. AGENCY CONCLUSIONS

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the FD&C Act and demonstrates that ZoaShield™ and BMD®, when used according to the label, are safe and effective for the indications listed in Section I.L. Additionally, data demonstrate that residues in food products derived from broiler chickens, replacement chickens, and growing turkeys administered ZoaShield™ and BMD® will not represent a public health concern when the combination medicated feed is used according to the label.