Date of Approval: September 18, 2020

FREEDOM OF INFORMATION SUMMARY

ANADA 200-690

ZoaShield™ 25%

(zoalene Type A medicated article)

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

Broiler and replacement chickens and growing turkeys

Broiler Chickens: For prevention and control of coccidiosis
Replacement Chickens: For development of active immunity to coccidiosis
Growing Turkeys: For prevention and control of coccidiosis

Sponsored by:

Pharmasone LLC

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-690

B. Sponsor

Pharmasone LLC
1800 Sir Tyler Dr.
Wilmington, NC 28405

Drug Labeler Code: 086125

C. Proprietary Name

ZoaShield™ 25%

D. Drug Product Established Name

Zoalene Type A medicated article

E. Pharmacological Category

Anticoccidial

F. Dosage Form

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

G. Amount of Active Ingredient

25% zoalene

H. How Supplied

50 lb (22.68 kg) bag

I. Dispensing Status

Over-the-counter (OTC)

J. Dosage Regimen

For chickens grown for meat purposes: Use 1 lb (454 g) of ZoaShield™ 25% per 2,000 lb (909 kg) of finished product to produce a feed containing 0.0125% zoalene. ZoaShield™ 25% should be thoroughly blended into the finished feed. Feed containing zoalene should be fed continuously as the only ration from the time chicks are placed in floor pens until they are slaughtered for meat.

For replacement chickens:
Feed containing zoalene can be used in a program to raise replacement birds. When used under conditions of exposure to coccidiosis, it will allow immunity to develop adequately to protect against losses due to the disease when the birds are placed on nonmedicated feed for egg laying purposes. The following tables

outline the type of feeding program to follow where complete formulated feed is the sole ration:

Starter Ration

Growing condition	% Zoalene per ton	ZoaShield™ 25% to be added per ton of feed (lb)	ZoaShield™ 25% to be added per ton of feed (g)
Severe exposure to coccidiosis expected	0.0125	1	454
Light to moderate exposure to coccidiosis expected	0.0083 to 0.0125	2/3 to 1	303 to 454

Grower Ration*

Growing condition	% Zoalene in feed	ZoaShield™ 25% to be added per ton of feed (lb)	ZoaShield™ 25% to be added per ton of feed (g)
Severe exposure to coccidiosis expected	0.0083 to 0.0125	2/3 to 1	303 to 454
Light to moderate exposure to coccidiosis expected	0.004 to 0.0083	1/3 to 2/3	151 to 303

***Grower ration not to be fed to birds over 14 weeks of age.**

For turkeys grown for meat purposes only:
When turkey poults are reared in confinement and severe exposure to coccidiosis is usually a problem, use 1½ lb (681 g) of ZoaShield™ 25% per ton (2,000 lb) of feed to produce a finished feed containing 0.0187% zoalene. Under the usual conditions of rearing turkey poults, or when turkey poults are on range, use 1 lb (454 g) of ZoaShield™ 25% per 2,000 lb (909 kg) of feed to produce a finished feed containing 0.0125% zoalene. The feed containing zoalene should be fed continuously until the birds are 14 to 16 weeks of age.

K. Route of Administration

Oral, in feed

L. Species/Class

Broiler and replacement chickens and growing turkeys

M. Indications

Broiler Chickens: For prevention and control of coccidiosis
Replacement Chickens: For development of active immunity to coccidiosis
Growing Turkeys: For prevention and control of coccidiosis

N. Reference Listed New Animal Drug (RLNAD)

Zoamix®; zoalene Type A medicated article; NADA 011-116; 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). 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, Pharmasone LLC, was granted a biowaiver for the generic product ZoaShield™ 25% (zoalene Type A medicated article) to be used in the manufacture of Type C medicated feeds. The generic drug product is a Type A medicated article to be used in the manufacture of Type C medicated feeds, 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 Zoamix® (zoalene Type A medicated article) Type A medicated article for use in the manufacture of Type C medicated feeds, sponsored by Zoetis Inc., under NADA 011-116, and was approved for use in broiler and replacement chickens and growing turkeys on May 4, 1960.

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 broiler and replacement chickens and growing turkeys:

A. Acceptable Daily Intake and Tolerances for Residues

An acceptable daily intake (ADI) is not cited for total residues of zoalene. The tolerances established for the RLNAD apply to the generic product. A tolerance of 6 parts per million (ppm) is established for residues of zoalene (3,5-dinitro-*o*-toluamide) and its metabolite 3-amino-5-nitro-*o*-toluamide 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.

B. Withdrawal Period

Because a biowaiver was granted and an extensive physicochemical comparison of ZoaShield™ 25% and the RLNAD was provided, CVM did not require *in vivo* Human Food Safety studies for this approval. A withdrawal period of 0 days has been established for zoalene Type A medicated article in broiler and replacement chickens and growing turkeys.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of zoalene 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 Summary 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 ZoaShield™ 25%:

Avoid inhaling dust
Avoid contact with eyes
Not for human use

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that ZoaShield™ 25%, 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 and replacement chickens and growing turkeys treated with ZoaShield™ 25% will not represent a public health concern when the product is used according to the label.