zoetis

Zoetis Inc.
333 Portage Street 7
Kalamazoo, Michigan 49007

September 25, 2018

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, Maryland 20852

Subject: **Suitability petition for alternate dosage form**
JINAD: 013-057
Sponsor: Zoetis Inc.
Product: Generic "Nicarbazin 25% Type A Medicated Article"

Division of Dockets Management,

Zoetis Inc. (the sponsor) is interested in filing an abbreviated new animal drug application (ANADA) for the proposed Generic "Nicarbazin 25% Type A Medicated Article." The product is to be indicated as an aid in preventing outbreaks of cecal *(Eimeria tenella)* and intestinal *(E. acervulina, E. maxima, E. necatrix,* and *E. brunetti)* coccidiosis in chickens.

The reference listed new animal drug (RLNAD) is Nicarb® (nicarbazin) 25% Type A Medicated Article with Microtracer®, NADA 009-476, Phibro Animal Health Corporation. The RLNAD is a *powdered* premix, whereas the generic product is a *granulated* premix. Accordingly, the customary Suitability Petition is enclosed (Attachment 1). Thank you for reviewing this submission.

Sincerely,

Pagariya Nandkishor
Project Team Leader
Zoetis Inc.

Enclosure

Attachment 1: Suitability Petition

Attachment 1. Suitability Petition

SUITABILITY PETITION

Generic "Nicarbazin 25% Type A Medicated Article"
Zoetis Inc., JINAD 013-057

Identification of Petitioner

This Suitability Petition is submitted on behalf of Zoetis Inc. ("Petitioner"), under Section 512 (n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Action Requested

Petitioner requests permission from the Commissioner of the Food and Drug Administration to file an Abbreviated New Animal Drug Application (ANADA) for a different dosage form of an approved pioneer product.

The proposed product is Generic "Nicarbazin 25% Type A Medicated Article," Zoetis Inc. The pioneer product is Nicarb® (nicarbazin) 25% Type A Medicated Article with Microtracer®, NADA 009-476, Phibro Animal Health Corporation. A product comparison is provided (Table 1).

Table 1. Product comparison

Parameter	— FDA-approved Product — Nicarb® (nicarbazin) 25% Type A Medicated Article with Microtracer® Phibro Animal Health Corporation	— Proposed Generic Product — Generic Nicarbazin 25% Type A Medicated Article Zoetis Inc.
Regulatory ID	NADA 009-476	—
Species	Chickens (except laying hens)	Chickens (except laying hens)
Active ingredient	Nicarbazin	Nicarbazin
Inactive ingredients	• Wheat middlings • Soybean oil • Microtracer®	• Calcium sulfate dihydrate USP • K-29/32 USP (polyvinylpyrolidone (PVP)) • Microtracer FS - Red #40 Lake • Water
Pharmacological category	Anticoccidial	Anticoccidial
Indications	As an aid in preventing outbreaks of cecal *(Eimeria tenella)* and intestinal *(E. acervulina, E. maxima, E. necatrix,* and *E. brunetti)* coccidiosis in chickens.	As an aid in preventing outbreaks of cecal *(Eimeria tenella)* and intestinal *(E. acervulina, E. maxima, E. necatrix,* and *E. brunetti)* coccidiosis in chickens.
Dosage form	Type A Medicated Article (powder)	Type A Medicated Article (granular)
How supplied	Type A Medicated Article (25% nicarbazin)	Type A Medicated Article (25% nicarbazin)

Attachment 1. Suitability Petition

Parameter	— FDA-approved Product — [1] **Nicarb® (nicarbazin) 25%** **Type A Medicated Article with Microtracer®** Phibro Animal Health Corporation	— Proposed Generic Product — **Generic Nicarbazin 25%** **Type A Medicated Article** Zoetis Inc.
Dosage	NICARB® (nicarbazin) 25% should be thoroughly and evenly mixed in the feed in accordance with current good manufacturing practice for feed. Type C medicated feeds should contain 0.01-0.02% nicarbazin. Uniformly mix 0.8-1.6 pounds of Nicarb 25% with one of the feed ingredients to make at least 10 pounds of premix before final mixing. Mix the resulting premix with feed to make 1 ton (2000 lb) of finished feed containing 0.01-0.02% nicarbazin.	Nicarbazin 25% Type A Medicated Article should be thoroughly and evenly mixed in the feed in accordance with current good manufacturing practice for feed. Type C medicated feeds should contain 0.01-0.02% nicarbazin. Uniformly mix 0.8-1.6 pounds of Nicarbazin 25% Type A Medicated Article with one of the feed ingredients to make at least 10 pounds of premix before final mixing. Mix the resulting premix with feed to make 1 ton (2000 lb) of finished feed containing 0.01-0.02% nicarbazin.
Route of administration	Oral consumption	Oral consumption
Product container	Bag, net weight 50 lb (22.68 kg).	Multi-layer paper bag, bottom heat-sealed, top sewn, net weight 50 lb (22.68 kg).
Manufacturing	Powder blend	Granulation
Administration	Use nicarbazin Type C medicated feed as the only ration from the time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard.	Use nicarbazin Type C medicated feed as the only ration from the time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard.

[1] Information for Nicarb® (nicarbazin) 25% Type A Medicated Article with Microtracer® was obtained from https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5a397494-e980-4f45-80e6-ab99ffdaf48a&type=display (rev. 1/2015)

Statement of Grounds

Petitioner wishes to register a new dosage form of the pioneer product, administered orally as a generic version of Nicarb® (nicarbazin) 25% Type A Medicated Article with Microtracer® (Appendix 1). This petition requests a change in dosage form from a powder formulation (the pioneer product) to a granular formulation (the proposed product) (Appendix 2). Both products contain the same active ingredient.

The generic formulation is an inorganic carrier-based product. Bulk density differences between the active ingredient (nicarbazin) and inactive ingredient (calcium sulfate dihydrate) are significant, so a high risk of segregation and dusting potential is anticipated with a simple powder blend formulation. An aqueous granulation process is preferred to reduce the risk of dust explosion hazard since nicarbazin has a low minimum ignition energy value. The granulation process yields a product with good particle size control and flow properties, which ensure easy handling during manufacturing and further mixing at feed mills, with low dusting to reduce user/handler safety concerns. The granulation approach is in line with the manufacturing technology and process used for Petitioner's other commercial MFA products. Therefore Petitioner proposes to manufacture the generic product with a granulation process rather than as a powder blend.

Attachment 1. Suitability Petition

The labeling content for the proposed product (Appendix 2) will parallel the labeling content for the pioneer product (Appendix 1), to include the following categories: description, active ingredient, registered claims, directions for use, mixing directions, warnings, and cautions.

Environmental Impact

Petitioner claims a categorical exclusion from the requirement to file an environmental impact assessment under 21 CFR 25.30(h). To the best of petitioner's knowledge, no extraordinary circumstances exist that may significantly affect the human environment (21 CFR 25.21).

Economic Impact

Petitioner will provide an economic impact analysis of this action if requested by the Commissioner after review of this Suitability Petition.

Confidential and/or Proprietary Information

In accordance with applicable provisions of the Freedom of Information Act (FOIA) and 21 CFR 20.61, Petitioner declares that no information contained within this Suitability Petition constitutes privileged or confidential trade secrets and/or commercial or financial information exempt from disclosure under exemption 4 of the FOIA.

Certification

To the best knowledge and belief of the undersigned on behalf of Petitioner, this Suitability Petition includes all information and views upon which the Petition relies, including representative data and information (if any) known to be unfavorable.

Pagariya Nandkishor
Project Team Leader
Zoetis Inc.

09.25.2018
Date

Appendices

Appendix 1: Pioneer Product Label
Appendix 2: Proposed Generic Product Label (Draft)