I-012646-P-0032-TS

Minor Use Animal Drug Program
Attention: Amy Omer, DVM
FDA Liaison for Minor Use Animal Drug Program
7500 Standish Place
Rockville, MD 20855

Re: Target Animal Safety technical section complete

Dear Dr. Omer:

We consider the Target Animal Safety technical section to be complete, based upon your submission and the information contained in I-012646-P-0032-TS and I-012646-P-0029-TS. The technical section is complete for the use of Safe-Guard® (fenbendazole) Type A medicated article to be used in the manufacture of Type C medicated feeds for the treatment and control of adult *Heterakis gallinarum* and *Capillaria* spp. in quail. We received the submission on August 13, 2024.

TARGET ANIMAL SAFETY

This technical section complete letter represents our finding that the studies and other information essential to determining target animal safety are complete and accepted. We also evaluate target animal safety in our review of other technical sections, particularly the Effectiveness and All Other Information technical sections.

Please note that the correct taxonomic nomenclature for the nematode *Heterakis gallinae* listed in the submission is *Heterakis gallinarum* (Madsen, 1949[1]). The indications in this approval have been updated to reflect this change.

LABELING

We appreciate your cooperation in including the draft labeling with this submission. We do not have any comments at this point. We will review the labeling in the Labeling Technical Section.

FREEDOM OF INFORMATION (FOI) SUMMARY

We appreciate your cooperation in including the relevant portions of the FOI summary with this submission. A copy of the Target Animal Safety section of the FOI Summary is enclosed. Please review the FOI Summary for accuracy and notify us if you find errors. CVM will prepare the final version of the FOI summary and will provide you a copy when the last technical section is complete.

[1] Madsen, H., 1949. *Heterakis gallinarum* (Schrank, 1788) nec *Heterakis gallinae* (Gmelin, 1790). J. Parasitol. 35(5): 543.

ALL FURTHER TARGET ANIMAL SAFETY INFORMATION

The information provided in this submission is acceptable. You do not need to resubmit the information when you submit the All Other Information (AOI) technical section. Please submit any additional information that you become aware of pertaining to target animal safety of fenbendazole in quail when you submit your AOI technical section.

Include a copy of this technical section complete letter when you submit your New Animal Drug Application. Please contact us if there are changes in the product development plan (e.g., indication, dosage regimen, product formulation) or you become aware of any issues that may impact the status of this technical section or your application. We will make a final decision on whether we can approve your application after we have reviewed all of the data for all applicable technical sections and any other information available to us, as a whole, and determined whether the requirements for approval described in the Federal Food, Drug, and Cosmetic Act have been met.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identified in this letter. If you have any questions or comments, please contact Dr. Janis Messenheimer, Branch Chief, Food Animal Branch 1, at (240) 402 0582 or at janis.messenheimer@fda.hhs.gov.

If you have questions or need assistance with the drug development process or project updates, contact your project manager. If you do not know who your project manager is, send an email to CVM.ONAPE.PM@fda.hhs.gov.

Sincerely,

{see appended electronic signature page}
Crystal Groesbeck, PhD
Director, Division of Food Animal Drugs
Office of New Animal Product Evaluation
Center for Veterinary Medicine

Enclosure
Draft section of Freedom of Information (FOI) Summary

Electronic Signature Addendum for Submission ID

I-012646-P-0032-TS

Signing Authority (Role)	Letter Date
Crystal Groesbeck (Division Director)	1/28/2025

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