I-012646-P-0029-TS

Minor Use Animal Drug Program
Attention: Amy Omer, DVM
FDA Liaison to the Minor Use Animal Drug Program
7500 Standish Place
MPN2, N379
Rockville, MD 20855

Re: Target Animal Safety technical section complete

Dear Dr. Omer:

Based upon your submission dated October 20, 2022, as amended on January 20, 2023 (T-0031), and the information contained in the investigational new animal drug (INAD) file, we consider the Target Animal Safety technical section to be complete. The technical section is complete for the use of fenbendazole Type A medicated article for the treatment and control of *Aulonocephalus* spp. in wild quail.

TARGET ANIMAL SAFETY

This technical section complete letter represents our finding that the study data 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.

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. The Target Animal Safety section of the FOI Summary has been revised, and a copy 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.

ALL FURTHER TARGET ANIMAL SAFETY INFORMATION

The information provided in this submission is acceptable. You do not need to re-submit 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 NADA. 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, Leader, Antiparasitic and Physiologic Drugs Team 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.ONADE.PM@fda.hhs.gov.

Sincerely,

{see appended electronic signature page}
Crystal Groesbeck, Ph.D.
Director, Division of Food Animal Drugs
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure(s):
Draft Section of Freedom of Information (FOI) Summary

Electronic Signature Addendum for Submission ID

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Signing Authority (Role)	Letter Date
Crystal Groesbeck (Division Director)	4/5/2023

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