DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

I-010062-P-0034-TS

NRSP-7
Attention: Amy L. Omer, DVM
FDA Liaison to the NRSP-7
Room#N376, MPN2, HFV-50
7500 Standish Place
Rockville, MD 20855

Re: Target Animal Safety technical section complete

Dear Dr. Omer:

Based upon the information you submitted on June 4, 2014, and amended on August 20, 2014 (T-0035), and on October 16, 2014 (T-0036), 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 SAFE-GUARD (fenbendazole) Type A medicated article for the removal and control of adult *Syngamus trachea* (gapeworm) in pheasants.

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.

DRAFT LABELING

We reviewed the draft labeling, however, our comments are limited to the target animal safety section. All other labeling comments will be shared with the pharmaceutical manufacturer of the drug product prior to submission of the supplement to add the indication for pheasants.

1. The Animal Safety section should be revised to read:

   A margin of safety study was conducted in growing pheasants to support the safety of Safe-Guard® in pheasants when 100 ppm fenbendazole is administered orally via medicated feed for 7 consecutive days. Safe-Guard® was administered to three groups of 40 pheasants at 100, 300, and 500 ppm fenbendazole orally in feed (1, 3, and 5 times the recommended label dose) for 21 consecutive days (3 times the recommended duration). Another group of 40 pheasants were provided non-medicated feed and used as a control group. The treatment effects on body weight, feed consumption, feathering, mortality, hematology, serum chemistry, gross necropsy, and histopathological parameters were

evaluated. No clinically significant effects related to the administration of Safe-Guard® were observed for any of the parameters evaluated.

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 OTHER INFORMATION

The "all other information" provided in this submission is acceptable. The sponsor does not need to re-submit the information when the AOI technical section is submitted.

ADDITIONAL COMMENT

1. You stated that you did not record RBC counts because a hematology test system (Becton Dickinson Unopette) was not available. In future studies, please record RBC counts by any method available.

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, duration of use) 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, you should reference the date and the principal submission identifier. If you have any questions or comments, please contact me at 240-402-0817. You may also contact Dr. Janis R. Messenheimer, Leader, Antiparasitic and Physiologic Drugs Team, at 240-402-0582.

Sincerely,

{see appended electronic signature page}
Cindy L. Burnsteel, DVM Director,
Division of Therapeutic Drugs for
Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure:
Draft Freedom of Information (FOI) Summary – Target Animal Safety