I-012646-P0028-HF

Minor Use Animal Drug Program
Attention: Dr. Amy L. Omer, DVM
FDA Liaison to the Minor Use Animal Drug Program
7500 Standish Place
Rockville, Maryland, 20855

Re: Human Food Safety technical section incomplete, information acceptable

Dear Dr. Omer:

Based upon your submission dated February 23, 2022, we consider the Human Food Safety technical section incomplete. Your submission contained a residue depletion study to support the approval of Safe-Guard® (fenbendazole) 20% Type A medicated article. Your new animal drug product is proposed for the treatment and control of *Aulonocephalus* spp. in quail.

We have the following comments:

We conclude that the submitted residue depletion study is acceptable for determining the withdrawal period for the use of fenbendazole in quail. The residue data in liver support a zero-day withdrawal period. We conclude that the Residue Chemistry component of the Human Food Safety technical section is complete. Microbial Food Safety was deemed complete under the B1 consulting review. However, because MUADP does not own the fenbendazole toxicology data nor have you provided a right of reference, the Human Food Safety technical section remains incomplete.

The status of each component of the Human Food Safety technical section is described in the following table.

Status of the Human Food Safety Technical Section for Safe-Guard® (fenbendazole) Type A medicated article in quail.

Components of the Human Food Safety Assessment	Status
Microbial Food Safety (Antimicrobial Resistance)	Complete P-0028
Toxicology	Incomplete
Residue Chemistry	Complete P-0028

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier at the top of this letter. If you have any questions or comments, please contact me at (240) 402-0850 or at

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

charli.long@fda.hhs.gov. You also may contact Dr. Lynn Friedlander, Leader, Residue Chemistry Team, at (240) 402-0703 or at lynn.friedlander@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}
Charli M. Long, Ph.D.
Director, Division of Human Food Safety
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Electronic Signature Addendum for Submission ID

I-012646-P-0028-HF

Signing Authority (Role)	Letter Date
Charli Long (Division Director)	8/16/2022

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.