



I-010062-P-0031-HF

NRSP-7

Attention: Dr. Margaret R. Oeller, D.V.M.
FDA Liason to the NRSP-7
7500 Standish Place, HFV-50
Rockville, MD 20855

Re: Residue depletion study in pheasants

Dear Dr. Oeller:

This letter responds to your submission dated October 22, 2012, to your Investigational New Animal Drug (INAD) file, I-010062-P-0031, regarding the proposed use of fenbendazole in pheasants. Our comments on your submission are provided below.

We conclude that the submitted tissue residue depletion study is acceptable for supporting a withdrawal period determination, and we assign a one-day withdrawal period. We conclude that all components of human food safety have been satisfied for the use of fenbendazole in pheasants at a rate of up to 100 ppm fenbendazole in feed for up to 7 days. A Technical Section Complete letter for Human Food Safety can be requested when permission to reference the toxicology data is provided.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact me at 240-276-8225. You may also contact Dr. Lynn G. Friedlander, Residue Chemistry Team Leader at 240-276-8226.

Sincerely,

{see appended electronic signature page}

Karen B. Ekelman, Ph.D.
Director, Division of Human Food Safety
Office of New Animal Drug Evaluation
Center for Veterinary Medicine