DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

I-009096-P-0026-NV

NRSP-7
Minor Use Animal Drug Program
Attention: Amy Omer, DVM
FDA Liaison to NRSP-7
Center for Veterinary Medicine
7500 Standish Place
Rockville, MD 20855

Re: Environmental Impact technical section complete for lasalocid sodium Type A medicated article in pheasants

Dear Dr. Omer:

Based upon the information you submitted on August 7, 2014, and amended on August 11, 2014 (T-0027), we consider the Environmental Impact technical section to be complete. The technical section is complete for the use of lasalocid sodium Type A medicated article for the control of coccidiosis associated with *Eimeria spp*. in pheasants. The proposed dosage is 113 g/ton feed and will be dispensed over the counter.

In your submission, you claimed a categorical exclusion under 21 CFR 25.33(d)(4) for the approval of lasalocid sodium for the intended uses listed above. Furthermore, you stated that to your knowledge, no extraordinary circumstances exist that may significantly affect the human environment. We agree that the proposed uses of this drug as described above fall within the claimed categorical exclusion and we are not aware of any extraordinary circumstances. Therefore, neither an environmental assessment nor an environmental impact statement is required.

When you submit your new animal drug application (NADA), your signature on the FORM FDA 356v re-certifies that the conditions of the categorical exclusion are still applicable at the time of your NADA submission.

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, 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, 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 Ms. Rebecca Cluster, Environmental Safety Team, at 240-402-0873. You may also contact Dr. Holly Zahner, Leader, Environmental Safety Team, at 240-402-0834.

Sincerely,

{see appended electronic signature page}
Veronica N. Taylor, Ph.D.
Director, Division of Scientific Support
Office of New Animal Drug Evaluation
Center for Veterinary Medicine