DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

I-011370-P-0037-EF
I-011370-P-0038-EF

U.S. Fish & Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief, AADAP
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Study Number SLICE-09-EFF-SAL-04 and the Effectiveness technical section

Dear Dr. Erdahl:

Based upon the information you submitted on October 21, 2011 (P-0037), and December 8, 2011 (P-0038), and the information contained in the investigational new animal drug file (INAD) 011370 we consider the Effectiveness technical section to be complete. The technical section is complete for the use of emamectin medicated feed for the control of *Salmincola californiensis* in freshwater-reared *Oncorhynchus mykiss*.

FOI Summary
We appreciate your cooperation in including the relevant portions of the draft FOI Summary for the Effectiveness technical section. A copy of the draft Effectiveness section of the FOI Summary is enclosed. Please review the FOI Summary for accuracy and notify us if you find errors.

Labeling
The draft indication and directions for use you provided in the P-0038 submission is acceptable.

All Other Information
We acknowledge your statement that there is no new information at this time pertaining to the use of emamectin benzoate to control *Salmincola* spp. in freshwater-reared *O. mykiss*. Please include any additional information that becomes available in the All Other Information technical section.

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, your correspondence should reference the date and the principal submission identifiers found at the top of this letter. If you have any questions or comments, please contact me at 240-276-8341. You may also contact Jennifer Matysczak, Leader, Aquaculture Drugs Team, at 240-276-8338.

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 Section of Freedom of Information (FOI) Summary: Effectiveness