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

Food and Drug Administration
Rockville MD 20857

I-006013-P-0122-TS

NRSP-7
Attention: Meg Oeller, D.V.M.
FDA Liaison to the NRSP-7
FDA/CVM/HFV-50
7500 Standish Place
Rockville, MD 20855

Re: Target Animal Safety technical section complete

Dear Dr. Oeller:

Based upon the information you submitted on May 13, 2013, and the information contained in investigational new animal drug file 006013, we consider the Target Animal Safety technical section to be complete. The technical section is complete for the use of AQUAMYCIN 100 (erythromycin) Type A medicated article administered at a dose of 100 mg erythromycin/kg body weight/day for 28 consecutive days for the control of mortality due to bacterial kidney disease associated with *Renibacterium salmoninarum* in freshwater-reared Chinook salmon.

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.

ALL OTHER INFORMATION
Please note the acceptable indication is "For the control of mortality due to bacterial kidney disease associated with *Renibacterium salmoninarum* in freshwater-reared Chinook salmon." Currently the designated indication is "For the control of mortality in freshwater-reared salmonids due to bacterial kidney disease associated with *Renibacterium salmoninarum."* All of the effectiveness and target animal safety studies were conducted with Chinook salmon and the published literature indicates potential safety concerns in freshwater-reared rainbow trout at the proposed dose. Depending on the designated sponsor's intentions, it may be prudent to ensure that the designated indication is revised to match the indication in the first sentence of this paragraph.

You did not address the All Other Information (AOI) technical section in this submission. Please include any information that becomes available in the AOI technical section. In addition, you have not submitted reports of activities under the INAD since 2008 when a report of activities during 2007 was submitted. All studies conducted under the INAD since 2008 should be summarized and submitted to address All Other Information and then annually. The outcome of studies with regard to effectiveness and animal safety should be addressed in these reports.

LABELING

Please include the following caution statement on the labeling: "Reduce handling or external stressors of fish during and for up to one month post therapy. Handling of fish receiving erythromycin may result in death. Signs of erythromycin toxicity include tetany, muscle spasms, abnormal swimming, or increased mortality."

FREEDOM OF INFORMATION (FOI) SUMMARY

We have prepared the Target Animal Safety section of the FOI Summary and a copy is enclosed. Please review the FOI Summary for accuracy and notify us if you find errors.

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 identifier. If you have any questions or comments, please contact me at 240-402-0817. You may also contact Dr. Jennifer Matysczak, Leader, Aquaculture Drugs Team, at 240-402-0588.

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 the Freedom of Information Summary: Target Animal Safety

Electronic Signature Addendum for Submission ID

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Signing Authority (Role)	Letter Date
Cindy Burnsteel (Division Director)	11/7/2013

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