

April 30, 2010

University of Florida  
Tropical Aquaculture Laboratory  
Attention: Craig Watson, M.Aq.  
Director, Tropical Aquaculture Laboratory  
1408 24<sup>th</sup> Street SE  
Ruskin, FL 33570

Re: Effectiveness technical section complete

Dear Mr. Watson:

Based upon the information you submitted on August 5, 2009, and amended on March 4, 2010 (T-0011) and the information contained in investigational new animal drug file 011128, we consider the Effectiveness technical section to be complete. The technical section is complete for the use of 17- $\alpha$  methyltestosterone in feed to increase the proportion of phenotypic males in swordtails (*Xiphophorus hellerii*).

#### ALL OTHER INFORMATION

We note that you did not submit additional information pertaining to Effectiveness in this submission. Please submit your All Other Information technical section, containing any additional information not previously submitted, when the last major technical section has been submitted and is likely to be complete. In the future, please include the available relevant “all other information” with each technical section, or note in your cover letter that there is no “all other information” pertaining to the technical section.

#### FREEDOM OF INFORMATION (FOI) SUMMARY

Thank you for providing suggested revisions for the draft Freedom of Information (FOI) Summary. We have revised the draft FOI Summary with regard to your first two requests for the “Study Locations” and “Results” sections. References to permanency and the statistical analyses and p-values associated with the “permanency” data collected during the field study were removed because the study in the current submission provides data showing the stability of the swords following MT treatment. In addition, the draft FOI Summary was revised for consistency with current CVM policy and procedures for format and language.

Please review the FOI Summary for accuracy and notify us if you find errors. If you request changes other than the correction of errors, we may re-open the Effectiveness technical section. We will prepare the final version of the FOI Summary and will provide you a copy when the last technical section is complete.

Include a copy of this technical section complete letter when a sponsor submits a 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 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 Dr. Jennifer Matysczak, Leader, Aquaculture Drugs Team, at 240-276-8338.

Sincerely,

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 FOI Summary