I-011236-P-0039-EF December 10, 2008

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

Re: Review of the Effectiveness technical section for 17α-methyltestosterone

Dear Dr. Erdahl:

Based on the information in your submission dated June 13, 2008, and the information contained in INAD 011236, the Division of Therapeutic Drugs for Food Animals considers the Effectiveness technical section for 17α-methyltestosterone (MT) Type C medicated feed for tilapia fry for the production of predominately (>80%) male populations of tilapia to be complete.

We have the following comments:

DRAFT LABELING

We appreciate your cooperation in including draft label language with the Effectiveness technical section. Please make the following revisions to the draft label language.

1. Please revise the Indication to read as follows:

   "For the production of predominately (>80%) male populations of tilapia."

   This indication is consistent with the results of the field trial included in the current submission.

2. Please include the following in the Dosage section:

   17α-methyltestosterone is administered in feed at a dosage of 9 mg 17α-methyltestosterone/kg of fish/day for 28 consecutive days. Administration should begin before the fish reach 14 days post-hatch.

FREEDOM OF INFORMATION (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 General Information and Effectiveness sections of the FOI Summary is enclosed. Please review the FOI Summary for accuracy and

notify us if you find errors. If you request changes other than the correction of errors, CVM may re-open the Effectiveness technical section.

ADDITIONAL COMMENT

We concurred with Protocol MT-05-EFF.2 in a letter dated May 17, 2006 (E-0016). In this protocol, the second criterion for demonstrating effectiveness was "The percent males in every (non-excluded) treated tank must be at least 80%." The protocol included in the current submission was titled Protocol MT-05-EFF.3. In this version of the protocol, the second criterion for demonstrating effectiveness was revised to state "The mean percentage of males in treated tanks must be greater than 80%." The data in the current submission were evaluated based on the effectiveness criteria in Protocol MT-05-EFF.2. One of the treated tanks at the third trial site (the second trial at SeaPac) did not contain at least 80% males (i.e., treatment successes), and the success rates in the treated tanks were lower than the success rates at the other two trial sites. However, the final study report for the third trial site provides an explanation for the lower treatment success rates. During the third trial, the fish were approximately one week older than the fish at the other two sites when the MT administration began. The lower treatment success rates were likely a result of the later start of 17α-methyltestosterone administration. Because you provided an adequate explanation for this difference, the data from all tanks for all three sites are acceptable to demonstrate effectiveness.

We will make a final decision of whether we can approve your application after we have reviewed all of the data for all applicable technical sections submitted in support of an administrative new animal drug application (NADA), NADA, or supplemental NADA, and any other information available to us, as a whole, and determined whether the requirements for approval set forth in the Federal Food, Drug, and Cosmetic Act have been met.

If you submit correspondence relating to your submission to the investigational file, you should reference the date and the principal submission identifier found at the top of this letter. If you have any questions, please contact me at 240-276-8341 or Dr. Jennifer Matysczak, Acting 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 Sections of the FOI Summary (General Information and Effectiveness)