

I-010697-G-0081-OT

SEP 16 2008

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

Re: Review a data development for target animal safety for AQUAFLO

Dear Dr. Erdahl:

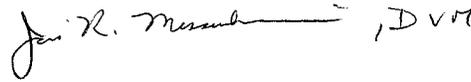
We agree that the studies you propose will be sufficient to complete the Target Animal Safety (TAS) technical section for the use of AQUAFLO (florfenicol) in freshwater-reared finfish at 10 to 15 mg florfenicol/kg of fish/day for 10 consecutive days (proposed dose). In your submission dated June 13, 2008, you submitted two tables which included information about completed TAS studies, as well as proposed TAS studies for the use of florfenicol in freshwater-reared finfish. The purpose of this submission was to request CVM concurrence that if the studies listed in both tables were completed and accepted, then the TAS technical section would be considered complete for the use of florfenicol at 10 to 15 mg florfenicol/kg of fish/day for 10 consecutive days in all freshwater cold- (i.e., salmonids), cool-, and warmwater finfish. You state that our concurrence would be based on our acceptance of all of the not yet submitted studies and that future label indications would depend upon completion of all other technical section requirements for that indication.

CVM agrees that the previously accepted data for the use of florfenicol in freshwater-reared salmonids and channel catfish provide adequate TAS data for the same finfish species at the proposed dose. Acceptable TAS studies in tilapia and hybrid striped bass will be adequate to complete the data requirements for the freshwater warmwater finfish component of the TAS technical section. An acceptable TAS study in yellow perch will be adequate to complete the freshwater coolwater finfish component of the TAS technical section for all freshwater finfish. We recommend that all planned studies be conducted in accordance with Good Laboratory Practice (GLP) standards. If this is not possible, the study should include as many characteristics of a GLP TAS study as can be included. We agree that the 1X dose be based on the 15 mg florfenicol/kg of fish/day dose. Further, we recommend that protocols for TAS studies not yet conducted be submitted for review and that concurrence on the protocol be reached with CVM prior to the conduct of the study.

CVM agrees that if all the listed studies are completed and found to be acceptable that the TAS technical section for the proposed florfenicol dose will be complete for all freshwater-reared finfish.

If you submit correspondence relating to this letter, you should reference this letter by date and the principal submission identifier found at the top of this letter. If you have any questions about this letter, please contact me at 240-276-8348 or Dr. Edward Chen, Acting Leader, Aquaculture Drugs Team at 240-276-8327.

Sincerely,

 , DVM

Janis R. Messenheimer, DVM
Acting Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine