



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 23 2009

I-010697-E-0089-TS
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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 target animal safety study protocol FLOR-08-TAS-SSB

Dear Dr. Erdahl:

We concur with the protocol you submitted on December 5, 2008, and amended on February 3, 2009 (T-0093). The protocol is a target animal safety study protocol FLOR-08-TAS-SSB. You submitted this protocol to the investigational new animal drug (INAD) file I-010697 for AQUAFLO (florfenicol) Type A medicated article. Florfenicol is proposed for the control of mortality due to Streptococcal septicemia associated *Streptococcus iniae* in hybrid striped bass.

Our concurrence means we fundamentally agree with the design, execution, and analyses proposed in your protocol, and represents a commitment that we will not later alter our perspectives on these issues unless public or animal health concerns appear that we did not recognize at the time of the protocol assessment. However, our concurrence with this protocol does not guarantee that the data obtained from a study that implements your protocol will support an approval. Because this concurrence does not extend to any subsequent changes you make to this protocol, you may want to seek our concurrence on the revised protocol if you make changes. When you submit a final study report, please be sure to include a copy of the protocol under which the study was actually conducted, and include any protocol deviations, amendments, and explanations.

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, Acting Leader, Aquaculture Drugs Team at 240-276-8338

Sincerely,

A handwritten signature in cursive script that reads "Cindy L. Burnsteel DVM". The signature is written in black ink and is positioned above the printed name and title.

Cindy L. Burnsteel, DVM
Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine