

I-011468-P-0017-HF

August 2, 2010

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

Re: Human food safety technical section complete

Dear Dr. Erdahl:

Based on the information you submitted on May 4, 2010, we consider the human food safety technical section to be complete. The human food safety technical section is complete for the use of channel catfish pituitary in fish.

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(s) found at the top of this letter. If you have any questions or comments, please contact me at 240-276-8225. You may also contact Dr. Lynn G. Friedlander, at 240-276-8226.

Sincerely,

Karen B. Ekelman, Ph.D.
Director, Division of Human Food Safety
Office of New Animal Drug Evaluation
Center for Veterinary Medicine