

I-011395-P-0012-HF

August 13, 2010

United States Department of the Interior
Attention: Mark P. Gaikowski
Interim Registration Officer
2630 Fanta Reed Road
La Crosse, WI 54603

Re: Human food safety technical section complete

Dear Mr. Gaikowski:

Based on the information you submitted on Feb 9, 2010 and the information contained in I-011395-P-0008-HF, we consider the human food safety technical section to be complete. The human food safety technical section is complete for the use of 17 α -methyltestosterone (17MT) in tilapia at 7 to 12 day old for 28 days with a minimal 120 day grow-out period after the 17MT dosing period.

The human food safety requirements for the use of 17MT in tilapia have been satisfied for toxicology, residue chemistry, and microbial food safety.

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. Kevin Gaido, the Acting Toxicology Team Leader, at 240-276-8212.

Sincerely,

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

Enclosure: FOI Summary Language