



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

I-011375-O-0029-OT

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

Re: Finfish treated with salmon gonadotropin releasing hormone analog

Dear Dr. Erdahl:

We have reviewed your submission dated January 26, 2012, regarding the investigational use of sGnRH $\alpha$  implants in fish. The following comments pertain to human food safety:

We conclude that a food-use authorization is not required for fish that remain on premises permanently or are destroyed.

We cannot assign an investigational withdrawal period for fish treated with sGnRH $\alpha$  implant at this time. We are unable to conduct a human food safety evaluation due to a lack of information provided on your product and concerns with potential human consumption of the implant and the formulation excipients. We provide general comments on requesting investigational food-use authorizations and comments specific to your implant under separate cover.

INVESTIGATIONAL LABELING

The appropriate investigational labeling required under 511.1(a) or (b) must be affixed to your investigational drug product before shipping your drug product for studies conducted under 21 CFR 511.1(a) or (b), respectively. Affix the investigational label to each individual drug container.

We remind you of the continued necessity to provide annual reports under the FDA/CVM Aquaculture Workload Plan. Your annual report should include: a) a brief summary of the past year's activities and accomplishments in each of the INAD technical sections; b) certification of accountability of all drugs shipped under the INAD, records maintenance for FDA inspection, and compliance with the provisions of 21 CFR Part 511, including notification of adverse effects relative to humans, target animals, or the environment resulting from the use of the investigational drug; c) a list of all investigators, facilities, and species treated; and d) a copy of the current study protocol(s) noting any modification or revision. We recommend that any changes to pivotal study protocols be reviewed by CVM prior to initiating further investigations.

ADDITIONAL COMMENTS

1. In order for us to complete our files, the disposition of all investigational animals and unused drugs must be reported to this office. Please refer to this letter by date and INAD number when reporting the details of clinical investigations or the disposition of investigational animals.
2. Promptly report to this office any adverse reactions that may suggest significant safety hazards.
3. You should obtain a material safety data sheet (MSDS) for the investigational drug and follow the information in the MSDS to protect all individuals who may be exposed to the investigational drug.

If you submit correspondence relating to this letter, you should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, contact Dr. Cindy Burnsteel, Director, Division of Therapeutic Drugs for Food Animals, at 240-276-8341.

Sincerely,

*{see appended electronic signature page}*  
Steven D. Vaughn, DVM  
Director  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine

**Electronic Signature  
Addendum for Submission ID**

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Signing Authority (Role)	Letter Date
Steven Vaughn (Office Director)	7/27/2012

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