



I-012186-O-0001-OT

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

Re: Food-use authorization for finfish treated with salmon gonadotropin releasing hormone analog

Dear Dr. Erdahl:

You are authorized 50,000 freshwater and marine finfish for human and animal food use. Edible tissues derived from experimental animals treated under the conditions described in this letter may be marketed for human consumption, for use in animal feeds, or released into public waters for possible human consumption. This authorization is in response to your submission dated July 20, 2012. This authorization for the use of OVARH (salmon gonadotropin releasing hormone) in freshwater and marine finfish is consistent with the public health.

Your categorical exclusion request submitted on July 20, 2012, is currently under review. You should await CVM's response to your claim before you begin conducting 21 CFR 511.1(b) studies.

FOOD-USE AUTHORIZATION

DRUG IDENTITY/FEED INGREDIENT IDENTITY	Salmon Gonadotropin-Releasing Hormone Analog (sGnRH _a , [des-Gly ¹⁰ , D-Arg ⁶ , Trp ⁷ , Leu ⁸]LH-RH-ethylamide)
Dosage Form	Soluble powder for dissolution in saline
SPECIES	Finfish
Class	Freshwater and marine finfish
Number of Animals	Up to 50,000
PERMITTED DOSING REGIMEN	Total dosage will not exceed 50 µg/kg body weight in 1 or 2 injections
Maximum Dose (or range)	
Route of Administration	Intraperitoneal or intramuscular injections

Frequency and Duration of Dosing	One or two injections, total dosage not to exceed 50 µg/kg body weight.
MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD	An investigational withdrawal period of at least 14 days for fish treated with sGnRHa established from the cessation of treatment: (1) the slaughter of fish for human consumption or (2) release into public receiving waters for possible human consumption.
MINIMUM INVESTIGATIONAL MILK DISCARD TIME	Not applicable
OTHER RESTRICTIONS OR CONDITIONS	The progeny of any treated fish can be marketed or slaughtered zero days after the last injection of broodstock.

The New Animal Drug Regulations, 21 CFR 511.1(b)(4), require the sponsor to submit specific information prior to each shipment or other delivery of the drug for clinical investigation in animals. You may file the notice of the drug shipment electronically to the Center for Veterinary Medicine (CVM) using FDA's eSubmitter tool. Please refer to the Center's electronic submission information on the CVM website at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/default.htm>. Alternatively, you can send one copy of the completed form to CVM.

This food-use authorization only applies to the treatment regimen stated above. Any change in the dosage regimen or the combining of this treatment with any other drug will require a separate food-use authorization. Drugs given to control animals must be administered in full compliance with the currently approved use. Your investigators should be made aware of their responsibilities under 21 CFR 511.1(b)(7)(ii) and (c)(1).

Clinical tests conducted under the provisions of this letter do not exempt investigational animals and their products from compliance with any other applicable inspection requirements (see 21 CFR 511.1(b)(5)(iii)).

INVESTIGATIONAL LABELING

You submitted investigational labeling to be included in the file. 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.

COUNTING NUMBERS OF FISH

You should note that this authorization is for a specific number of fish. You should begin counting the number of fish used from the date you receive our letter starting at zero.

Please provide the total number of fish used towards this authorization in your annual reports. We remind you that a fish treated more than once still only counts as a single fish toward the authorization.

Additional numbers of fish may be requested in the future. A request for additional fish should be made with sufficient lead time to allow us to process an amended authorization.

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.
4. We recommend that you request a presubmission conference to discuss the requirements for approval of this product.

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)	10/24/2012

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.