



I-008061-D-0170-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: Amended food-use authorization for finfish treated with luteinizing hormone-releasing hormone analogue

Dear Dr. Erdahl:

You are authorized 125,000 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 April 17, 2015. This amended authorization for the use of luteinizing hormone-releasing hormone analogue (LHRHa) in finfish is consistent with the public health. Previous authorizations are superseded.

AMENDED FOOD-USE AUTHORIZATION

DRUG IDENTITY	Luteinizing Hormone-Releasing Hormone Analog (des-Gly ¹⁰ , [D-Ala ⁶]LH-RH Ethylamide)
Dosage Form	solution
SPECIES	Fish
Class	All finfish
Number of Animals	125,000
PERMITTED DOSING REGIMEN	100 µg /kg body weight
Maximum Dose (or range)	
Route of Administration	IM or IP
Frequency and Duration of Dosing	Single injection (up to 100 µg/kg body weight) or multiple injections (total dosage not to exceed 100 µg/kg body weight)

MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD	An investigational withdrawal period of 14 days for fish treated with the LHRH analog is established from the cessation of treatment until (1) the slaughter of the 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 use of LHRH analog pellet implants is not authorized in food fish.

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).

In addition, we remind you that a sponsor must submit specific information prior to each shipment or other delivery of the drug for clinical investigation in animals (see 21 CFR 511.1(b)(4)). 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. Furthermore, we note that 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

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. Previous authorizations are superseded.

Your previous food use authorization granted September 10, 2014 (D-0165), authorized the treatment of 25,000 fish. In this submission you stated that the D-0165 authorization was exceeded. Please determine the number of fish that have been treated under D-0165. Any fish exceeding the D-0165 authorization must be deducted

from this authorization (D-0170). 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.

ANNUAL REPORTS

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. We recommend that you contact us and the manufacturing sponsor to discuss plans for meeting technical section requirements for the proposed indication.
2. 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.
3. Promptly report to this office any adverse reactions that may suggest significant safety hazards.
4. You should obtain a safety data sheet (SDS) for the investigational drug and follow the information in the SDS 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. If you have any questions or comments, please contact Dr. Cindy L. Burnsteel, Director, Division of Therapeutic Drugs for Food Animals at 240-402-0817.

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)	7/27/2015

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