



MAR 29 2010

I-008061-D-0151-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: Amended food-use authorization for fish treated with luteinizing hormone-releasing hormone analogue

Dear Dr. Erdahl:

You are authorized 10,000 fish 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 January 6, 2010 (D-0151). This amended authorization for the use of luteinizing hormone-releasing hormone analogue injectable in fish is consistent with the public health. Previous authorizations are superseded.

AMENDED FOOD-USE AUTHORIZATION

<b>DRUG IDENTITY</b>	LHRH analog (des-Gly <sup>10</sup> , [D-Ala <sup>6</sup> ]LH-RH Ethylamide)
Dosage Form	Injectable
<b>SPECIES</b>	Fish
Class	Domestic and wildstock
Number of Animals	10,000
<b>PERMITTED DOSING REGIMEN</b>	
Maximum Dose (or range)	100 µg /kg b.w.
Route of Administration	Intramuscular or intraperitoneal injections
Frequency and Duration of Dosing	Single (up to 100 µg/kg) or multiple injections (5 µg/kg), total dosage will not exceed 100 µg/kg.

<b>MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD</b>	An investigational withdrawal period of at least 14 days for fish treated with the LHRH analog (des-Gly <sup>10</sup> , [D-Ala <sup>6</sup> ]LH-RH Ethylamide) 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.
<b>MINIMUM INVESTIGATIONAL MILK DISCARD PERIOD</b>	Not applicable
<b>OTHER RESTRICTIONS OR CONDITIONS</b>	The use of LHRH analog pellet implants is not authorized in food fish.

This food-use authorization only applies to the treatment regimen(s) 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). Please refer to the Center's electronic submission information on the CVM website at <http://www.fda.gov/cvm/esubstoc.html>. Alternatively, you can send three copies 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)).

#### 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.

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.

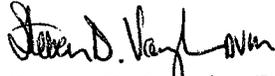
#### ADDITIONAL COMMENTS

1. In order for us to complete our files, the disposition of all investigational animals and unused drugs should be reported to this office, as well as adverse reactions observed. Please refer to this letter by date and INAD number when reporting the details of clinical investigations or the disposition of investigational animals.
2. We remind you that the investigational new animal drug must be manufactured, processed, packaged, and labeled in such a way as to maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to investigations made with the drug (21 CFR Parts 210 and 211).
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 meeting to further discuss your product development plan with us.
5. The investigational use of LHRH analog (des-Gly<sup>10</sup>, [D-Ala<sup>6</sup>]LH-RH Ethylamide) injectable in fish continues to fall within the categorical exclusion in 21 CFR 25.33(e). Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. A categorical exclusion from preparation of an EA and an EIS does not relieve you of the responsibility for determining and meeting all Federal, State, and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of the investigational drug.

Please notify CVM if the scope of your investigation changes (e.g., if additional facilities will treat fish, and/or if the protocol changes in ways that could result in increased environmental exposure, etc.).

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

Sincerely,



Steven D. Vaughn, DVM

Director

Office of New Animal Drug Evaluation

Center for Veterinary Medicine