DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

I-008391-D-0086-OT

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

Re: Amended food-use authorization for fish treated with common carp pituitary

Dear Dr. Erdahl:

You are authorized all 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 September 19, 2011. This amended authorization for the use of common carp pituitary (CCP) in all finfish is consistent with the public health.

AMENDED FOOD-USE AUTHORIZATION

DRUG IDENTITY/FEED INGREDIENT IDENTITY	Common Carp Pituitary
Dosage Form	Powder, for suspension
SPECIES	Food Fish
Class	All finfish
Number of Animals	15,000 (begin counting with D-0082)
PERMITTED DOSING REGIMEN Maximum Dose (or range) Frequency and Duration	Up to 25 mg/kg body weight total administered dose. The investigational drug may be administered up to two times, with the total administered dose not to exceed 25 mg/kg body weight.
Route of Administration	IM or IP injection
MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD	Zero
MINIMUM INVESTIGATIONAL MILK DISCARD TIME	Not applicable
OTHER RESTRICTIONS OR CONDITIONS	None

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/cvm/esubstoc.html. 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 of your D-0082 authorization (April 21, 2011).

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 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, please 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

I-008391-D-0086-OT

Signing Authority (Role)	Letter Date
Steven Vaughn (Office Director)	12/6/2011

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