



Food and Drug Administration
Rockville MD 20857

I-008391-D-0054

JUL - 7 2006

United States Department of the Interior
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: Request for an amended authorization for common carp pituitary to induce gamete maturation in finfish

Dear Dr. Erdahl:

You are authorized to (1) market for human food use the edible tissues derived from experimental animals or (2) release into public waters experimental animals for possible human consumption a total of 13,200 finfish under the conditions described in this letter. We have completed our review of your submission and find that an investigational exemption for the use of common carp pituitary in finfish is consistent with the public health.

AMENDED AUTHORIZATION

DRUG	Common carp pituitary
Dosage Form	Aqueous solution
Route of Administration	IM or IP injection
SPECIES	Finfish
Class	At facilities described in Attachment 1 of submission D-0037 (dated February 4, 2003)
Number of Animals	13,200
MAXIMUM DOSE (or Range) Frequency and Duration	25 mg/kg body weight Multiple times
MINIMUM WITHDRAWAL PERIOD	Zero
RENDERING	Fish may be rendered at any time
Other Restrictions	None

ENVIRONMENTAL CONSIDERATIONS

Your claim for the investigational use of common carp pituitary continues to fall within the categorical exclusion in 21 CFR 25.33(e). Therefore, neither an environmental assessment (EA) nor an environmental impact statement is required. This categorical exclusion from preparation of an EA and an environmental impact statement 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.

You are responsible for complying with the Federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES), as well as any applicable ground-water pollution requirements, for all investigational sites covered under this INAD. You must contact the offices responsible for issuing NPDES permits, and other similar permits, to be certain they have no objection to the use and release 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 which could result in increased environmental exposure, etc.).

GENERAL COMMENTS

You should begin counting the number of animals used from the date you receive this letter. Previous authorizations are superseded. As in the past, please supply the total number of animals used along with your reports.

Having a specific number of animals, rather than annual numbers, facilitates our tracking under the INAD. We remind you that an animal that has been treated more than once still only counts as a single animal toward the authorization.

As you track the total number of animals used by your investigators, a request for additional animals should be made with sufficient lead time to allow us to process an amended authorization.

Clinical investigations for this INAD cover only the treatment regimen stated above. Your investigators should be made aware of their responsibilities under Section 511.1(b)(7)(ii) and Section 511.1(c)(1).

The new animal drug regulations, Section 511.1(b)(3) and (4) require the sponsor to submit specific information prior to each shipment or other delivery of the drug for clinical investigation in animals. The agency has devised a form which you as the sponsor may use to report shipments for clinical trials. You may file the notice of the drug shipment electronically to CVM. Please refer to the Center's electronic submission information on the CVM website at <http://www.fda.gov/cvm/esubstoc.html>.

We remind you of the continued necessity to provide annual reports under the FDA/CVM Aquaculture Workload Plan. Your annual report should comprise: a) a brief summary of the past year's activities and accomplishments in each of the technical sections for the NADA;

b) certification of accountability of all drugs shipped under the INAD, records maintenance for FDA inspection, compliance with the provisions of 21 CFR 511 and 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 viewed by CVM prior to initiating further investigations.

If you submit correspondence relating to this letter, you should reference this letter by date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact Dr. Joan C. Gotthardt, Director, Division of Therapeutic Drugs for Food Animals, at 301-827-7571.

Sincerely,



Steven D. Vaughn, DVM

Director

Office of New Animal Drug Evaluation
Center for Veterinary Medicine