



Food and Drug Administration
Rockville MD 20857

INAD 8061 D0107 & D0108

• Dr. David Erdahl
National INAD Coordinator
United States Department of the Interior
Fish and Wildlife Service
4050 Bridger Canyon Road
Bozeman, Montana 59715

AUG 15 2003

Dear Dr. Erdahl:

We refer to your submissions dated January 31 (D0107), and February 10 (D0108), 2003, concerning your investigational new animal drug (INAD) exemption for the use of luteinizing hormone-releasing hormone analogue (LHRHa) to induce gamete maturation in a variety of finfish. Your submissions requested a renewal of your current INAD authorization to allow for the following:

1. January 31, 2003 - To request a renewal authorization to your INAD 8061 which expired on August 14, 2001, and to allow for treatment of a total of 3,950 fish with LHRHa to induce gamete maturation in a variety of fish at 25 facilities.
2. February 10, 2003 - To allow for treatment a total of 2,100 American shad (*Alosa sapidissima*) and Hickory shad (*Alosa mediocris*) with LHRHa at the USFWS Susquehanna River facility located in Harrisburg, Pennsylvania.

You also indicated that the currently authorized protocol for INAD 8061 will be strictly adhered to.

AMENDED AUTHORIZATION

We have completed our review and find that an investigational exemption for the use of the injectable form of this LHRH analog is consistent with the public health as requested. An investigational withdrawal period of at least 14 days for fish treated with the LHRH analog (des-Gly¹⁰, [D-Ala⁶]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. In contrast, we need data on the release of LHRH analog from the pellet implant in the fish so that an investigational withdrawal time can be assigned. Therefore, we do not authorize the use of the pellet implants. Accordingly, we authorize you to market for human food use the edible tissues derived from experimental animals treated in the following manner.

DRUG	LHRH analog des-Gly ¹⁰ , [D-Ala ⁶]LH-RH Ethylamide
Dosage Form	Injectable
Route of Administration	Intramuscular or intraperitoneal injections
SPECIES	Fish
Class	Domestic and wildstock
Number of Animals	6,050
MAXIMUM DOSE (or Range)	100 µg /kg b.w.
Frequency and Duration	Single (up to 100 µg/kg) or multiple injections (5 µg/kg), total dosage will not exceed 100 µg/kg.
MINIMUM WITHDRAWAL PERIOD	An investigational withdrawal period of at least 14 days for fish treated with the LHRH analog (des-Gly ¹⁰ , [D-Ala ⁶]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.
RENDERING	Fish may be rendered at any time.
OTHER RESTRICTIONS	The use of LHRH analog pellet implants is not authorized in foodfish.

Furthermore, you are authorized to include the USFWS Susquehanna River Coordinators Office, Harrisburg, Pennsylvania as a cooperator, and to treat American shad (*Alosa sapidissima*) and Hickory shad (*Alosa mediocris*) with LHRHa at the aforementioned facility.

ENVIRONMENTAL SAFETY CONSIDERATIONS

Your claim for the investigational use of LHRHa to induce gamete maturation in a variety of finfish species falls within the categorical exclusion in 21 CFR 25.33(e). Your submission states that to your knowledge, no extraordinary circumstances exist which may significantly affect the human environment. 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

We request that you provide an updated list of the species to be treated at the facilities included in your submission of January 31, 2003.

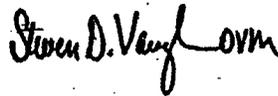
Furthermore, we remind you of the necessity to provide annual reports under the FDA CVM Aquaculture Workload Plan. Your annual report should comprise: a) a brief summary of the past year's activities and accomplishments in each of the technical sections for the NADA; b) certification of accountability of all drugs shipped under the INAD, records maintenance for FDA inspection, compliance with the provisions of 21 CFR Part 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 for the next year's studies, indicating additions and deletions from the previous year; and d) any modification to the study protocol.

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).

Future correspondence regarding these submissions to the file for your INAD exemption should be identified by the date of this letter and our file numbers, INAD 8061 D 0107 and D 0108 and be submitted to the Document Control Unit, HFV-199. Please include only one request per submission, clearly stating the request in the first paragraph of the submission.

If you have any questions or comments regarding this correspondence, please telephone Dr. Donald Prater, Leader, Aquaculture Drugs Team at 301-827-7567.

Sincerely yours,



Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine