



I-011669-A-0000-OT

DEC 19 2007

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

Re: Request for investigational new animal drug exemption file and slaughter authorization

Dear Dr. Erdahl:

We grant your request dated September 6, 2007, as amended on October 9, 2007, for the establishment of an investigational new animal drug (INAD) exemption file for 35% PEROX-AID (35% hydrogen peroxide) immersion. 35% PEROX-AID is proposed for the control of mortality due to certain ectoparasites in a variety of freshwater and marine finfish and for the control of mortality due to external columnaris and bacterial gill disease in freshwater-reared finfish. You requested a categorical exclusion from the requirement to prepare an environmental assessment (EA) and declared that, to your knowledge, no extraordinary circumstances exist. In addition, you provided copies of investigational labeling.

For administrative purposes, we have assigned your file number INAD 011669 for the above referenced use of 35% PEROX-AID in finfish. Please refer to this number in all drug shipments and correspondence concerning the drug while it is in investigational use.

**AUTHORIZATION FOR THE USE OF EDIBLE PRODUCTS**

You are authorized to treat up to a total of 21 million finfish as described in your correspondence dated September 6, 2007, and October 9, 2007. We have no human food safety concerns with the slaughter of fish treated with hydrogen peroxide at up to 100 ppm for 60 minutes or 200 ppm for 30 minutes for three treatments.

**INVESTIGATIONAL LABELING**

You provided intended investigational labeling language to be included in the file. This labeling is consistent with the requirements set forth in 21 CFR 511.1(a) and (b). The investigational labeling should be affixed to your investigational drug product prior to shipment and this investigational label should be affixed to each individual drug container.

**NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION**

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>.

You must maintain records of dates, amount of drug received in each shipment, and batch or code mark of each shipment for a period of two years after such shipment and delivery. These records should be made available for inspection and copying upon our request.

#### ENVIRONMENTAL CONSIDERATIONS

We find your claims for investigational uses of 35% PEROX-AID (hydrogen peroxide) in freshwater and marine finfish fall within the categorical exclusion in 21 CFR 25.33(e), subject to the reporting limitations described below. Your submissions state 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 (EIS) is required. These categorical exclusions from the preparation of an EA do 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 and your site investigators remain responsible for complying with the Federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES), as well as any applicable groundwater pollution requirements. For all investigational sites covered under this INAD, site investigators must report INAD use of 35% PEROX-AID to the permitting authority authorized to administer the NPDES program for the receiving waters into which a facility discharges [see 40 CFR 451.3(a)]. The permitting authority should also be informed of the acute water quality benchmark of 0.7 mg/L that has been derived by FDA for hydrogen peroxide. The acute benchmark concentration is not an effluent discharge limit and should not be interpreted as such. However, it can be used by the appropriate NPDES authority in conjunction with site-specific information (e.g., allowable size of mixing zone and the extent of dilution in receiving water) to determine if a specific discharge limitation and/or effluent monitoring may be needed for hydrogen peroxide at specific aquaculture facilities.

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.).

#### ADDITIONAL COMMENTS

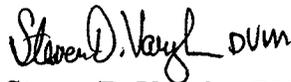
1. We remind you that the investigational new animal drug must be manufactured, processed, packaged, and labeled in such a way as to maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to investigations made with the drug.
2. In order for us to complete our files, the disposition of all investigational animals and unused drugs must 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.

3. CVM encourages you to discuss study design issues and submit protocols to the Center for review prior to initiating a study. Guidances for specific study design can be found on the CVM webpage.
4. CVM recommends that you request a meeting to further discuss your proposed claim and product development plan.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier(s) 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 240-276-8342.

Sincerely,



Steven D. Vaughn, DVM

Director

Office of New Animal Drug Evaluation

Center for Veterinary Medicine