



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

I-011375-X-0000-CE

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: Claim for a categorical exclusion for investigational use for OVAPLANT (sGnRHa) in all finfish

Dear Dr. Erdahl:

Your June 19, 2012, claim for a categorical exclusion (CE), meets the criteria for CE under 21 CFR 25.33(e) for the investigational use of OVAPLANT (salmon gonadotropin releasing hormone analogue; sGnRHa) implants. The drug is proposed for investigational use in finfish to induce gamete maturation (ovulation and spermiation). The CE is requested in conjunction with your amended authorization letter dated April 26, 2012, requesting an additional 20,000 fish to be treated under INAD 11-375. Your submission also adequately states that to your knowledge no extraordinary circumstances exist that may significantly affect the human environment (21 CFR 25.21). We agree that the proposed uses of this drug as described above fall within the claimed CE and we are not aware of any extraordinary circumstances. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required.

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. Prior to first use of OVAPLANT, the offices responsible for issuing NPDES permits, and other similar permits, for the sites of use, must be contacted to be certain they have no objection to the use and release of the investigational drug. In addition, this CE from the preparation of an EA and an EIS does not relieve you of the responsibility for determining and meeting all other Federal, State, and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of investigational drugs.

Provided you comply with the conditions in the paragraph above, we have limited environmental concerns for the continued investigational use of OVAPLANT in finfish. Therefore, you no longer need to request a new CE if the scope of your investigations changes (you wish to add additional facilities, fish species, numbers of fish, etc.), unless these changes are expected to result in extraordinary circumstances per 21 CFR 25.21 (i.e., serious harm to the environment).

This CE only addresses the investigational use of your product. Before submitting your administrative new animal drug application (NADA), a separate request for a CE or preparation of an EA for the NADA is required.

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. Eric Silberhorn, Acting Team Leader of the Environmental Safety team, at 240-276-8224.

Sincerely,

*{see appended electronic signature page}*  
Veronica N. Taylor, Ph.D.  
Director, Division of Scientific Support  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine

**Electronic Signature  
Addendum for Submission ID**

I-011375-X-0030-CE

<b>Signing Authority (Role)</b>	<b>Letter Date</b>
Veronica Taylor (Division Director)	9/26/2012

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