



I-012186-X-0002-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 OvaRH (sGnRH $\alpha$ ) in freshwater and marine finfish

Dear Dr. Erdahl:

Your July 20, 2012, claim for a categorical exclusion (CE) meets the criteria for CE under 21 CFR 25.33(e) for the investigational use of OvaRH (salmon gonadotropin releasing hormone analogue; sGnRH $\alpha$ ) as an injectable solution. The drug is proposed for investigational use in freshwater and marine finfish to induce gamete maturation. 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 OvaRH, the offices responsible for issuing NPDES permits, and other similar discharge permits, for the investigational site(s) 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.

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 me at (240) 276-8169. You may also contact

Dr. Eric Silberhorn, Acting Team Leader, 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-012186-X-0002-CE

| Signing Authority (Role)            | Letter Date |
|-------------------------------------|-------------|
| Veronica Taylor (Division Director) | 10/31/2012  |

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