



I-011741-X-0018-CE

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

Re: Claim of categorical exclusion for investigational use of AQUI-S (eugenol)

Dear Dr. Erdahl:

Your April 21, 2011, claim for a categorical exclusion (CE) from the requirement to prepare an environmental assessment meets the criteria for CE under 21 CFR 25.33(e) for the investigational use of AQUI-S E (50% eugenol) and AQUI-S 20E (10% eugenol). Your submission also adequately states that to your knowledge no extraordinary circumstances exist that may significantly affect the human environment. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required.

The drugs are proposed for investigational use in all freshwater and marine finfish as an immersion treatment for sedation to a handleable condition.

This CE from the preparation of an EA and an EIS 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 investigational drugs.

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 eugenol, the offices responsible for issuing NPDES permits, and other similar discharge permits, for site(s) of use, must be contacted to be certain they have no objection to the use and release of the investigational drug.

In the future, changes to your study protocol(s) or investigational conditions (e.g., additional facilities or new fish species) under this INAD may be made without the need for a new CE request. In your Annual Report, you must list all new facilities that have used the investigational drug and provide assurance that all new facilities have reported to their EPA or state NPDES permitting authority on the use of the investigational drug. In addition, if new information becomes available to you, which indicates that extraordinary circumstances may exist as described in 21 CFR 25.21, you should inform CVM immediately so that we may determine if the CE continues to apply. A new CE request or preparation of an EA may be needed if new information becomes available that indicates that investigational use of the drug could lead to a potential for serious harm to the environment (i.e., extraordinary circumstances may exist).

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, your correspondence 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 Mr. Charles Eirkson, Leader, Environmental Safety Team, at 240-276-8173, or Dr. Eric Silberhorn of the Environmental Safety Team at 240-276-8224.

Sincerely,

{see appended electronic signature page}

Anna B. Nevius, Ph.D.

Acting Director, Division of Scientific Support
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

**Electronic Signature
Addendum for Submission ID**

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Signing Authority (Role)	Letter Date
Charles Eirkson (Division Director) - Acting	9/13/2011

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