



I-011370-X-0053-CE

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

Re: Claim for a categorical exclusion for investigational use of SLICE (emamectin benzoate) in marine fish species

Dear Dr. Erdahl:

We have reviewed your June 24, 2013, claim for a categorical exclusion (CE) under 21 CFR 25.33(e) for the investigational use of SLICE (emamectin benzoate) medicated feed in marine fish species. The drug is currently proposed for investigational use in freshwater fish for control of mortality caused by external parasites. In association with an amended food use authorization (D-0052), you would like to extend investigational use to marine fish species. Your submission 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 investigational use of this drug falls within the claimed CE; however, you have not identified the locations of proposed use, indicated what species of fish will be treated, or provided additional facility-specific information that will allow us to us to make a determination on the potential for extraordinary circumstances to exist, that is, whether investigational use of SLICE may result in significant environmental effects. We are not opposed to use of SLICE on marine fish species or at marine sites, but based on the environmental fate and effects information available to us for emamectin benzoate, we cannot rule out the potential for extraordinary circumstances (i.e., serious harm to the environment) depending on the exposure scenario and specific site(s) of use. Therefore, we cannot accept your current claim for a CE for the use of SLICE in marine fish species.

At this time, we are not requiring that you prepare an environmental assessment (EA) for use on marine species; rather you should resubmit your claim for a CE with the information described below for the facilities that will be conducting investigational studies with SLICE on marine species.

In the future, you do not necessarily need to claim a CE in association with any new requests for food use authorizations for use of SLICE; however, a CE should always be requested when you intend to add new investigational facilities to your INAD protocol(s), or if you intend to make changes to your investigational use protocol affecting the drug dosage or concentration, treatment duration, frequency of use, or indications of use, or any other changes that may increase environmental exposure to emamectin benzoate (e.g., releases of the drug in effluents) at individual use sites.

Going forward, in order for us to make a determination on whether to accept a claim of CE or to require preparation of an EA for use of SLICE in marine species, please include the information described below when making any CE requests for this drug. This information is similar to that which we have previously asked you to submit when making CE requests for investigational use of SLICE in freshwater fish and when adding new facilities to your INAD. In addition, whenever making a claim of CE for SLICE or any other drug, be sure to include a statement that to your knowledge no extraordinary circumstances exist that may significantly affect the human environment (21 CFR 25.21).

Information Needed to Support CE Requests for SLICE:

For each facility where investigational use of SLICE in marine species is proposed, submit the following: 1) facility name, location, and owner/operator, 2) the fish species to be treated, 3) biomass of fish (kg) to be treated per treatment episode, 4) number of treatment episodes per year, 5) total biomass of fish (kg) to be treated per year, 6) treatment duration (days), 7) treatment rate ( $\mu\text{g}$  emamectin benzoate/kg fish), 8) average effluent flow rate (gallons/min), 9) identity of receiving water body for the facility's effluent and its average flow rate (gallons/min), 10) a brief description of fish husbandry (e.g., ponds, raceways, recirculating systems, net pens) and water use at the facility (e.g., single pass, serial reuse), 11) a description of the water treatment or solids removal processes (if any) at the facility that may affect the concentration of the drug entering the environment (e.g., in-line or off-line settling ponds, quiescent or settling zones, drum filtration), and 12) whether or not there is the possibility for concurrent or overlapping treatments with SLICE in the same facility (i.e., two or more raceways/tanks/ponds might be treated at the same time).

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, Environmental Safety Team, at [eric.silberhorn@fda.hhs.gov](mailto:eric.silberhorn@fda.hhs.gov) or Dr. Holly Zahner, Leader, Environmental Safety Team, at [holly.zahner@fda.hhs.gov](mailto:holly.zahner@fda.hhs.gov).

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**

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<b>Signing Authority (Role)</b>	<b>Letter Date</b>
Veronica Taylor (Division Director)	10/7/2013

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