



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 08 2010

I-011370-X-0010-CE

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

Re: Claim for a categorical exclusion for investigational use of SLICE

Dear Dr. Erdahl:

Your December 22, 2009, claim for a categorical exclusion (CE) from the requirement to prepare an environmental assessment, amended January 7, 2010 (T-0010) and March 30, 2010 (T-0015), meets the criteria for CE under 21 CFR 25.33(e) for the investigational use of SLICE (emamectin benzoate) medicated feed at a total of 21 facilities in 9 different states. In your prior submission dated August 20, 2009 (T-0009), you adequately stated 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 drug is proposed for investigational use in finfish for control of parasitic copepods at the following facilities:

1. Coleman NFH, Anderson, CA
2. Poudre SF, Bellvue, CO
3. Kootenai Tribal Conservation Aquaculture, Bonners Ferry, ID
4. SeaPac of Idaho Magic Springs, Hagerman, ID
5. SeaPac of Idaho Pristine Springs, Jerome, ID
6. Clear Springs - Briggs Creek Fish Hatchery, Buhl, ID
7. Clear Springs - Briggs Creek West, Buhl, ID
8. Clear Springs - Middle Hatchery, Buhl, ID
9. Clear Springs - Snake River Farm, Buhl, ID
10. Jake Wolf SFH, Topeka, IL
11. Little Grassy SFH, Makanda, IL
12. Phoenix Salmon US Inc. - Bingham Hatchery, Bingham, ME
13. Phoenix Salmon US Inc. - Gardner Lake Hatchery, East Machias, ME
14. Phoenix Salmon US Inc. - Oquossoc, Oquossoc, ME

15. Maryland DNR / Mirant Power Company – Chalk Point Generating Station, Aquasco, MD
16. Maryland DNR / Mirant Power Company – Potomac River Generating Station, Alexandria, VA
17. Maryland DNR / University of Maryland – Aquaculture and Restoration Laboratory, Cambridge, MD
18. Maryland DNR – Manning SFH, Brandywine, MD
19. Rock Creek SFH, Idleyld, OR
20. Crystal River SFH, Carbondale, CO
21. Thad Cochran National Warmwater Aquaculture Center, Stoneville, MS

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.

All investigational facilities are responsible for assuring compliance with the Federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES) before investigational use of SLICE may begin.

Assurance of compliance should be provided as follows:

- Each facility must report to its NPDES Authority prior to using SLICE and inform them of any conditions/restrictions on drug use or release.
- Each facility must obtain and document approval from the NPDES Authority prior to using SLICE for the first time.
- You must report and document the approval for each facility in your Annual Report to CVM.

In addition, please be aware of the following conditions associated with your CE:

- You must request a new categorical exclusion for protocol changes affecting the drug dosage or concentration, treatment duration, frequency of use, or indications of use (including the addition of a new species at a facility) that may increase environmental exposure at individual use sites.
- You must request a new categorical exclusion if new information becomes available which indicates that extraordinary circumstances as described in 21 CFR 25.21 may exist due to use of the drug.
- If you wish to add additional facilities to your INAD, you will need to provide the following facility-specific information and request a new categorical exclusion to cover the additional facilities: 1) facility name and location, 2) fish species to be treated, 3) biomass of fish (kg) to be treated per treatment episode, 4) number of

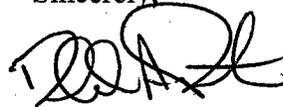
treatment episodes per year, 5) total biomass of fish (kg) to be treated per year, 6) treatment duration (days), 7) treatment rate (μg emamectin benzoate/kg fish), 8) average effluent flow rate (gallons/min), and 9) identity of receiving water and its average flow rate (gallons/min). You should also indicate 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).

This CE only addresses the investigational use of SLICE. Preparation of an EA will be required in support of the new animal drug application (NADA) for this drug.

Please note that that CVM will be working with the drug's NADA sponsor to see that appropriate environmental exposure data are generated at representative investigational use sites to support the future environmental assessment of SLICE for the NADA approval. You and/or your site investigators may be requested to help with this undertaking.

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 me at 240-276-8177. You may also contact Charles Erikson, Leader, Environmental Safety Team, at 240-276-8173.

Sincerely,



Donald A. Prater, D.V.M.
Director, Division of Scientific Support
Office of New Animal Drug Evaluation
Center for Veterinary Medicine