DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 23 2009

. I-009321- P-0114-NV

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: Information related to the effluent discharges of chloramine-T

Dear Dr.Erdahl:

We have reviewed the information provided in your submission dated April 22, 2009. The information addresses environmental safety concerns over the potential release of chloramine-T in effluents at concentrations greater than 0.1 ppm at some facilities using this drug under investigational use. Based on the submitted information and your assurance that in all future trials, the effluent concentration will either: 1) be less than 0.1 ppm or 2) if $\geq$ 0.1 ppm, in compliance with discharge levels set by local National Pollutant Discharge Elimination System (NPDES) permitting agencies, the existing categorical exclusion from the requirement to prepare an environmental assessment can continue to apply for investigational use of chloramine-T.

The following clarifies your responsibilities for continuance of the categorical exclusion:

- Each facility conducting trials under your INAD must report investigational use of chloramine-T to their NPDES authority and inform them of the effluent discharge limit of 0.1 ppm for this drug.
- In each of your Quarterly Reports, you must provide assurance that all investigational facilities are in compliance with their reporting requirements to the NPDES authority.
- You may add investigational facilities to your INAD via Annual and Quarterly Reports, if you give distinct assurance of compliance with the reporting requirements described above for each new facility.
- As needed the Environmental Safety Team will review Annual Reports along with the Aquaculture Drugs Team and, if needed, will request additional information.

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 or Charles Erikson, Leader, Environmental Safety Team at (240) 276-8173.

Sincerely,

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