



P-005893-A-0000-OT

JUL 28 2008

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

Re: Federal Register notice announcing availability of data in Public Master File 005893

Dear Dr. Erdahl:

We grant your request dated May 24, 2007 (P-005893-A-0000), and amended on January 23, 2008 (P-005893-T-0001), for the establishment of a Public Master File (PMF) for chloramine-T immersion when administered at a dose of 12 to 20 mg/L in a continuous flow water supply or as a static bath for 60 minutes once daily on alternate or consecutive days for 3 treatments to control mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp. For administrative purposes, we have assigned your file number PMF 005893. You also requested that the availability of the information and data in the PMF be announced in the Federal Register. A notice of satisfactory data contained in PMF 005893 will be published in the Federal Register and the information will be available for public disclosure and use by any sponsor.

We conclude that your effectiveness and target animal safety data are satisfactory to support those aspects of a new animal drug application (NADA) or supplemental NADA for the use of chloramine-T for the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp.

An NADA or supplemental NADA should include, in addition to reference to the PMF, animal drug labeling, and other data needed for approval, such as data concerning human food safety, environmental safety and manufacturing methods, facilities and controls.

Your submission dated May 24, 2007 (P-005893-A-0000), contained a draft Freedom of Information (FOI) Summary. Thank you for providing this document. We have revised this document now entitled 'A Summary of Safety and Effectiveness Data' and have enclosed a copy with this letter. Please review the Summary for accuracy and notify us if you find any errors. If you request changes other than the correction of errors, CVM may re-open the effectiveness or the target animal safety technical sections. The Summary of Safety and Effectiveness Data in PMF 005893 will be placed in the PMF, and the Federal Register notice will announce its availability.

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 Donald A Prater, D.V.M., Acting Director, Division of Therapeutic Drugs for Food Animals, at 240-276-8343.

Sincerely,

A handwritten signature in black ink, appearing to read "Bernadette Dunham". The signature is fluid and cursive, with a long horizontal stroke at the end.

Bernadette M. Dunham, D.V.M., Ph.D.
Director
Center for Veterinary Medicine

Enclosure:

Summary of Safety and Effectiveness Data in PMF 005893