



United States Department of the Interior



U.S. FISH & WILDLIFE SERVICE
AQUATIC ANIMAL DRUG APPROVAL PARTNERSHIP PROGRAM
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January 23, 2008

Dr. Joan Gotthardt
Director, Division of Therapeutic Drugs
for Food Animals
Document Control Unit, HFV-199
Center for Veterinary Medicine
7500 Standish Place, MPN-2
Rockville, MD 20855

Dear Dr. Gotthardt:

The purpose of this submission is to request that the enclosed materials be amended to Public Master File (PMF) 005-893 for the use of chloramine-T in fish. A letter requesting the establishment of a PMF for the use of chloramine-T as an immersion treatment to control mortality caused by external bacterial pathogens in a variety of fish species was submitted to CVM on May 24, 2007. The PMF will serve as a repository for efficacy and target animal safety information and data required to support a sponsor's New Animal Drug Application (NADA) for chloramine-T.

This submission includes three copies of the abstract from Target Animal Safety Study Number BFTC-99-CHLT-TAS-LKT-01 titled "The Safety of Chloramine-T Use on Lake Trout *Salvelinus namaycush*." This study demonstrates that the maximum proposed therapeutic treatment concentration of 20 mg/L chloramine-T is safe for use on fingerling lake trout being reared at a water temperature of ~12°C. Also enclosed are three copies of a revised Table of Contents for PMF 005-893. An electronic copy of all materials is provided for your convenience.

If you have questions regarding the above-described request, please contact Dr. David Erdahl, Branch Chief, U. S. Fish and Wildlife Service, AADAP Program at (406)-994-9904. We would like to thank you in advance for your time and consideration with respect to the above-described request.

Sincerely,

Dr. David Erdahl
Branch Chief, AADAP Program

Attachments (3 copies of each)

1. Target Animal Safety Final Study Report Abstract (Study Number BFTC-99-CHLT-TAS-LKT-01)
2. Revised Table of Contents for PMF 005-893