

INAD 4000 P-0093

David Erdahl, Ph.D.
National INAD Coordinator
USFWS Fish Technology Center
4050 Bridger Canyon Road
Bozeman, Montana 59715

SEP 13 2002

Dear Dr. Erdahl:

We refer to your submission dated April 1, 2002, as amended August 22, 2002, to your investigational new animal drug (INAD) file for chloramine-T. You requested review of a study completed to demonstrate the safety of chloramine-T administered as a bath to juvenile rainbow trout, *Oncorhynchus mykiss*.

Based on information in this submission and the information in submissions dated September 28, 2001, and July 12, 2001, the Division of Therapeutic Drugs for Food Animals considers the SAFETY technical section complete for the purpose of recommending approval of a New Animal Drug Application for the use of chloramine-T administered as a 60 minute bath at a concentration up to 20 mg/L on three consecutive or alternate days to freshwater-reared salmonids.

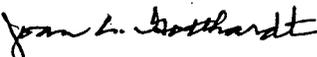
A final decision on the approval of the application will be made when all the data for all technical sections are viewed as a whole and it is determined that:

- 1) the information contained in and referenced by the application supports approval;
- 2) the GMP status of each manufacturing facility is current and satisfactory;
- 3) if a claim for categorical exclusion was made, conditions for the categorical exclusion are still applicable;
- 4) there is no new information that would preclude the approval of the application.

Future correspondence regarding this submission to the files for your INAD exemption should be identified by the date of the correspondence and our file number, INAD 4000 P-0093, and be addressed to the Document Control Unit, HFV-199. A copy of this technical section complete letter should be included in the Administrative NADA.

If you have any questions or comments regarding this correspondence, please telephone Dr. Joan C. Gotthardt, Leader, Aquaculture Drugs Team at 301-827-7571.

Sincerely yours,


for Janis R. Messenheimer, D.V.M.
Acting Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine