



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

INAD 10-697 P-0016

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David A. Erdahl
National INAD Coordinator
USFWS, National INAD Office
Bozeman Fish Technology Center
4050 Bridger Canyon Rd.
Bozeman, MT 59715

OCT 4 2002

Dear Dr. Erdahl:

We refer to your submission dated April 10, 2002, to your investigational new animal drug (INAD) file for the use of florfenicol (Aquaflor™) as an oral antibacterial in freshwater and marine fish. You requested the review of a field study completed to demonstrate the effectiveness of florfenicol-medicated feed administered at a dose of 10 mg florfenicol/kg of fish/day for 10 days to control mortality in fingerling westslope cutthroat trout (*Oncorhynchus clarki lewisi*) due to bacterial coldwater disease, caused by *Flavobacterium psychrophilum*.

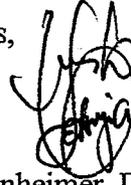
We have completed our review and have the following comments. The study was well-controlled and was conducted in accordance with the principles of Good Clinical Practice. You concluded that the lower mortality seen in the treated group provides evidence of effectiveness and that the late stage of the disease impacted the results of the study. However, for a study to be considered acceptable for demonstrating the effectiveness of a therapeutic drug, the difference in the results between the treated and control groups should be statistically significant. The mortality data was re-analyzed to determine if any difference in the mortality between the florfenicol and treated group existed. A mixed model using treatment group, day and the interaction between group and day as fixed effects and the tanks within treatment as a random effect for the pre-treatment period, for the post-treatment period and for the total study period was used. **No statistically significant differences were seen during any of the periods.**

Therefore, this study does not support the effectiveness of florfenicol against coldwater disease in cutthroat trout. Few drugs are effective every time they are administered. The results of this study will be considered when additional data are submitted for the effectiveness technical section.

Future correspondence regarding this submission to the file for your INAD exemption should be identified by the date of this letter and our file number, INAD 10-697 P-0016, and be submitted to the Document Control Unit, HFV-199. Please include only one request per submission, clearly stating the request in the first paragraph.

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



United States Department of the Interior

FISH AND WILDLIFE SERVICE
FISH TECHNOLOGY CENTER
4050 BRIDGER CANYON ROAD
BOZEMAN, MONTANA 59715
(406) 587-9265/FTS 585-4900



April 10, 2002

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

Dear Dr. Gotthardt:

The purpose of this submission is to request a formal review of the enclosed Final Study Report (FSR) titled "The efficacy of florfenicol-medicated feed to control mortality of fingerling westslope cutthroat trout (WCTT) *Oncorhynchus clarki lewisi* caused by bacterial coldwater disease, causative agent *Flavobacterium psychrophilum*." The FSR is identified by Study Number FLOR-01-EFF-05. Please note that we also request that the FSR be included in the florfenicol medicated feed efficacy technical section in support of a New Animal Drug Approval for florfenicol, and that the FSR be filed in the U.S. Fish and Wildlife Service Investigational New Animal Drug (INAD) file #10-697. We refer to your file number INAD 10-697 E-0011, dated February 28, 2002.

The enclosed FSR demonstrates the efficacy of florfenicol-medicated feed to control mortality in WCTT caused by bacterial coldwater disease when administered at a dosage of 10 mg florfenicol/kg of fish/day for 10 days. This florfenicol-medicated feed study was conducted under research study protocol FLOR-01-EFF (1st revision, submitted to CVM January 16, 2002) at the U. S. Fish and Wildlife Service's Bozeman Fish Technology Center, Bozeman, MT. A copy of the study protocol including standard operating procedures not contained within the FSR is also enclosed.

The current sponsor of INAD 10-697 is William Knapp, Deputy Assistant Director - Fisheries, U.S. Fish and Wildlife Service, 4401 N. Fairfax Dr., Arlington, VA 22203. We would like to thank you in advance for your time and consideration with respect to the above-described request. If you have any questions, please contact Dr. David Erdahl, National INAD Office, Bozeman, MT at (406) 587-9265, ext. 125.

Sincerely,

Dr. David Erdahl
National INAD Coordinator

enclosures