A CLINICAL FIELD TRIAL TO DETERMINE:

The Efficacy of Florfenicol-Medicated Feed to Control Mortality of Westslope Cutthroat Trout Fry *Oncorhynchus clarki lewisi* Caused by Bacterial Coldwater Disease, Causative Agent *Flavobacterium psychrophilum*

Study Number: FLOR-01-EFF-12

Study Director

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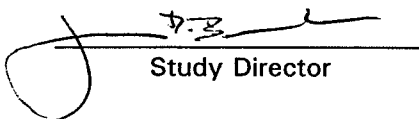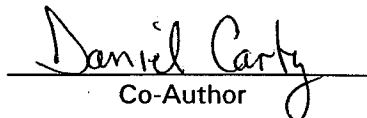(406) 563-2531

Testing Site: Washoe Park Trout Hatchery
Montana Fish, Wildlife & Parks
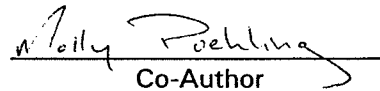600 Pennsylvania St.
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Study start date: August 26, 2002

Study end date: September 19, 2002

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1/06/03	1/06/03	01/06/03
Date	Date	Date

Abstract

The U. S. Fish and Wildlife Service's (USFWS) National Investigational New
Animal Drug Office (NIO) designed and conducted an efficacy study to generate data
needed to obtain U.S. Food and Drug Administration approval for the use of florfenicol-
medicated feed to control mortality in hatchery-reared salmonids diagnosed with
bacterial coldwater disease (CWD), causative agent *Flavobacterium psychrophilum*.
The study was conducted according to Good Clinical Practices at the Washoe Park
Trout Hatchery (TH; Montana Fish, Wildlife & Parks, Anaconda, MT) in August, 2002,
by staff from the NIO and Washoe Park TH following guidelines described in Study
Protocol Number FLOR-01-EFF (2nd revision, revised and signed April 1, 2002; Bowker
2002). The study objective was to compare mortality between westslope cutthroat trout
(CTT) fry *Oncorhynchus clarki lewisi* fed florfenicol-medicated feed and westslope CTT
fry fed non-medicated feed. Fish used in the study had been diagnosed with CWD by
presumptive identification of *F. psychrophilum* from fish sampled from the test
population 1 d before the start of the study. A completely randomized design procedure
was used to assign a treatment condition of either "treated" or "untreated" to each of 12
test tanks. Test fish in six of the test tanks were fed florfenicol-medicated feed at a
target dosage of 10 mg florfenicol/kg of fish/d for 10 consecutive days. Test fish in the
other six test tanks were fed non-medicated feed during the same 10-d period. The
study lasted 25 d and consisted of a 1-d acclimation period, a 10-d treatment period,
and a 14-d post-treatment period. Following the treatment period, test fish in all 12 test

tanks were fed non-medicated feed. Blinding techniques were employed to minimize bias in data collection. Total mortality that occurred during the treatment and post-treatment periods of the study was the primary response variable. The null hypothesis tested was that mean percent total mortality of test fish in treated tanks was equal to or greater than mean percent total mortality in untreated tanks (H_o: $\mu_{treated} \geq \mu_{untreated}$). The alternative hypothesis was H_a: $\mu_{treated} < \mu_{untreated}$. Based on a one-tailed t-test for two independent samples, mean percent total mortality in the treated group (75.0%) was significantly less ($P \leq 0.001$) than mean percent total mortality in the untreated group (94.0%). The higher than expected mortality among treated test fish was considered to have been due to factors such as: (1) the suspected high virulence of the *F. psychrophilum* strain isolated from fish in this study; (2) starting the study 3 - 4 d after the detection of increased mortality and observation of clinical signs indicative of CWD; and (3) because salmonid fry are particularly susceptible to CWD (Holt 1993; Brown et al. 1997; Bader and Starliper 2002). In spite of the high mortality in both treated and untreated groups of test fish, results from this study demonstrated that florfenicol-medicated feed treatment therapy was efficacious in controlling mortality in westslope CTT fry caused by CWD.