

A CLINICAL FIELD TRIAL TO DETERMINE:

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

Study Number: FLOR-01-EFF-04

Study Director

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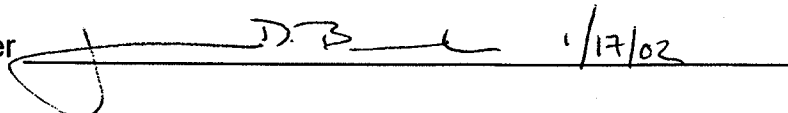
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ORIGINAL

**Testing Site: Murray Springs Trout Hatchery
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5475 Sophie Lake Road
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Study start date: October 2, 2001
Study end date: November 11, 2001
Date report submitted to CVM: January 17, 2002

James D. Bowker

A handwritten signature of James D. Bowker, consisting of a stylized 'J', 'D', and 'B' followed by a horizontal line. To the right of the signature, the date '1/17/02' is handwritten.

Abstract

The United States 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 at Murray Springs Trout Hatchery (TH; Eureka, MT) by staff from the NIO and Murray Springs TH following guidelines described in Study Protocol Number FLOR-01-EFF. The objective of the study was to compare mortality between fingerling westslope cutthroat *Oncorhynchus clarki* fed florfenicol-medicated feed and fingerling westslope cutthroat (CTT) fed non-medicated feed. Fish used in the study had been diagnosed with bacterial CWD by identification of *F. psychrophilum* cultures grown on Tryptone-Yeast Extract agar (TYE) that had been streaked with spleen tissue from fish sampled at the start of the study and confirmed by polymerase chain reaction (PCR). On day one of the study a completely randomized design procedure was used to assign a treatment condition of either "treated" or "untreated" to each test tank. Test fish in 4 of the 8 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 4 test tanks were fed non-medicated feed during the same 10-d period. Following the treatment period, test fish in all 8 test tanks were fed non-medicated feed. Blinding techniques were employed to ensure that study

participants involved in day-to-day data collection did not know which test tanks of fish were fed medicated feed and which test tanks of fish were fed non-medicated feed.

The study lasted 41 d and consisted of a 1-d acclimation period, a 10-d treatment period, and a 30-d post-treatment period. Total mortality that occurred during the treatment and post-treatment periods of the study was the primary response variable.

Percent total mortality for each test tank was calculated by dividing the number of dead fish removed from each test tank during the treatment and post-treatment periods by the number of live fish transferred to each test tank at the beginning of the study. At the end of the study, mean percent total mortality in the group treated with florfenicol-medicated feed was lower (1.9%) than the mean percent total mortality in the group not treated with florfenicol-medicated feed (3.2%), although differences were not significant ($P = 0.332$). Mean mortality among treated tanks was controlled within 4 - 5 d whereas mean mortality in untreated tanks was not controlled until day 29 of the post-treatment period. Although mortality in two of the untreated tanks was relatively low throughout the entire study period, cumulative mortality in the other two untreated tanks continued to increase throughout the study. The disparity in the disease level among untreated test tanks may have resulted in lower than expected mean mortality at the end of the study. It was suspected that had there been a more uniform level of disease in all test tanks, differences in total mortality between treated and untreated groups would have been more dramatic.