

A CLINICAL FIELD TRIAL TO DETERMINE:

The Efficacy of Florfenicol-Medicated Feed to Control Mortality of
Fingerling Steelhead Trout *Oncorhynchus mykiss* Caused by Bacterial Coldwater
Disease, Causative Agent *Flavobacterium psychrophilum*

Study Number: FLOR-01-EFF-06

Study Director

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Testing Site:

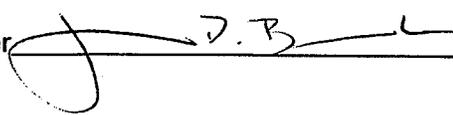
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Abstract

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 the Makah National Fish Hatchery (NFH; Neah Bay, WA) in May, 2002, by staff from the NIO and Makah NFH 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 steelhead trout *Oncorhynchus mykiss* fed florfenicol-medicated feed and steelhead trout fed non-medicated feed. Fish used in the study had been diagnosed with CWD by presumptive identification of *F. psychrophilum* isolated from fish sampled from the reference population on the first day 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. At the end of the study, mean percent total mortality in the treated group (2.0%) was significantly lower ($P = 0.065$) than the mean percent total mortality in the untreated group (5.0%). Results from this study demonstrate that florfenicol-medicated feed treatment therapy is efficacious in controlling mortality in steelhead trout caused by CWD.