

A CLINICAL FIELD TRIAL TO DETERMINE:

**The Efficacy of Florfenicol-Medicated Feed to Control Mortality of
Fingerling Hybrid Striped Bass Caused by Bacterial Streptococcal Septicemia,
Causative Agent *Streptococcus iniae***

Study Number: FLOR-01-EFF-02.b

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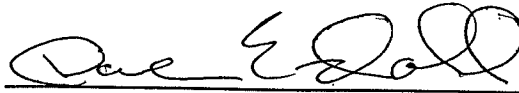
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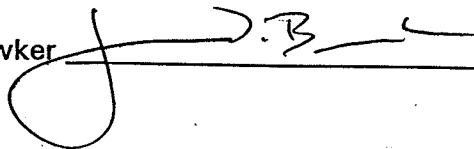
Study start date: August 14, 2001
Study end date: September 6, 2001
Date report submitted to CVM: February 10, 2003

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2/10/03

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2/10/03

Abstract

The United States Fish and Wildlife Service's (USFWS) National Investigational New Animal Drug Office (NIO) assisted in designing and assisting in conducting 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 fishes. This study was conducted at Kent SeaTech (Mecca, CA) by staff from Kent SeaTech and the NIO following guidelines described in Study Protocol Number FLOR-01-EFF. The objective of the study was to compare mortality in hybrid striped bass *Morone saxatilis x americana* caused by bacterial streptococcal septicemia (strep), causative agent *Streptococcus iniae* fed florfenicol-medicated feed and hybrid striped bass fed non-medicated feed. Fish used in the study had been diagnosed with strep by identification of *S. iniae* cultures grown on TSA and 5% sheep blood that had been streaked with brain and kidney from fish sampled before the start of the study. A completely randomized design procedure was used to allocated test fish to test tanks and to assign a treatment condition of either "treated" or "untreated" to each test tank. Test fish in 3 of the 6 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 3 test tanks were fed non-medicated feed during the same 10-d period. Following the treatment period, test fish in all 6 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 24 d and consisted of a 10-d treatment period and a 14-d post-treatment period. Source water to the test tanks came directly from the test tank that held the reference study population. 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 period and post-treatment period by the number of fish transferred to each test tank at the beginning of the study. Mean percent total mortality on any study day between day 4 and 17 in the treated tanks was significantly lower than mean percent total mortality in the untreated tank. At the end of the study, mean percent total mortality in tanks treated with florfenicol-medicated feed (32.7%) was lower than mean percent total mortality in the tanks not treated with florfenicol-medicated feed (37.3%). However, differences were not significant ($P = 0.377$). *Streptococcus iniae* bacteria were present in kidney and/or brain tissue of fish from untreated test tanks sampled 1 and 7 d post-treatment, but were not present in kidney or brain tissue of fish from treated test tanks. Consequently, we concluded that the florfenicol-medicated feed therapy was effective in controlling the presence of *S. iniae* and in controlling mortality in hybrid striped bass caused by strep.