A CLINICAL FIELD TRIAL TO DETERMINE:

The Efficacy of Florfenicol-Medicated Feed to Control Mortality of Hybrid Striped Bass *Morone chrysops* x *M. saxatilis* Caused by Strep, Causative Agent *Streptococcus iniae*

Study Number: FLOR-01-EFF.3-19

ORIGINAL

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Abstract

The U. S. Fish and Wildlife Service's (USFWS) Aquatic Animal Drug Approval Partnership (AADAP) program 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 hybrid striped bass (HSB) *Morone chrysops x M. saxatilis* diagnosed with Strep, causative agent *Streptococcus iniae*. The study was conducted according to Good Clinical Practices at the Kent SeaTech Corporation Fish Production Facility (KST; Mecca, CA) in September 2003, by staff from the AADAP and KST following guidelines described in Study Protocol Number FLOR-01-EFF.3 (3rd revision, revised and signed September 27, 2002; Bowker 2002). The study objective was to compare mortality between subadult HSB fed either florfenicol-medicated feed and subadult HSB fed non-medicated feed. Fish used in the study had been diagnosed with Strep by presumptive and confirmatory identification of *S. iniae* from fish sampled from the test population before treatments were administered. Three hundred fish from the reference population were split equally into six test tanks (n = 50 fish/tank). A completely randomized design procedure was used to assign a treatment condition of either "treated" or "untreated" to each of six test tanks. Test fish in three 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 three 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 six test tanks

were fed non-medicated feed. Blinding techniques were employed to minimize data collection bias. Total mortality that occurred during the treatment and post-treatment periods of the study was the primary response variable. Based on a one-tailed t-test for two independent samples, total mortality in the treated group (n = 29 total fish) was significantly less ($P = 0.030$) than total mortality in the untreated group (n = 78 total fish). Daily mortality in treated tanks returned to near-zero 7-8 d after the medicated feed regimen started. Daily mortality in untreated tanks did not return to near-zero, and cumulative mortality continued to rise throughout the study. Based on the significant difference in total mortality at the end of the study between treated and untreated groups of fish and the pattern of cumulative mortality throughout the study, results from this study demonstrated that florfenicol-medicated feed treatment therapy was efficacious in controlling mortality in subadult HSB caused by Strep.