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-03

Study Director

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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 Washoe Park State Fish Hatchery (SFH; Montana Fish, Wildlife & Parks, Anaconda, MT) by staff from the NIO and Washoe Park SFH following guidelines described in Study Protocol Number FLOR-01-EFF. The objective of the study was to document that mortality of fingerling westslope cutthroat trout Oncorhynchus clarki diagnosed with CWD and fed florfenicol-medicated feed was lower than mortality of fingerling westslope cutthroat trout diagnosed with CWD and fed non-medicated feed. Fish used in the study had been diagnosed with CWD based on: (1) observation of signs and symptoms of CWD; and (2) identification of F. psychrophilum cultures grown on Tryptone-Yeast Extract agar (TYE) that had been streaked with spleen tissue from fish sampled 3 d before the start of the study. Consequently, mortality observed during the study among test fish was attributed to CWD. The study lasted 31 d and consisted of a 7-d acclimation period, a 10-d treatment period, and a 14-d post-treatment period. On day one of the study, test fish held in one tank were randomly and evenly distributed into four test tanks. On the first day of the treatment period test tanks were randomly assigned a treatment condition of

either "treated" or "untreated." Test fish in 2 of the 4 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 two test tanks were fed non-medicated feed during the same 10-d period. Following the treatment period, test fish in all four 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. 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 group treated with florfenicol-medicated feed (4.6%) was lower than the mean percent total mortality in the group not treated with florfenicol-medicated feed (7.3%). Although differences were not significant (*P* = 0.333), it appeared that florfenicol-medicated feed administered at the target dosage was effective in controlling mortality in cutthroat trout caused by CWD.