

Oxytetracycline-Injectable Clinical Field Trials - INAD 9027

Year 2008 Annual Summary Report on the Use of Oxytetracycline-Injectable in Field Efficacy Trials

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Summary

The efficacy of injectable oxytetracycline (OTI) to prevent and/or control mortality of test fish caused by certain fish pathogens was evaluated under Compassionate Investigational New Animal Drug Exemption #9027 for the purpose of collecting pivotal and ancillary efficacy data to support a new animal drug approval for OTI; however, no studies were completed during calendar year 2008 (CY08).

Introduction

In warmwater fish culture, injectable oxytetracycline has been found to be efficacious for the control of bacterial hemorrhagic septicemia, pseudomonas disease, and enteric septicemia of catfish caused by *Edwardsiella ictaluri*. Fish culturists have also reported oxytetracycline to be effective against flexibacteriosis in catfish, sturgeon, paddlefish, temperate basses, sunfishes, and other fish species. There is speculation that an injectable form of oxytetracycline will also be effective in controlling mortality of

other fishes caused by systemic bacterial infections. Although integrated fish health management practices are often successful in preventing many fish disease outbreaks, adverse environmental conditions, fish handling procedures, physiological changes related to the onset and completion of spawning, and other culture-related factors can lead to severe disease outbreaks requiring prompt treatment. Therefore, an injectable antibiotic has the potential to effectively prevent losses to broodstock and other valuable non-feeding fish. Such treatment also reduces the discharge of infectious agents into the environment, thereby reducing the spread of disease to both cultured and wild fish.

Treatment strategies for the use of oxytetracycline as an injectable (OTI) have been designed primarily to prevent or control pre- and post-spawning mortality in valuable broodstock populations. The overall objective of these studies was to minimize the impact of disease on fish health, fish quality, and survival in order to fully meet fishery management objectives. As many factors can affect the success or failure of oxytetracycline therapy, data were collected on a variety of parameters to help determine appropriate use patterns for OTI under routine fish culture conditions. These data should provide valuable information with respect to potential OTI use patterns in aquaculture.

Current Study Protocol for OTI INAD #9027

Please see the attached current study protocol for OTI INAD #9027. Please note no changes have occurred to this study protocol.

Facility Sign-up List

Please see “Table 1. Facilities and Names of Investigators” for facilities that signed-up to participate in the OTI INAD #9027 during CY08. The following facility received OTI during CY08 but never used the drug: Texas Freshwater Fisheries.

Correspondence sent to OTI Participants

Please see the attached correspondence that was sent to all OTI participants after the AADAP Office received their sign-up form for calendar year 2008.

Number of Treated Fish under Slaughter Authorization

Total number of treated fish during CY08 was zero. The total number of treated fish to count against the slaughter authorization dated January 11, 2008 is zero.

Summary of Study Results

No studies were conducted under OTI INAD #9027 during CY08.