

# Other AQUI-S20 Activities:



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**Approval Coordination Workshop**  
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**Jackson, Wyoming**



**AADAP**  
Aquatic Animal Drug Approval  
Partnership Program

# What activities?



- **Light sedation of freshwater salmonids**
  - Pre-transport loading, grading and sorting, staging broodstock, and transporting fish at low densities
  - Protocol development
  - MUMS grant applications/planned studies
- **Immediate-release of marine fish following sedation in the field**
  - H-submission - to Support Use of AQUIS-20E as an Immediate-Release Sedative for Use on Marine Finfish
  - INAD use only
- **Other planned activities**



# Light sedation



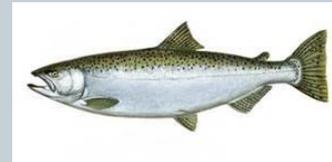
- **Protocol development/concurrence**
  - **The Efficacy of AQUI-S20E to Lightly Sedate Freshwater Salmonids for Extended Periods at Lower Densities**
    - ✦ **May 2014, April, July, August, and Sept 2015**
  - **Protocol concurrence Sept 2015**
- **Study procedures/Experimental design**
  - **Dose – 3 mg/L eugenol**
  - **Duration – pivotal time – 2 h; up to 5 h**
  - **15 test tanks – 10 treated and 5 control tanks; 30 fish/tank**
  - **Lose of equilibrium, inability to swim, can be caught by hand, position in water column**
    - ✦ **T = 0, 5, 15, 30, 45, and 60 min and then hourly thereafter for up to 5 h**
    - ✦ **Meet all criteria for light sedation at each observation period**
    - ✦ **Fisher's Exact Test**



# Game Plan



- **Planned studies**
  - **Rainbow trout and cutthroat trout**
    - ✦ **USFWS Bozeman Fish Technology Center**
    - ✦ **Work around disease trials**
    - ✦ **Late Summer/Fall 2016**
  - **Chinook salmon**
    - ✦ **IDFG Eagle Fish Health Lab**
    - ✦ **Coordinate with EFHL staff**
    - ✦ **Need healthy fingerling test fish**
- **MUMS Grant applications**
  - **Submitted Dec 2015 – 3 separate applications**
  - **Awarded May 2016**



# Immediate Release - Marine Fish



- **For field use under INAD #11-741**
  - 3-d withdrawal period for hatchery use
- **Document development (H-submission)**
  - **Submitted June 2015**
    - ✦ **Need for immediate release sedative for marine fish**
      - Referenced the need that was described in the UMESC H-submission that was submitted to CVM October 12, 2011
    - ✦ **US marine recreational/commercial landings – 2013**
      - Species most likely to be captured for fisheries management
      - Fewer marine fish are captured, sedated, measured/sampled and returned to the environment compared to freshwater fish
    - ✦ **Area of total inland waters and oceanic waters**
      - Area of oceanic water is nearly 17 × greater than that of the total inland water
  - **CVM response**
    - ✦ **Information was not sufficient to support request**
    - ✦ **Provided useful comments**



# Immediate Release for Marine Fish



- **Document development**
  - **Submitted Jan 2016**
    - ✦ **Same sections as previous submission**
    - ✦ **Capture methods and efficiencies for marine fish**
      - Described passive and active fish capture methods (Fisheries Techniques 2012)
      - Capture efficiencies – different geographic regions, comparable to freshwater
      - Dependent upon population density, fish size and shape, behavior, water current and temperature, bottom substrate and vegetation
    - ✦ **Tag and recapture studies of marine fish and sharks**
      - Cited 12 studies
      - Reported duration of tagging period, tag recovery, and time at liberty



# CVM Response and next AADAP steps



- **Concurred**
  - Consumption of immediate-released sedated fish is infrequent
  - Acute Reference Dose (2 mg eugenol/kg fish) previously established for freshwater fish
  - Based on consumption value of 0.3 kg fish/d
    - ✦ Safe concentration calculated to be 400 mg eugenol/kg fish
- **AADAP action**
  - Requested amended food slaughter authorization for immediate release use on marine fish
  - 100 d review time



# Other planned activities



- **Target animal safety – Marine fish**
  - Protocol development
  - Work with partners – need to find GLP facility
- **Light sedation – efficacy - non salmonids**
  - Protocol development
  - Confirm behaviors are similar to salmonids
    - ✦ Catchability, position in water column, etc
  - Pilot testing
- **Light sedation – safety – salmonids**
  - Experimental design
  - Work with CVM's Aquaculture and BioStatistics teams
  - Lots of pilot testing
    - ✦ Determine doses/durations to test, fish behaviors, metrics



# Questions?



Questions?

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