

DEVELOPMENT OF A DOSE RANGE-FINDING PILOT PROTOCOL FOR OXYTETRACYCLINE - HCL

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**22TH ANNUAL USFWS AQUACULTURE DRUG APPROVAL COORDINATION WORKSHOP
JACKSON, WYOMING, JUNE 9-10, 2016**



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- Prior studies were not supportive of the claim of effectiveness.
- CVM – conduct pilot work to “identify a dose that will be consistently effective under a broad range of conditions associated with columnaris disease” before further pivotal studies.
- AADAP – submitted pilot protocol that did not require masking, randomizations, dose verification, record of feeding behavior, and allowed a reduction in fish health sampling.

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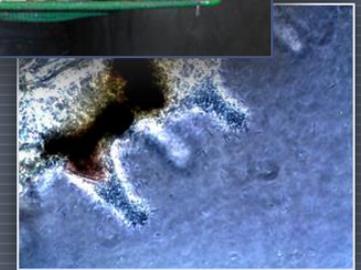
- **CVM did not accept protocol**
 - Randomize treatments
 - State minimum number of fish / tank
 - Include one group at 80 mg OTC-HCl/L or above
 - Conduct dose verification
 - Revise statistical model
- **We've started to re-write the protocol based on CVM suggestions**
 - At best, concurrence in August



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June – August, 2016:

- **Richloam Fish Hatchery (FL FWCC)**
 - Columnaris / channel catfish
 - Dose range pilot (60, 80, 100 mg OTC-HCl /L)
 - Pivotal study to follow
- **South Otselic Hatchery (NY DEC)**
 - Columnaris / tiger muskellunge
 - Pivotal study at higher dose (e.g., 100 mg OTC-HCl /L)
- **Washoe Park Trout Hatchery (MT FWP)**
 - Coldwater / cutthroat trout
 - Dose range pilot (60, 80, 100 mg OTC-HCl /L)
 - Pivotal study to follow



QUESTIONS?

