



FINAL AGENDA



14th Annual Aquaculture Drug Approval Coordination Workshop

July 29 – 31, 2008

The Holiday Inn ▪ Bozeman, Montana

Associated meetings:

July 28, 2008: - Round Table Discussion with CVM on parasites and posttreatment duration
- 17 α -methyltestosterone coordination meeting

August 01, 2008: - National Aquaculture Drug Research Forum (NADRF)
- National Aquaculture Industry Therapeutic Agent Program (NAI-TAP)

Hosted by: U.S. Fish & Wildlife Service (USFWS) – Aquatic Animal Drug Approval Partnership (AADAP) Program

Event Sponsors: Aquatic Life Sciences, Axcentive SARM, Bimeda, Carus Chemical, Eka Chemicals, Frontier Scientific, Intervet, Novartis Animal Health, Schering-Plough Animal Health Corp., and Skretting/BioOregon

Session moderators: Jim Bowker, USFWS-AADAP, Mark Gaikowski, U.S. Geological Survey (USGS) Upper Midwest Environmental Sciences Center (UMESC), and Dave Straus, U.S. Department of Agriculture (USDA)/Agriculture Research Service (ARS) Stuttgart National Aquaculture Research Center (SNARC)

Monday, July 28 (Bozeman Fish Technology Center – Large Conference Room)

- 9:00 – 12:30 PM** Round table discussion with Center for Veterinary Medicine (all invited)
- Efficacy studies to control parasite infestations
 - Technical presentation: Parasites, their diagnosis and considerations for evaluation – Courtney Coddington, CVM Student Intern
 - Efficacy study posttreatment duration
- 2:00 – 4:00 PM** 17 α -methyltestosterone coordination meeting
- 2:00 – 4:00 PM** Early registration at the Holiday Inn
- 4:00 – 6:00 PM** Early registration at Montana Ale Works, 611 E. Main St. (downtown Bozeman)
- 4:00 – 8:00 PM** Welcome Social at Montana Ale Works (*sponsored by: Aquatic Life Science Inc. and Eka Chemicals, Inc.*)



Tuesday, July 29 (Holiday Inn)

- 7:00 – 8:15** Workshop Registration
- 8:15 – 8:35** Howdy – howdy, housekeeping, agenda format, and extracurricular activities
Dave Erdahl, USFWS-AADAP
- 8:35 – 8:40** Welcome
- Dr. Stuart Leon
Chief, Division of National Fish Hatchery System
USFWS
- 8:40 – 9:20** Agency Perspectives on Aquatic Species Drug Approval Efforts
- Steve Vaughn
Director, Office of New Animal Drug Evaluations
U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM)
 - Gary Frazer
Assistant Director, Fisheries and Habitat Conservation
USFWS
 - Steve Sharon
Chair, Drug Approval Working Group (DAWG)
Association of Fish and Wildlife Agencies (AFWA)
 - David Bornholdt
Acting Regional Executive, Midwest Area
USGS – Biological Resources Discipline (BRD)

OVERVIEW PRESENTATIONS FROM CVM

- 9:20 – 9:35** Update from CVM's Aquaculture Drugs Team – Don Prater, CVM Aquaculture Team
- 9:35 – 9:50** FDA's MUMS Office and NRSP-7 Overview – Meg Oeller, CVM Office of Minor Use and Minor Species
- 9:50 – 10:10** **BREAK** (*sponsored by: Carus Chemical Co.*)

RECENT DRUG APPROVAL SUCCESS.....YES, WE HAVE MORE REASONS TO CELEBRATE!!

- 10:10 – 10:20** **TERRAMYCIN[®] 200 for Fish** – Roz Schnick, National Coordinator for Aquaculture NADA's (NCANADA) for Paul Duquette, Phibro Animal Health
- 10:20 – 10:30** **AQUAFLO[®]** – Palma Jordan, Schering-Plough Animal Health Corp.

THEMATIC PRESENTATIONS

- 10:30 – 10:45** Technical Presentation: Partnerships: The Key to AFWA Project Successes – Roz Schnick, NCANADA



Tuesday, July 29 (con't)

- 10:45 – 11:00** Technical Presentation: Imperatives for fish health management in open ocean aquaculture: Kona Kampachi[®] as the pioneering species – Jennica Lowell, Kona Blue
- 11:00 – 11:10** Technical Presentation: USFWS - American Fisheries Society Partnership: How everybody wins – Curry Woods and Jesse Trushenski, AFS

APPROVAL STATUS OF ORIGINAL AFWA PROJECT DRUGS

- 11:10 – 11:50** **35% PEROX-AID[®]** (hydrogen peroxide)
- Key participants: Dave Lovetro, Eka Chemicals; USFWS; USGS; Florida Fish & Wildlife Conservation Commission (FFWCC); Kona Blue; NCANADA; CVM
 - FDA-approved:
For the control of mortality in: (1) freshwater-reared finfish eggs due to fungus; (2) freshwater-reared salmonids due to bacterial gill disease; (3) coolwater finfish and channel catfish due to columnaris
 - Game plan for expanded claims to include:
 1. *For the control of mortality in:*
 - a) *Cultured warmwater finfish due to columnaris*
 - b) *All freshwater-reared finfish (except channel catfish) due to saprolegniasis*
 2. *For the control of parasite infestations in:*
 - a) *Cultured finfish (survey)*
 - Overview of Parasite Round Table Discussion
 - Discussion
 - 35% PEROX-AID[®] status summary
- 11:50 – 1:00** **LUNCH – on your own**
- 1:00 – 1:35** **HALAMID[®]** (chloramine-T)
- Key participants: Ed Bisinger, Axcentive SARL (represented by Eduardo Martinez, International Specialty Chemicals Inc.); USFWS; FFWCC; USGS-UMESC; NCANADA; CVM
 - Game plan for initial approval: The proposed initial claims include
 1. *For use to control mortality caused by (1) bacterial gill disease in all freshwater-reared salmonids, and (2) external columnaris in walleye (alternate/consecutive day treatment) and largemouth bass (consecutive day treatment)*
 - Game plan for expanded approvals include:



Tuesday, July 29 (con't)

1. *For use to control mortality caused by columnaris in all freshwater-reared salmonids, all coolwater (except walleye) and warmwater finfish caused by columnaris (alternate or consecutive day treatment)*

- HALAMID[®] status update

1:35 – 1:50

Technical Presentation: Water quality parameters: Considerations for collecting and reporting – Stacey Gore, CVM Aquaculture Team

1:50 – 2:10

Triangle Brand Copper Sulfate[®] (Copper sulfate)

- Key participants: Dave Fisher, Phelps Dodge; USDA-ARS; NCANADA; CVM
- Game plan for initial approval: The proposed initial claim is:
 1. *For use to control mortality caused by Ich in catfish reared in earthen ponds*
- Game plan for expanded claims include:
 1. *For use to control mortality caused by fungus in channel catfish eggs in flow through systems*
- Triangle Brand Copper Sulfate[®] status update

2:10 – 2:25

CAIROX[®] (Potassium permanganate)

- Key participants: John Boll, Carus Chemical Company; USDA-ARS; NCANADA; CVM
- Game plan for initial approval includes:
 1. *For use to control mortality caused by columnaris in hybrid striped bass*
- Game plan for additional claim includes:
 1. *For use to control mortality caused by columnaris in channel catfish*
- CAIROX[®] status update

2:25 – 3:00

Open Discussion

3:00 – 3:20

BREAK (*sponsored by: Carus Chemical Co.*)

3:20 – 3:30

AFWA perspective on Aquaculture Drug Approvals – Ron Regan, Resource Director, AFWA

3:30 – 3:50

Formalin-F[®], Paracide-F[®], and Parasite-S[®] (Formalin)

- Key participants: Various sponsors; CVM-Office of Research; NCANADA; CVM
- Technical Presentation: CVM study of formalin to reduce mortality associated with saprolegnia infection in catfish – Renate Reimschuessel, CVM Office of Research
- Game plan for expanded approval include:
 1. *For use to control mortality caused by saprolegniasis in all freshwater-reared finfish*
- Formalin status update



Tuesday, July 29 (con't)

3:50 – 4:25

TERRAMYCIN[®] 200 For Fish (Oxytetracycline medicated feed)

- Key participants: Paul Duquette, Phibro Animal Health Corp.; USFWS; USGS; NCANADA; USDA's North Central Regional Aquaculture Center (NCRAC) Project; CVM
- Game plan for expanded claims include:
 1. *For use to control mortality caused by columnaris in all freshwater salmonids*
 2. *For use to control mortality in cool- and warmwater fish caused by motile aeromonas disease*
 3. *For use to mark skeletal tissue of all salmonids*
- Technical Presentation: Strategies to control mortality caused by MAS in cool and warmwater finfish – Mark Gaikowski, USGS-UMESC
- Technical Presentation: Overview of efforts to expand skeletal marking claim based on INAD data – Tom Bell, USFWS-AADAP
- TERRAMYCIN[®] 200 For Fish status update

4:25

Door Prize Drawing!! (*sponsored by Frontier Scientific, Inc.*)

6:00 – 9:00 PM

Ice-Breaker Bar-B-Q at Hyalite Reservoir – Please ride the free Yellow Bus, leaving the Holiday Inn at 5:30pm. (*sponsored by: Schering-Plough Animal Health Corp. / Intervet Inc.*)

Wednesday, July 30 (Holiday Inn)

8:00 – 8:15 AM

Technical presentation: USFWS Public Master Files – Nicole Lawson, USFWS-AADAP

APPROVAL STATUS OF ORIGINAL AFWA PROJECT DRUGS (CONTINUED)

8:15 – 9:15

AQUAFLO[®] (florfenicol)

- Key participants: Schering-Plough Animal Health Corp.; Mississippi State University (MSU); USFWS; USGS; Kent SeaTech Corp; FFWCC; NCANADA; CVM
- FDA-approved for:

Controlling mortalities caused by (1) enteric septicemia in channel catfish (full approval); (2) columnaris in channel catfish (conditional approval); (3) coldwater disease in all freshwater-reared salmonids (full approval); furunculosis in all freshwater-reared salmonids (full approval)
- Game plan for expanded approvals include:
 1. *For use to control mortality caused by columnaris in all freshwater-reared salmonids*
 2. *For use to control mortality in hybrid striped bass and tilapia caused by Streptococcus iniae*

Wednesday, July 30 (con't)



3. *For use to control mortality in cool- and warmwater fish caused by motile aeromonas disease*
4. *For use to control mortality in cool- and warmwater fish caused by columnaris disease*
5. *For use in salmonids and cool and warmwater fish at 15 mg/kg body weight*

- Technical Presentation: Evaluation of various AQUAFLO[®] dosages to control mortality due to *S. iniae* in hybrid striped bass – Vaughn Ostland, Kent SeaTech Corp.
- AQUAFLO[®] status update

9:15 – 9:35

BREAK (sponsored by: Axcentive SARL)

9:35 – 10:05

AQUI-S[®] (isoeugenol)

- Key participants: USGS; USFWS; CVM; NCANADA; AQUI-S New Zealand Ltd.
- Status and results from the NTP study; implications of the Delany Clause
- Status of 1) residue depletion studies; 2) environmental fate studies; 3) TAS studies; 4) Gibbs-HEPES method validation; and 5) status of USFWS INAD.
- Sponsor (AQUI-S New Zealand Ltd.) Perspective
- Public stakeholder perspective

10:05 – 11:30

Zero Withdrawal Sedative Dilemma and Solutions – Round Table Discussion
Key participants; NCANADA, DAWG members, CVM, Prospective sponsors

- Technical Presentation: Zero withdrawal sedative dilemma and solutions – Roz Schnick, NCANADA

11:30 – 12:45

LUNCH – on your own

NON-AFWA PROJECT DRUGS: THE OLD AND THE NEW

12:45 – 1:30

MASCULINIZING FEED FOR TILAPIA[®] (17 α -methyltestosterone)

- Key participants: Dave Brock, Rangen, Inc.; USFWS; USGS; NCANADA; Ron Phelps, Auburn University; Kevin Fitzsimmons, University of Arizona, American Tilapia Association and Western Regional Aquaculture Center; CVM.
- Game plan for initial approval includes:
 1. *For use to produce predominantly male populations of tilapia* (Efficacy; TAS; Environmental; Method transfer study)
- Overview of the July 28th MT session
- Game plan for additional claims include:
 1. *For use to increase the proportion of phenotypic male swordtails*
 2. *For use to produce phenotypic male rainbow trout*



Wednesday, July 30 (con't)

- Technical Presentation Update: Effectiveness of MT to increase the proportion of phenotypic male swordtails *Xiphophorus* spp.” – update provided by AADAP courtesy of Roy Yanong, University of Florida - Tropical Aquaculture Laboratory (UF-TAL)
- 17 α -methyltestosterone status update

1:30 – 2:00

Porphyryns (AquaFrin™ – lauryl methyl pyrifrin) – a novel photochemical technique for use as a microbicide

- Key participants: Bert Israelsen, Jason Henderson, Glenn Prestwich, Tim Miller, Jerry Bommer, Frontier Scientific Inc./Echelon Biosciences Inc; AADAP
- Game plan for initial approval includes:
 1. *Control mortality caused by saprolegniasis in freshwater and marine finfish*
- INAD exemption and slaughter authorization
- Technical presentation: AquaFrin™: A safe and effective photo-activated antimicrobial agent for aquaculture – Glenn Prestwich
- AquaFrin™ status update

2:00 – 2:15

Overview of potential Aquatic Life Science, Inc. aquaculture products, **SE-MARK®** (calcein), **OVAPRIM®** (sGnRHa + additive injectable), **OVAPLANT®** (sGnRHa implant), and **AQUACALM®** (metomidate)

- Key participant: Tom Goodrich representing ALS Inc.

2:15 – 2:45

AQUAMYCIN 100® (erythromycin)

- Key Participants: Paul Rice, Bimeda; Christine Moffitt, USGS Coop Research Unit, University of Idaho; National Research Support Project #7; CVM-OR; NCANADA; CVM; USGS-UMESC
- Game plan for initial approval includes:
 1. *For use to control mortality caused by bacterial kidney disease in all freshwater-reared salmonids (Christine Moffitt)*
- Introduction: Erythromycin to control bacterial kidney disease in salmonids: Overview of project progress – Christine Moffitt, USGS Coop. Research Unit, U of Idaho
- Sponsor Presentation: Sponsor’s Progress – Paul Rice, Bimeda
- Technical Presentation: Toxicity of erythromycin to *Daphnia magna* in a flow-through, chronic exposure test system – Jeff Meinertz, USGS-UMESC
- Technical Presentation: Physical/chemical properties and microbial toxicity of erythromycin thiocyanate and transformation products – Jeff Meinertz and Mark Gaikowski, USGS-UMESC
- Discussion – all



Wednesday, July 30 (con't)

- 2:45 – 3:00** **MinnFinn[®]** (22.0% hydrogen peroxide + 4.5% peracetic acid)
Key Participants: Randy Wenthold, MinnTech; Paul Curtis, AquaSolver LLC
- Technical Presentation: MinnFin[®]: Efficacy in the treatment of bacterial and parasitic infections in koi, *Cyprinus carpio* – Paul Curtis, AquaSolver
- 3:00 – 3:20** **BREAK** (sponsored by: Axcentive SARL)

ODDS AND ENDS – TECHNICAL PRESENTATIONS

- 3:20 – 3:35** Use of antibiotics improves rainbow trout eyed egg survival – Mike Barnes, South Dakota Game, Fish, and Parks
- 3:35 – 3:50** Generalized linear mixed models and their use in aquaculture studies – Todd Blessinger, CVM Biometrics Team
- 3:50 – 4:00** Efficacy and toxicity of iodophores as egg disinfectants – Mark Gaikowski, USGS-UMESC
- 4:00 – 4:15** Experimental use of isometamidium chloride hydrochloride (IMC or trypanidium) to control mortality of adult chinook salmon from *Cryptobia salmositica* – Martin F. Chen, Washington Dept. Fish and Wildlife
- 4:15 – 4:25** The chemistry, manufacturing, and controls (CMC) technical section: The big picture of a long-term commitment – James Nitao, CVM Biotherapeutics Team
- 4:25 – 4:40** Environmental Assessments: Overview, scoping and suggestions for expediting and optimizing the process – Eric Silberhorn, CVM Environmental Safety Team and Mark Gaikowski, USGS-UMESC
- 4:45 - 4:55** Status of fish toxicant registrations – Roz Schnick, NCANADA
- 4:55** **Door Prize Drawing!!** (sponsored by Frontier Scientific, Inc.)

Thursday, July 31 (Holiday Inn)

- 8:00 – 9:45** **Use of Biologics in Aquaculture**
Moderator: Phil Klesius, USDA-ARS, Aquatic Animal Health Research Lab (AAHRL)
- Introduction and overview of session – Phil Klesius, USDA-ARS, AAHRL
 - Fish vaccine diversity: Advantages and disadvantages – Craig Shoemaker, USDA-ARS, AAHRL
 - Field evaluation of a modified live *Flavobacterium columnare* vaccine in trout at a North Carolina hatchery – Julie Bebak, USDA-ARS, AAHRL
 - *Flavobacterium columnare*, a virulent live culture: Safety and efficacy study at field dose in largemouth bass – Mike Matthews, FFWCC Bass Conservation Center
 - Research evaluation of a modified live *Streptococcus iniae* vaccine in hybrid striped bass – Vaughn Ostland, Kent SeaTech Corp.



Thursday, July 31 (con't)

- Research to market: Enteric redmouth bacterin in rainbow trout – John Drennan, Schering-Plough Animal Health Corp.
- Oral vaccination of Atlantic salmon *Salmo salar* against salmonid rickettsial septicemia (SRS) – Tom Goodrich, Advanced BioNutrition Corp.

9:45 – 10:00 **BREAK** (sponsored by: Skretting / BioOregon)

10:00 – 10:30 Round Table Biologics Panel Discussion – “Research-to-Market” of Fish Vaccines – Moderator: Julie Bebak USDA-ARS, AAHRL

- mass vaccination strategies,
- cost-effective fish vaccines,
- researcher-manufacturer links, and other topics

10:30 – 11:15 **SLICE**[®] (emamectin benzoate in a 0.2% formulation)

- Key participants: Dick Endris, Schering-Plough Animal Health; USFWS; CVM; Carolyn Gunn, Colorado Division of Wildlife; Shari Hanson, UF-TAL
- Game plan for initial approval; the proposed initial claim includes:
 1. *For use to control mortality caused by sea lice in cultured salmonids*
- Game plan for additional claim(s)
 1. *For use to control mortality caused by external parasites in freshwater-reared finfish*
- Technical Presentation: Use of emamectin benzoate for elimination of *Salmincola californiensis* in rainbow trout – Carolyn Gunn, Colorado Division of Wildlife
- Technical Presentation: Efficacy of emamectin benzoate medicated feed for control of fish louse (*Argulus* spp.) in goldfish *Carassius auratus* – Shari Hanson, UF-TAL
- SLICE[®] status update

11:15 – 11:40 **Common Carp Pituitary** (and other potential Low Regulatory Priority drug candidates)

- Sponsor (none identified), USFWS, NCANADA, CVM, and Hybrid Catfish Company
- Game plan for Low Regulatory Priority listing includes:
 1. *For use to induce gamete maturation in catfish*
- Can CCP be added to the LRP list? If so, what studies (e.g., target animal safety), if any, will be required?
- Technical presentation: Channel Catfish Pituitary – Roger Yant, Hybrid Catfish Company presented by Ron Phelps, Auburn University
- Procedures to minimize transfer of pathogens
- Other compounds that may be added to the LRP list



Thursday, July 31 (con't)

- 11:40 – 11:45** **REWARD[®]** (Diquat)
- Key participants: Sponsor (none identified); USFWS; Iowa Department of Natural Resources; USDA-ARS; NCANADA; CVM
 - Game plan for initial approval; the proposed initial claim includes:
 1. For use to control (1) mortality caused by external columnaris in all freshwater-reared finfish, and (2) saprolegniasis in channel catfish eggs
 - REWARD[®] status update
- 11:45 – 11:50** National Aquaculture Drug Research Forum
- Update
 - Next scheduled meeting – Friday, August 01 (9:00 – 11:30 am)
- 11:50 – 12:00** National Aquaculture Industry Therapeutic Agent Program
- The National Aquaculture Industry Therapeutic Agent Program (NAI-TAP) was formed because of concerns that the federal-industry structure of the JSA's Working Group on Aquaculture Drugs, Biologics, and Pesticides (WGADBP) may be violating the Federal Advisory Committee Act (FACA). NAI-TAP plans on continuing most of the mission and objectives of the WGADBP through an industry-driven group that would not be subject to FACA.
 - Next scheduled meeting – Friday, August 01 (1:00 – 5:00 pm)
- 12:00 – 12:15** Wrap-up, plans for 15th Annual Aquaculture Drug Approval Coordination Workshop; Little Rock, Arkansas
- 12:15** **Door Prize Drawing!!** (*sponsored by Frontier Scientific, Inc.*)
- 2:00 – 7:00** **Decompression Rafting Trip on the Yellowstone River** – Leave the Holiday Inn at 12:30pm, must be on the river, ready-to-float by 2:00pm (~60-min drive to the river)! (*sponsored by: Novartis Animal Health and Bimeda*)

Friday, August 01 (Bozeman Fish Technology Center – Large Conference Room)

- 9:00 – 11:30** National Aquaculture Drug Research Forum NADRF meeting
- Agenda to be provided prior to meeting
- 11:30 – 1:00** **LUNCH – on your own**
- 1:00 – 5:00** National Aquaculture Industry Therapeutic Agent Program
- Agenda to be provided prior to meeting