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# FINAL AGENDA

## 14<sup>th</sup> 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  $\alpha$ -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)

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### 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  $\alpha$ -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<sup>®</sup> 200 for Fish** – Roz Schnick, National Coordinator for Aquaculture NADA’s (NCANADA) for Paul Duquette, Phibro Animal Health
- 10:20 – 10:30 [AQUAFLO<sup>®</sup>](#) – 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<sup>®</sup> 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<sup>®</sup>** (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*
  - [Status Overview – David Lovetro, Eka Chemicals](#)
  - Technical Presentation: [Confirming saprolegniasis model in freshwater fish – Mark Gaikowski, USGS-UMESC](#)
  - Technical Presentation: [Status of USFWS Efforts to Expand the 35% PEROX-AID<sup>®</sup> Label – Nicole Lawson, USFWS-AADAP](#)
  - 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 – Mark Gaikowski](#)
  - Discussion
  - 35% PEROX-AID<sup>®</sup> status summary
- 11:50 – 1:00**     **LUNCH – on your own**
- 1:00 – 1:35**     **HALAMID<sup>®</sup>** (chloramine-T)
- Key participants: Ed Bisinger, Axcentive SARL (represented by Eduardo Martinez, International Specialty Chemicals Inc.); USFWS; FFWCC; USGS-UMESC; NCANADA; CVM
  - [Halamid<sup>®</sup> Status Update – Ed Bisinger representing Acentive SARL](#)



Tuesday, July 29 (con't)

- 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)*
- Technical Presentation: [Status of USFWS Efforts to Expand the Initial Chloramine-T \(Halamid<sup>®</sup> Pharma Grade\) Label – Miranda Dotson, USFWS-AADAP](#)
- Game plan for expanded approvals include:
  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)*

**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<sup>®</sup>** (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<sup>®</sup> status update

**2:10 – 2:25** **CAIROX<sup>®</sup>** (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<sup>®</sup> status update

**2:25 – 3:00** Open Discussion

**3:00 – 3:20** **BREAK** (sponsored by: Carus Chemical Co.)



Tuesday, July 29 (con't)

- 3:20 – 3:30 [AFWA perspective on Aquaculture Drug Approvals – Ron Regan, Resource Director, AFWA](#)
- 3:30 – 3:50 **Formalin-F<sup>®</sup>, Paracide-F<sup>®</sup>, and Parasite-S<sup>®</sup>** (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
- 3:50 – 4:25 **TERRAMYCIN<sup>®</sup> 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<sup>®</sup> 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](#)



Wednesday, July 30 (con't)

## APPROVAL STATUS OF ORIGINAL AFWA PROJECT DRUGS (CONTINUED)

8:15 – 9:15

### **AQUAFLO<sup>®</sup>** (florfenicol)

- Key participants: Schering-Plough Animal Health Corp.; Mississippi State University (MSU); USFWS; USGS; Kent SeaTech Corp; FFWCC; NCANADA; CVM
- Technical presentation: [USFWS Efforts to Assist Expansion of the Label Claims for Aquaflor<sup>®</sup> - Jim Bowker, USFWS-AADAP](#)
- 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*
  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<sup>®</sup> dosages to control mortality due to S. iniae in hybrid striped bass – Vaughn Ostland, Kent SeaTech Corp.](#)
- AQUAFLO<sup>®</sup> status update

9:15 – 9:35

### **BREAK** (sponsored by: Axcentive SARL)

9:35 – 10:05

### **AQUI-S<sup>®</sup>** (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



Wednesday, July 30 (con't)

**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<sup>®</sup>** (17  $\alpha$ -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.
- Technical presentation: [17  \$\alpha\$ -Methyltestosterone: Pivotal Efficacy Update – Dan Carty, USFWS-AADAP](#)
- 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 28<sup>th</sup> 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*
- 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  $\alpha$ -methyltestosterone status update

**1:30 – 2:00** **Porphyryns (AquaFrin<sup>™</sup> – 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<sup>™</sup>: A safe and effective photo-activated antimicrobial agent for aquaculture – Glenn Prestwich](#)
- AquaFrin<sup>™</sup> status update



Wednesday, July 30 (con't)

- 2:00 – 2:15** Overview of potential Aquatic Life Science, Inc. aquaculture products, **SE-MARK**<sup>®</sup> (calcein), **OVAPRIM**<sup>®</sup> (sGnRHa + additive injectable), **OVAPLANT**<sup>®</sup> (sGnRHa implant), and **AQUACALM**<sup>®</sup> (metomidate)
- [Update from Aquatic Life Sciences – Tom Goodrich](#)
  - Key participant: Tom Goodrich representing ALS Inc.
- 2:15 – 2:45** **AQUAMYCIN 100**<sup>®</sup> (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
- 2:45 – 3:00** **MinnFinn**<sup>®</sup> (22.0% hydrogen peroxide + 4.5% peracetic acid)  
Key Participants: Randy Wenthold, MinnTech; Paul Curtis, AquaSolver LLC
- Technical Presentation: [MinnFin<sup>®</sup>: 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](#)



**Wednesday, July 30 (con't)**

- 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.
  - [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



Thursday, July 31 (con't)

- 10:30 – 11:15** **SLICE<sup>®</sup>** (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<sup>®</sup> 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
- 11:40 – 11:45** **REWARD<sup>®</sup>** (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<sup>®</sup> status update
- 11:45 – 11:50** National Aquaculture Drug Research Forum
- Update
  - Next scheduled meeting – Friday, August 01 (9:00 – 11:30 am)



**Thursday, July 31 (con't)**

- 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 15<sup>th</sup> Annual Aquaculture Drug Approval Cooh<sup>http://www.fws.gov/fisheries/aa</sup> Workshop; Little Rock, Arkansas
- [Preview slides of next year's meeting site – Dave Straus, USDA-SNARC](#)
- 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