



# AGENDA

## 15<sup>th</sup> Annual USFWS Aquaculture Drug Approval Coordination Workshop



June 09 – 11, 2009

Hosted by:

U.S. Department of Agriculture, Agricultural Research Service –  
[Harry K. Dupree Stuttgart National Aquaculture Research Center](#) (SNARC)

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### Associated meetings:

- June 12, 2009:
- National Aquaculture Drug Research Forum (NADRF)
  - Working Group for Aquaculture Chemicals (WGAC)

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Venue: [La Quinta Inn & Suites Downtown Conference Center](#); Little Rock, Arkansas, USA

Event Sponsors: [Arkansas Agriculture Department - Aquaculture Division](#), Arkansas Bait and Ornamental Fish Grower's Association, [Arkansas Catfish Promotion Board](#), [Aquatic Life Sciences](#), [B. L. Mitchell Inc.](#), [Bimeda](#), [Freeport-McMoRan Copper & Gold Inc.](#), [Frontier Scientific Inc.](#), [Intervet/Schering-Plough Animal Health Corp.](#), and [USDA/ARS Professional Activities grant](#)

Session moderators: [Jim Bowker](#), U.S. Fish & Wildlife Service – [Aquatic Animal Drug Approval Partnership Program](#) (USFWS/AADAP)

[Mark Gaikowski](#), U.S. Geological Survey [Upper Midwest Environmental Sciences Center](#) (USGS/UMESC)

[Dave Straus](#), U.S. Department of Agriculture/Agricultural Research Service, [Harry K. Dupree Stuttgart National Aquaculture Research Center](#) (USDA/ARS/SNARC)

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### Monday, June 08

- 1:00 – 3:00 pm** Tours of USDA's Stuttgart National Aquaculture Research Center (1.25 hr drive from hotel) available upon request. Contact Dave Straus or Cindy Ledbetter at 870-673-4483 to make arrangements. [Click here](#) for driving directions from hotel.
- 2:00 – 4:00pm** Early registration at the [La Quinta Conference Center](#), Room Bush 41
- 4:00 – 6:00pm** Early registration at [Vino's Pizza Pub & Brewery](#), 923 West 7<sup>th</sup> St. (5 blocks west)
- 4:00 – 8:00pm** Welcome Social at Vino's (*sponsored by*: Freeport-McMoRan Copper & Gold Inc.)



## Tuesday, June 09 (La Quinta Conference Center – Grand Ballroom)

**7:00 – 8:15am** Workshop Registration

**8:15 – 8:30am** Welcome and Introduction

- Dr. Don Freeman, Director – Harry K. Dupree Stuttgart National Aquaculture Research Center

**8:30 – 8:45am** Welcome, housekeeping, agenda format, and extracurricular activities

- Dr. Dave Straus, USDA/ARS/SNARC

**8:45 – 9:40am** Agency Perspective

- Dr. Jeff Silverstein, USDA/ARS  
National Program Leader – Aquaculture
- Dr. Beth Luddy, USFDA/CVM  
Deputy Director – Science Policy
- Dr. Stuart Leon, USFWS  
Chief, Division of Fisheries and Aquatic Resource Conservation
- Jack Waide, USGS  
UMESC Deputy Center Director
- Kevin Amos, NOAA Fisheries  
National Aquatic Animal Health Coordinator

**9:40 – 10:10am** **Regional Aquaculture, Industry Perspective**

- Dr. Eric Park, President, Arkansas Bait and Ornamental Fish Grower's Association  
Industry perspective
- Wayne Branton, President, Catfish Farmers of Arkansas  
Industry perspective
- Dr. Carol Engle, University of Arkansas – Pine Bluff  
Fisheries and Aquaculture

### **RECENT DRUG INDEX SUCCESS**

**10:10 – 10:15am** **Ovaprim® and a surprise announcement**

Western Chemical Inc. – Dr. Jim Brackett

**10:15 – 10:30am** **BREAK** (*sponsored by: B.L. Mitchell Inc.*)

**10:30 – 10:35am** **DOOR PRIZE RAFFLE** (*sponsored by: Intervet/Schering Plough Animal Health*)

### **OVERVIEW PRESENTATIONS FROM CVM**

**10:35 – 10:50am** USFDA/CVM, Dr. Jennifer Matysczak – Update from CVM's Aquaculture Drugs Team

**10:50 – 11:05am** USFDA's MUMS Office, Dr. Dorothy Bailey – Indexing

**11:05 – 11:15am** USFDA/OR, Charles Gieseke – Update from FDA's Office of Research



## Tuesday, June 09 (continued)

### THEMATIC PRESENTATIONS

**11:15 – 11:30am** Dr. Jesse Trushenski, SIU & AFS/FCS President Elect – USFWS-AFS partnership

**11:30 – 11:45am** Bonnie Johnson, USFWS/AADAP – USFWS National INAD Program overview

**11:45 – 11:55am** Steve Sharon, Chair, Drug Approval Working Group (DAWG) of the Association of Fish and Wildlife Agencies (AFWA) – AFWA perspective on aquaculture drug approvals for the public sector

**11:55 – 12:05pm** Roz Schnick, National Aquaculture NADA Coordinator perspective on all aquaculture drug approvals

**12:05 – 1:30pm** **LUNCH – on your own**

**APPROVAL STATUS OF ORIGINAL AFWA PROJECT DRUGS** (See Addendum for current and future approvals)

**1:30 – 2:05pm** **35% PEROX-AID<sup>®</sup>** (hydrogen peroxide)

- USFWS/AADAP, Jim Bowker – Expanding the label for 35% PEROX AID<sup>®</sup> - Control of mortality due to external columnaris in warmwater finfish - an update
- USGS/UMESC, Maren Tuttle-Lau – Efficacy of 35% PEROX AID<sup>®</sup> to reduce *Gyrodactylus* spp. infestation density on coaster brook trout *Salvelinus fontinalis* at the Iron River NFH
- USFWS/AADAP, Niccole Lawson – Expanding the 35% PEROX AID<sup>®</sup> label – an update
- Comments from Eka Chemical/ALS/Western Chemical, Status, and Discussion

**2:05 – 2:40pm** **HALAMID<sup>®</sup> AQUA** (chloramine-T)

- USFWS/AADAP, Jim Bowker – Chloramine-T - Control of mortality due to external columnaris in warmwater finfish - an update
- USGS/UMESC, Jeff Meinertz – Modification of the determinative method for p-TSA, the chloramine-T marker residue
- USFWS/AADAP, Jim Bowker – Chloramine-T white paper argument - an overview
- Western Chemical, Ron Malnor – Strategy to market
- Comments, discussion, and status

**2:40 – 3:05pm** **Triangle Brand Copper Sulfate<sup>®</sup>** (copper sulfate)

- USDA/ARS/SNARC, Dr. Dave Straus –Effectiveness and safety of copper sulfate to catfish eggs
- Comments from Freeport-McMoRan, status, and discussion

**3:05 – 3:35pm** **CAIROX<sup>®</sup>** (potassium permanganate)

- USDA/ARS/SNARC, Drew Mitchell – A challenge method for infecting fish with *Flavobacterium columnare* using high fish density and an ultra-low, flow-through water system



## Tuesday, June 09 (continued)

- USDA/ARS/SNARC, Dr. Ahmed Darwish – Therapeutic assessment of potassium permanganate at early stages of experimental acute infection of *Flavobacterium columnare* in channel catfish (*Ictalurus punctatus*)
- USFWS/AADAP, Dr. Dave Erdahl – Potassium permanganate white paper
- USFWS/AADAP, Jim Bowker – Industry unmet label claim needs
- Comments, status, and discussion

**3:35 – 3:50pm** **BREAK** (*sponsored by:* Intervet/Schering Plough Animal Health)

**3:50 – 3:55pm** **DOOR PRIZE RAFFLE** (*sponsored by:* Intervet/Schering Plough Animal Health)

**3:55 – 4:15pm** **Formalin-F, Formacide-B, Paracide-F, and Parasite-S** (formalin)

- USFDA/OR, Charles Giesecker – Formalin treatment for saprolegnia infection in channel catfish
- Comments, status, and discussion

**4:15 – 4:30pm** **45 Years of Efforts toward Aquaculture Drug Approvals: A Perspective**

- Roz Schnick – National Aquaculture NADA Coordinator

**4:30 – 4:35pm** **DOOR PRIZE RAFFLE** (*sponsored by:* Frontier Scientific, Inc.)

**5:30 – 8:00pm** **Catfish Supper** – Transportation will be arranged. Located at the [Witt Stephens Jr. Central Arkansas Nature Center](#), River Market District, 602 Clinton Ave. (*sponsored by:* Arkansas Catfish Promotion Board)

## Wednesday, June 10 (La Quinta Conference Center – Grand Ballroom)

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

**8:00 – 9:10am** **AQUAFLO<sup>®</sup>** (florfenicol)

- USFWS/AADAP, Bonnie Johnson – Florfenicol INAD #10-697 - Expanding use to 15 mg/kg fish body weight/day
- USGS/UMESC, Maren Tuttle-Lau – UMESC efforts to approve TM-200<sup>®</sup> or Aquaflor<sup>®</sup> to control motile aeromonad septicemia
- USFWS/AADAP, Jim Bowker – Aquaflor<sup>®</sup> medicated feed efficacy trial - Update
- USDA/ARS/SNARC, Cindy Ledbetter – Safety of Aquaflor<sup>®</sup> to sunshine bass: In-life phase
- USFWS/AADAP, Jim Bowker – Aquaflor<sup>®</sup> target animal safety study on yellow perch
- Idaho DF&G, Doug Munson – Control mortality of chinook salmon due to bacterial kidney disease – a planned study
- Comments from Intervet/Schering-Plough Animal Health, status, and discussion

**9:10 – 9:30am** **TERRAMYCIN<sup>®</sup> 200 For Fish** (oxytetracycline medicated feed)

- USFWS/AADAP, Dan Carty – Efficacy of TERRAMYCIN<sup>®</sup> 200 for Fish for the skeletal marking of rainbow trout
- Comments, status, and discussion



## Wednesday, June 10 (continued)

### NON-AFWA PROJECT DRUGS: THE OLD AND THE NEW

#### 9:30 – 10:20am **MASCULINIZING FEED FOR TILAPIA**<sup>®</sup> (17 $\alpha$ -methyltestosterone)

- USFWS/AADAP, Dan Carty – 17MT efficacy technical section “complete” for tilapia
- National Aquaculture NADA Coordinator, Roz Schnick - Funding by NCRAC and WRAC for the analytical transfer and target animal safety study
- USGS/UMESC, Jeff Meinertz – Analytical 17  $\alpha$ -methyltestosterone feed method transfer study
- USDA/ARS/SNARC, Dr. Dave Straus –Target animal safety study and protocol development
- Auburn University, Dr. Ron Phelps – Environmental safety, update (presented by Dr. Tom Bell, USFWS/AADAP)
- USFWS/AADAP, Dr. Tom Bell – 17  $\alpha$ -methyltestosterone timeline
- Comments, status, and discussion

#### 10:20 – 10:40am **BREAK** (sponsored by: Aquatic Life Science Inc.)

#### 10:40 – 10:45am **DOOR PRIZE RAFFLE** (sponsored by: Intervet/Schering Plough Animal Health)

#### 10:45 – 11:10am **Porphyrins (AquaFrin**<sup>™</sup>) – a novel photochemical technique for use as a microbicide

- USFWS/AADAP, Dr. Dave Erdahl – Compassionate INAD exemption and slaughter authorization
- Update from Frontier Scientific, Inc., Tim Miller
- Comments from Frontier Scientific, Inc., status, and discussion

#### 11:10 – 11:30am Aquatic Life Sciences Inc., Dr. Jim Brackett - Overview of potential Aquatic Life Science, Inc. aquaculture products, **SE-MARK**<sup>®</sup> (calcein), **OVAPRIM**<sup>®</sup> (sGnRH $\alpha$ + additive injectable), **OVAPLANT**<sup>®</sup> (sGnRH $\alpha$ implant), and **AQUACALM**<sup>®</sup> (metomidate)

#### 11:30 – 12:00pm **AQUAMYCIN 100**<sup>®</sup> (erythromycin)

- USGS/UMESC, Jeff Meinertz – Chronic toxicity of erythromycin thiocyanate to *Daphnia magna*
- USGS/UMESC, Mark Gaikowski – Overview of progress
- USGS/UMESC, Mark Gaikowski – Progress on the environmental assessment
- Comments, status, and discussion

#### 12:00 – 1:30pm **LUNCH – on your own**

#### 1:30 – 1:50pm **SLICE**<sup>®</sup> (emamectin benzoate in a 0.2% formulation)

- USFWS/AADAP, Dr. Dave Erdahl - SLICE<sup>®</sup> INAD update
- Comments from Intervet/Schering Plough Animal Health, status, and discussion



## Wednesday, June 10 (continued)

### **1:50 – 3:15pm**    **Sedatives**

- AFWA, Steve Sharon – Status of immediate withdrawal sedatives: how we got from where we started to where we are now
- NOAA, Kevin Amos – Update of NOAA/Pacific NW sedative task force
- National Aquaculture NADA Coordinator, Roz Schnick – Update on all sedative needs and what we need to do to meet those needs
- USFWS/AADAP, Dr. Tom Bell – Status of benzocaine genotoxicity study
- USGS/UMESC, Jeff Meinertz – Status of eugenol total residue depletion study
- USFWS/AADAP, Dr. Dave Erdahl – Establishing INADs
- USGS/UMESC, Mark Gaikowski and Jeff Meinertz – Studies to evaluate the time to first feeding of fish after sedation
- USFWS/AADAP, Jim Bowker – Potential immediate release sedatives – here we go again
- Comments, status, and discussion

### **3:15 – 3:30pm**    **BREAK** (*sponsored by:* Intervet/Schering Plough Animal Health)

### **3:30 – 3:35pm**    **DOOR PRIZE RAFFLE** (*sponsored by:* Intervet/Schering Plough Animal Health)

### **3:35 – 4:30pm**    **Use of Biologics in Aquaculture – Moderated by Craig Shoemaker**

- The Flavobacterium challenge
- Question: What do fish fear? Answer: Streptococcus!

### **4:30 – 4:35pm**    **DOOR PRIZE RAFFLE** (*sponsored by:* Frontier Scientific, Inc.)

## Thursday, June 11 (La Quinta Conference Center – Grand Ballroom)

### **8:00 – 8:45am**    **CVM Presentations**

- Aquaculture Drugs Team, Dr. Susan Storey – End Review Amendment (ERA) process
- Environmental Safety Team, Dr. Eric Silberhorn – Water quality benchmarks for aquaculture drugs: What, when, why and how
- Human Food Safety Division, Dr. Steve Yan – FDA’s Guidance’s #152 and #159: Similarities and differences

### **8:45 – 9:05am**    **Regional Aquaculture, Industry Perspective**

- Mike Freeze, Keo Fish Farm and NAA
- Joey Lowery, President, Catfish Farmers of America

### **9:05 – 9:50am**    **Technical Presentations - General**

- Dr. Alf Haukenes, University of Arkansas-Pine Bluff – Field trial evaluations of carp pituitary, catfish pituitary, and LHRHa at inducing ovulation in channel catfish



## Thursday, June 11 (continued)

- Mark Gaikowski and Maren Tuttle-Lau, USGS/UMESC – An Evaluation of the efficacy of iodophor disinfection of walleye *Sander vitreum* and northern pike *Esox lucius* to control viral hemorrhagic septicemia virus
- Charles Giesecker, USFDA/OR – A survey of drug effects on a renal monogenean *in vitro*

**9:50 – 10:05am** **BREAK** (*sponsored by:* Bimeda and B.L. Mitchell, Inc.)

**10:05 – 10:10am** **DOOR PRIZE RAFFLE** (*sponsored by:* Intervet/Schering Plough Animal Health)

**10:10 – 11:25am** **Technical Presentations - Ectoparasites**

- Dr. Thomas Meinelt, Leibniz-Institute of Freshwater Ecology and Inland Fisheries – Peracetic acid, an alternative to fight fish ectoparasites!?
- Mark Gaikowski and Maren Tuttle-Lau, USGS/UMESC – Parasite-related aquatic animal health issues
- Dan Carty, USFWS/AADAP – In pursuit of label claims for the control of fish parasites with emphasis on the importance of parasite enumeration, an overview of a presentation by Sarah L. Poynton, Ph.D. (Associate Professor of Molecular and Comparative Pathology, The Johns Hopkins University School of Medicine, Baltimore)
- Drew Mitchell, USDA/ARS/SNARC – Parasite assessment and fish survival: Tools for the evaluation of copper sulfate and potassium permanganate tank treatments for Ichthyobodosis on sunshine bass
- Mark Gaikowski, USGS/UMESC and Todd Blessinger, FDA/CVM, Biometrics Team – Treatment efficacy protocol development

**11:25 – 11:30am** National Aquaculture Drug Research Forum

- Update
- Next scheduled meeting – Friday, June 12

**11:30 – 11:35am** Working Group for Aquaculture Chemicals

- Update
- Next scheduled meeting – Friday, June 12

**11:35 – 12:00pm** Wrap-up, plans for 16<sup>th</sup> Annual Aquaculture Drug Approval Coordination Workshop back in Bozeman, MT

**1:00 – 7:00pm** **Industry Tours** – Leave the La Quinta Conference Center at 1:00pm, transportation will be arranged. Tour includes visits to Anderson Minnow Farm, Pool Fisheries (ornamental fish), Hopper-Stevens Hatchery (catfish) and Keo Fish Farm (hybrid striped bass, grass carp, minnows, ornamentals, etc.). Crawfish-boil Supper will be held at Keo Fish Farm following the tour (*sponsored by:* USDA/ARS Professional Activities grant).

## Friday, June 12 (La Quinta Conference Center – Room Bush 41)

**8:00 – 10:15am** National Aquaculture Drug Research Forum (NADRF) meeting

- See attached agenda - focus of meeting will be on study designs to evaluate treatments to control external parasites of fish

**10:30 – 12:30pm** Working Group for Aquaculture Chemicals (WGAC) meeting

- Agenda to be provided prior to meeting



**ADDENDUM**  
**to the Agenda for the**  
**15<sup>th</sup> Annual USFWS Aquaculture Drug Approval Coordination Workshop**

**LABEL EXPANSIONS**  
See the [QUICK REFERENCE GUIDE](#) for all approved drugs and their uses

**35% PEROX-AID®**

FDA/CVM-approved:

- (1) For the control of mortality due to fungus of freshwater-reared finfish eggs
- (2) For the control of mortality due to bacterial gill disease of freshwater-reared salmonids
- (3) For the control of mortality due to external columnaris of coolwater finfish and channel catfish

Planned expanded label claim:

- (1) For the control of mortality due to external columnaris of freshwater-reared warmwater finfish
- (2) For the control of mortality due to saprolegniasis of all freshwater-reared finfish (except channel catfish)
- (3) For the control of certain ectoparasite infestations in freshwater-reared finfish

**AQUAFLO®**

FDA/CVM-approved (full and conditional approvals):

- (1) For the control of mortality due to enteric septicemia in catfish
- (2) For the control of mortality due to columnaris disease in catfish
- (3) For the control of mortality due to furunculosis in freshwater-reared salmonids
- (4) For the control of mortality due to coldwater disease in freshwater-reared salmonids

Planned expanded label claim:

- (1) For use to control mortality due to columnaris disease in all freshwater-reared salmonids
- (2) For use to control mortality due to *Streptococcus iniae* in hybrid striped bass and tilapia
- (3) For use to control mortality due to motile aeromonas disease in cool- and warmwater fish
- (4) For use to control mortality due to columnaris disease in cool- and warmwater fish
- (5) For use in freshwater-reared finfish at 15 mg florfenicol/kg body weight/d for 10 d

**AquaFrin™**

Initial approval (planned):

- (1) For use to control mortality due to saprolegniasis in freshwater-reared salmonids

**AQUAMYCIN 100®**

Initial approval (planned):

- (1) For use to control mortality due to bacterial kidney disease in all freshwater-reared salmonids

**CAIROX<sup>®</sup>**

Initial approval (planned):

- (1) For use to control mortality due to external columnaris in hybrid striped bass

Planned expanded label claim:

- (1) For use to control mortality due to external columnaris in channel catfish

**Formalin-F, Paracide-F, Parasite-S, and Formacide-B**

FDA/CVM-approved:

- (1) Control of external protozoa in all finfish
- (2) Control of monogenetic trematodes in all finfish
- (3) Control of protozoan parasites in penaeid shrimp
- (4) Control fungi of the family Saprolegniaceae in all finfish eggs

Planned expanded label claim:

- (1) For use to control mortality caused by saprolegniasis in all freshwater-reared finfish

**HALAMID<sup>®</sup> AQUA+**

Initial approval (planned):

- (1) For the control of mortality due to bacterial gill disease in all freshwater-reared salmonids
- (2) For the control of mortality due to external columnaris in walleye
- (3) For the control of mortality due to external columnaris of freshwater-reared warmwater finfish

Planned expanded label claim:

- (1) For the control of mortality due to external columnaris of freshwater-reared coolwater species

**Triangle Brand Copper Sulfate<sup>®</sup>**

Initial approval (planned):

- (1) For use to control mortality caused by Ich in catfish reared in earthen ponds

Planned expanded label claim:

- (1) For use to control mortality caused by fungus in channel catfish eggs in flow through systems

**MASCULINIZING FEED FOR TILAPIA<sup>®</sup>**

Initial approval (planned):

- (1) For use to produce predominantly male populations of tilapia

Planned expanded label claim:

- (1) For use to increase the proportion of phenotypic male swordtails
- (2) For use to produce phenotypic male rainbow trout

**REWARD<sup>®</sup>**

Initial approval (planned):

- (1) For use to control mortality in all freshwater-reared finfish caused by external columnaris
- (2) For use to control saprolegniasis in channel catfish eggs

**SLICE<sup>®</sup>**

Initial approval (planned):

- (1) For use to control mortality due to sea lice in cultured salmonids

Planned expanded label claim:

- (1) For use to control mortality due to external parasites in freshwater-reared finfish

**TERRAMYCIN<sup>®</sup> 200 for Fish**

FDA/CVM-approved:

- (1) For the control of bacterial hemorrhagic septicemia and pseudomonas disease in catfish
- (2) For the control of gaffkemia in lobster
- (3) For the control of ulcer disease, furunculosis, bacterial hemorrhagic septicemia, and pseudomonas disease in salmonids
- (4) For the control of mortality due to coldwater disease in freshwater-reared salmonids
- (5) For the control of mortality due to columnaris disease in all freshwater-reared *Oncorhynchus mykiss*
- (6) Mark skeletal tissue in Pacific salmon

Planned expanded label claim:

- (1) For control of mortality due to columnaris disease in all freshwater-reared salmonids
- (2) For control of mortality due to motile aeromonas disease in cool- and warmwater finfish
- (3) For use to mark skeletal tissue of all salmonids