

**12th Annual Aquaculture Drug Approval Coordination Workshop
August 1 - 2, 2006
South Hall Ballroom, La Crosse Center, La Crosse, WI
and
National Aquaculture Drug Research Forum
August 3, 2006
Cleary Center, University of Wisconsin-La Crosse, La Crosse, WI**

Monday, July 31

Registration and Opening Reception

- 4:00 – 6:00 Early registration in the Radisson Hotel lobby
- 6:00 Opening reception at Ebenezer's Wood-fired Pizza and Grille (2 beverage tickets included with registration; refer to the maps in the workshop binder for location)

Tuesday, August 1

Registration, Continental Breakfast, Welcome, and Opening Remarks

- 7:30 – 8:15 Registration and continental breakfast, South Hall Ballroom, La Crosse Center
- 8:15 – 8:30 Announcements

Welcome!
Bill Gingerich
Chemistry and Physiology Branch Chief
Upper Midwest Environmental Sciences Center (UMESC), USGS

Mike Jawson
Center Director, UMESC, USGS

- 8:30 – 9:00 Lead-off hitters
- Meg Oeller
FDA Liaison to NRSP-7 Minor Use Program and the Office of Minor Use and
Minor Species
Center for Veterinary Medicine (CVM), FDA

Gary Whelan
Fish Production Manager
Michigan Department of Natural Resources Fisheries Division

Meet the FDA

- 9:00 – 9:20 “An overview of the drug approval process”
“Answers to questions you might never think to ask: Tips gleaned from my first 8 months at CVM”
Dr. Jennifer Matysczak, Aquaculture Drugs Team, CVM, FDA
- 9:20 – 9:40 “A-0000 ack letter vs. A-0000 auth letter and what all that stuff in the letter means”
Dr. Susan Storey, Aquaculture Drugs Team, CVM, FDA
- 9:40 – 10:00 “Statistical considerations when designing TAS and effectiveness studies”
Mr. Dave Petullo, Biometrics Team, CVM, FDA

10:00 – 10:30 Break

- 10:30 – 10:50 “Phase II environmental assessment: Data, process, and new risk mitigation options”
Dr. Eric Silberhorn, Environmental Safety Team, CVM, FDA
- 10:50- 11:00 “Overview of CVM’s microbial food safety evaluation”
Dr. Roger Jones, Microbial Food Safety Team, Division of Human Food Safety, FDA
- 11:00 – 11:10 “Assessment of effects of antimicrobial new animal drug residues in food on human intestinal flora”
Dr. S. Steve Yan, Microbial Food Safety Team, Division of Human Food Safety, FDA
- 11:10 – 11:30 “The manufacturing technical section: A fish out of water?”
Dr. James Nitao, Biotherapeutics Team, Division of Manufacturing Technologies, FDA

11:30 – 12:45 Lunch, on your own (refer to the “Event Planner” brochure in your workshop binder for nearby locations)

Status of original IAFWA project drugs

- 12:45 – 1:00 “Overview of public aquaculture sector survey to determine unmet label claims for IAFWA project drugs”
Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications (NADA coordinator)
- 1:00 – 1:40 Hydrogen peroxide (PEROX-AID®)

The original objective, where we're at with respect to the objective, and what remains to be done to satisfy the objective for hydrogen peroxide
Roz Schnick, NADA coordinator

Presentations of work completed within the last year on hydrogen peroxide
Environmental safety, Bill Gingerich, UMESC, USGS

Sponsor perspective on PEROX-AID®
Dave Lovetro, Eka Chemicals, Inc. representative

The IAFWA Project survey results of the current state needs for hydrogen peroxide
Roz Schnick, NADA coordinator

Open discussion to address unmet label claims and state needs for hydrogen peroxide
Steve Sharon, Drug Approval Working Group (DAWG) representative and Don Prater, CVM, FDA

1:40 – 2:30 Isoeugenol (AQUI-S®)

The original objective, where we're at with respect to the objective, and what remains to be done to satisfy the objective for isoeugenol
Roz Schnick, NADA coordinator

Presentations of work completed within the last year on isoeugenol
Efficacy, Jim Bowker, AADAP, USFWS
Human food safety, Jeff Meinertz, UMESC, USGS
Target animal safety, Jim Bowker, AADAP, USFWS

Sponsor perspective on AQUI-S®
Jan Holland and Tom Goodrich, AQUI-S® New Zealand representatives

The IAFWA Project survey results of the current state needs for isoeugenol
Roz Schnick, NADA coordinator

Open discussion to address unmet label claims and state needs for isoeugenol
Steve Sharon, DAWG representative and Don Prater, CVM, FDA

2:30 – 2:50 Formalin (Formalin-F®, Paracide-F® and Parasite-S®)

The original objective, where we're at with respect to the objective, and what remains to be done to satisfy the objective for formalin
Roz Schnick, NADA coordinator

Presentations of work completed within the last year on formalin

Efficacy, Renata Reimscheuessel, Research Biologist, CVM Office of Research, FDA

Sponsor perspective on Parasite-S®
Jim Powell, Aquatic Life Sciences, Inc. representative

The IAFWA Project survey results of the current state needs for formalin
Roz Schnick, NADA coordinator

Open discussion to address unmet label claims and state needs for formalin
Steve Sharon, DAWG representative and Don Prater, CVM, FDA

Tour the UMESC (included with registration)

- 3:10 Load bus in front of the La Crosse Center
- 3:20 Depart for the UMESC
- 3:40 – 4:30 Tour the UMESC (refer to the “Event Planner” brochure in your workshop binder for a description of the event)
- 4:40 Load the bus and depart
- 5:00 Return to the Radisson Hotel

Paddlewheel Riverboat Cruise (included with registration)

- 6:10 Arrive at the La Crosse Queen paddlewheel boat for boarding (walking distance from the La Crosse Center and the Radisson Hotel)
- 6:30 – 8:30 Paddlewheel boat cruise (refer to the “Event Planner” brochure in your workshop binder for a description of the event)

Wednesday, August 2

Continental breakfast and announcements

- 7:00 – 7:45 Continental breakfast, South Hall Ballroom, La Crosse Center
- 7:45 – 8:00 Announcements

Developing disease models with fish moderated by Don Prater, CVM, FDA

- 8:00 – 9:00 “Why develop disease models with fish”
Bill Gingerich, UMESC, USGS

“Developing a disease model for infesting fish with Saprolegnia - HARD WORK AND SERENDIPITY”

Renata Reimscheuessel Research Biologist, CVM Office of Research, FDA

“Development of infectious disease models”

Ahmed Darwish, Harry K. Dupree Stuttgart National Aquaculture Research Center (SNARC), USDA

“Elements of a disease model for infecting cool and warm water fish with columnaris”

Maren Tuttle, UMESC, USGS

“Disease models and clinical field trials, experiences at home and abroad”

Jeff Rach and Sue Schleis, UMESC, USGS

9:00 – 9:45 Florfenicol (Aquaflor®)

The original objective, where we're at with respect to the objective, and what remains to be done to satisfy the objective for florfenicol

Roz Schnick, NADA coordinator

Presentations of work completed within the last year on florfenicol

Efficacy, Jim Bowker, AADAP, USFWS

Efficacy, Alan Johnson, Rathbun Fish Culture Research Facility, Iowa DNR

Target animal safety, Dave Straus, SNARC, USDA

Sponsor perspective on Aquaflor®

Dick Endris and Palma Jordan, Schering-Plough Animal Health representatives

The IAFWA Project survey results of the current state needs for florfenicol

Roz Schnick, NADA coordinator

Open discussion to address unmet label claims and state needs for florfenicol

Steve Sharon, DAWG representative and Don Prater, CVM, FDA

9:45 – 10:15 Break

10:15 – 11:00 Chloramine-T (Halamid®)

The original objective, where we're at with respect to the objective, and what remains to be done to satisfy the objective for chloramine-T

Roz Schnick, NADA coordinator

Presentations of work completed within the last year on chloramine-T

Efficacy, Jim Bowker, AADAP, USFWS

Efficacy, Alan Johnson, Rathbun Fish Culture Research Facility, Iowa DNR

Environmental safety, Bill Gingerich, UMESC, USGS
Microbial food safety, Roz Schnick, NADA coordinator

Sponsor perspective on Halamid®
Ed Bisinger, Axcentive SARL representative

The IAFWA Project survey results of the current state needs for chloramine-T
Roz Schnick, NADA coordinator

Open discussion to address unmet label claims and state needs for chloramine-T
Steve Sharon, DAWG representative and Don Prater, CVM, FDA

11:00 – 11:15 Copper sulfate (Triangle Brand Copper Sulfate®)

The original objective, where we're at with respect to the objective, and what remains to be done to satisfy the objective for copper sulfate
Roz Schnick, NADA coordinator

Presentations of work completed within the last year on copper sulfate
Environmental safety, Dave Straus, SNARC, USDA

Sponsor perspective on Triangle Brand Copper Sulfate®
Dave Fisher, Phelps Dodge Sales Company representative

The IAFWA Project survey results of the current state needs for copper sulfate
Roz Schnick, NADA coordinator

Open discussion to address unmet label claims and state needs for copper sulfate
Steve Sharon, DAWG representative and Don Prater, CVM, FDA

11:15 – 11:35 Potassium permanganate (CAIROX®)

The original objective, where we're at with respect to the objective, and what remains to be done to satisfy the objective for potassium permanganate
Roz Schnick, NADA coordinator

Presentations of work completed within the last year on potassium permanganate
Efficacy, Dave Straus, SNARC, USDA
Environmental safety, Dave Straus, SNARC, USDA

Sponsor perspective on CAIROX®
John Boll, Carus Chemical Company representative

The IAFWA Project survey results of the current state needs for potassium permanganate
Roz Schnick, NADA coordinator

Open discussion to address unmet label claims and state needs for potassium permanganate

Steve Sharon, DAWG representative and Don Prater, CVM, FDA

11:35 – 12:50 Lunch, on your own (refer to the “Event Planner” brochure in your workshop binder for nearby locations)

12:50 – 1:15 Oxytetracycline medicated feed (TERRAMYCIN® For Fish)

The original objective, where we're at with respect to the objective, and what remains to be done to satisfy the objective for oxytetracycline medicated feed
Roz Schnick, NADA coordinator

Presentations of work completed within the last year on oxytetracycline medicated feed

Environmental safety, Verdel Dawson, UMESC, USGS contractor

Sponsor perspective on TERRAMYCIN® For Fish

Roz Schnick for Phibro Animal Health

The IAFWA Project survey results of the current state needs for oxytetracycline medicated feed

Roz Schnick, NADA coordinator

Open discussion to address unmet label claims and state needs for oxytetracycline medicated feed

Steve Sharon, DAWG representative and Don Prater, CVM, FDA

1:15 – 1:40 Oxytetracycline immersion (OxyMarine®, OXYTETRACYCLINE HCL SOLUBLE POWDER-343®, and TERRAMYCIN-343®)

The original objective, where we're at with respect to the objective, and what remains to be done to satisfy the objective for oxytetracycline immersion

Roz Schnick, NADA coordinator

Presentations of work completed within the last year on oxytetracycline immersion

Efficacy, Jeff Rach, UMESC, USGS

Environmental safety, Verdel Dawson, UMESC, USGS contractor

Sponsor perspective on TERRAMYCIN-343®

George Kohan, Aquatic Health Resources LLC representative for Pfizer, Inc.

The IAFWA Project survey results of the current state needs for oxytetracycline immersion

Roz Schnick, NADA coordinator

Open discussion to address unmet label claims and state needs for oxytetracycline immersion

Steve Sharon, DAWG representative and Don Prater, CVM, FDA

1:40 – 1:50 Proposed 1 year work plans for original IAFWA Project drugs
Dave Erdahl, AADAP, USFWS
Bill Gingerich, UMESC, USGS
Dave Straus, SNARC, USDA
Roz Schnick, NADA coordinator

1:50 – 2:20 Break

Status of non-original project drugs

2:20 – 2:30 “Introduction to non-IAFWA projects for aquaculture drug approvals”
Roz Schnick, NADA coordinator

2:30 – 2:40 Sulfadimethoxine and ormetropim (Romet-30® and ROMET-TC®)

Where we’ve been, where we’re at, and where we’re going with sulfadimethoxine and ormetropim
Roz Schnick

Presentations of work completed within the last year on sulfadimethoxine and ormetropim
None.

Sponsor perspective on Romet-30® and ROMET-TC®
Roz Schnick for PHARQA AS

2:40 – 2:55 Erythromycin (AQUAMYCIN 100®)

Where we’ve been, where we’re at, and where we’re going with erythromycin
Christine Moffitt

Presentations of work completed within the last year on erythromycin
Christine Moffitt

Sponsor perspective on AQUAMYCIN 100®
Paul Rice, Bimeda representative

2:55 – 3:30 17 α -Methyltestosterone (MASCULINIZING FEED FOR TILAPIA®)

Where we've been, where we're at, and where we're going with 17 α -methyltestosterone
Tom Bell, USFWS, AADAP

Presentations of work completed within the last year on 17 α -methyltestosterone
Efficacy, Jim Bowker, USFWS, AADAP
Environmental safety, Terry Barry, University of Wisconsin-Madison
Human food safety, Terry Barry, University of Wisconsin-Madison
Target animal safety, Anita Kelly, Southern Illinois University

Sponsor perspective on MASCULINIZING FEED FOR TILAPIA®
Roz Schnick for Rangen, Inc.

3:30 – 3:45 Calcein (SE-MARK®)

Where we've been, where we're at, and where we're going with calcein
Tom Bell, AADAP, USFWS

Presentations of work completed within the last year on calcein
Efficacy, Tom Bell, AADAP, USFWS

Sponsor perspective on SE-MARK®
Jim Powell, Aquatic Life Sciences, Inc. representative

3:45 – 3:55 SLICE® for freshwater parasites

Where we've been, where we're at, and where we're going with SLICE®
Dave Erdahl, AADAP, USFWS

Presentations of work completed within the last year on SLICE®
None

Sponsor perspective on SLICE®
Dick Endris, Schering-Plough Animal Health representative

3:55 – 4:05 Proposed work plans for non-Project drugs
Dave Erdahl, AADAP, USFWS
Bill Gingerich, UMESC, USGS

4:05 – 4:15 “Aquaculture NADA coordinator’s perspective on non-IAFWA project drugs”
Roz Schnick, NADA coordinator

4:15 – 4:20 Plans for next year’s workshop

4:20 End of the 12th Annual Aquaculture Drug Approval Coordination Workshop

Catered picnic (included with registration)

- 5:00 Load bus at Radisson Hotel (riverside of hotel)
- 5:15 Depart for Rosalie (Roz) Schnick's house for a picnic
- 5:45 – 8:30 Catered picnic (refer to the "Event Planner" brochure in your workshop binder for a description of this event)
- 6:45 Load bus for the La Crosse Loggers game (refer to the "Event Planner" brochure in your workshop binder for a description of the event) and first return trip to the Radisson hotel
- 6:50 Bus departs
- 8:30 Load bus for final return trip to the Radisson Hotel

Thursday, August 3

- 8:00 Load bus at Radisson Hotel (riverside of hotel) and travel to Great Hall of the Cleary Alumni and Friends Center, UW-La Crosse (if driving, parking permit needed and can be picked up from Jeff Meinertz) for the National Aquaculture Drug Research Forum meeting

National Aquaculture Drug Research Forum

Background and Purpose

The National Aquaculture Drug Research Forum (NADRF) is associated with the Joint Subcommittee on Aquaculture (JSA) Working Group on Quality Assurance in Aquaculture Production (WGQAAP). The goal of the NADRF is to identify and resolve issues challenging researchers working to gain FDA approval of aquaculture drugs. To achieve this goal, the NADRF works to (1) provide a forum for information exchange, (2) educate, and (3) broadly disseminate information relative to developing drugs for use in aquaculture.

The most recent Forum meeting was held in February, 2006 in conjunction with the 2006 Aquaculture America Conference in Las Vegas. At this meeting, discussion focused on finalizing the Aquaculture Drug Approval Research Subject Matter Expert Director, and designing or using an existing website to host research study protocols and standard operating procedures.

During the next meeting, the bulk of the time will be made available for break out sessions where Technical Project Team participants will discuss their work tasks. At the end of the break-out sessions, each Project Team will be asked to provide a short update on work activities. As is the practice of the JSA WGQAAP, this special session is open to all with an interest to participate and contribute to the activities focused on supporting research and advancing the aquaculture drug approval process.

Agenda (Jeff Meinertz and Jim Bowker - Moderators)

Opening comments

General discussion topics

- (1) Decision making team and Decision making process
- (2) Update on posted Research Study Protocols and Standard Operating Procedures
- (3) Tour the Website
- (4) Discuss difficulties associated with posting Protocols and SOP's
- (5) Break out groups
- (6) Update from Technical Project Teams
 - Efficacy
 - Environmental Safety
 - Analytical Methods
 - Antimicrobial Resistance
 - Education Outreach

Topics discussed during previous meetings

Efficacy – (Co-Leaders – Jim Bowker and Don Prater)

- (1) Utility of disease models to develop efficacy data to reduce pivotal field efficacy data requirements for aquaculture drug approvals
- (2) Impact of secondary pathogens on field efficacy data – when do they confound study results

Environmental Safety – (Co-Leaders – Chuck Eirkson and vice-Mark Gaikowski)

- (1) Determination of methods to model predicted environmental concentrations (PECs)
- (2) Reaching consensus on methods to estimate PECs
- (3) Validation of methods to estimate PECs through field monitoring of applied chloramine-T and hydrogen peroxide treatments
- (4) Derivation of water quality criteria and effluent discharge limit calculations

Analytical Methods – (Co-Leaders – Jeff Meinertz and Jim Nitao)

- (1) Validation of methods used to verify dose for efficacy, target animal safety, and human food safety studies – how much validation is enough?
- (2) How are methods used to support environmental safety studies validated for the determination of drug concentration in water, sediment, or other matrices?

Antimicrobial Resistance (Christine Moffitt and Steve Yan)

The group discussed the general data requirements for microbial food safety evaluation under GFI#152. It was the intent of this group to gain a better understanding of the complete data and information requirements necessary to address the antimicrobial food and safety concerns and be able to use this understanding to facilitate addressing such concerns for future aquaculture drug applications.

Education Outreach (Gary Jensen and Susan Storey)

Open discussion topics

11:30

Load bus and return to the Radisson Hotel

