

**U.S. Fish & Wildlife Service
11th Annual Drug Approval Coordination Workshop**

August 2 - 3, 2005

**Holiday Inn
5 Baxter Lane, Bozeman, MT
Gallatin Room**



Agenda

Tuesday, August 2

8:00 - 8:15am	Registration	Gallatin Room
8:15 - 8:30	Howdy, Housekeeping, and Introductions	Dave Erdahl Jim Bowker Mark Gaikowski Jeff Meinertz
8:30 - 8:45	Welcoming Comments: Acting Director of the USFWS	Matt Hogan
8:45 - 9:15	Perspective of Potential Drug-Related Fisheries Research Opportunities: Science Advisor to the DOI Secretary	Jim Tate
	Moderators - Mark Gaikowski and Jim Bowker	
9:15 - 9:30	Summary of IAFWA Project: History and Partnerships	Eric Schwaab Roz Schnick
9:30 - 9:45	CVM Aquaculture Team Perspective of Drug Approval Efforts	Don Prater
9:45 - 10:00	MUMS Update Positive Impact of MUMS Legislation	Randy MacMillan Roz Schnick
10:00 - 10:30	BREAK !!	
10:30 - 10:45	CVM Environmental Team Assessment of the Aquaculture Drug Approval Process	Chuck Eirkson Eric Silberhorn
	EPA's Effluent Limitations Needed for Chemical Discharge from Aquaculture Facilities	Carla Fromm
10:45 - 11:00	Regulation of Aquatic Biologics	Melisse Schilling

Tuesday, August 2 (continued)

11:00 - 12:00	Status of Aquaflor® Initial Label Claim All Fish Label Claim Data Gaps	Sponsor Perspective (SPAH) Efficacy (M. Gaikowski) HFS (M. Gaikowski) TAS (Dave Straus) CVM Perspective NADA Coordinator Perspective
12:00 - 12:15	A Few Words in Memory of Tommie Crawford	Mike Mason
12:15 - 1:30	LUNCH !!	
1:30 - 1:45	NRSP-7 Minor Use Animal Drug Program Species Grouping for Aquaculture	Paul Bowser
1:45 - 2:00	Completing the Technical Section	Don Prater
2:00 - 2:15	Secondary Pathogens or Concomitant Infections / Infestations & All Other Information Technical Section	Susan Storey
2:15 - 3:00	Status of AQUI-S Initial Label Claim All Freshwater Fish Label Claim Data Gaps	Sponsor Perspective (AQUI-S New Zealand) Efficacy (Molly Bowman) TAS (Dan Carty) HFS (Jeff Meinertz) Catfish Fillet Quality (Brian Small) Catfish Physiological Response (B. Small) CVM Perspective NADA Coordinator Perspective
3:00 - 3:15	BREAK !!	
3:15 - 3:30	Status of Hydrogen Peroxide Initial Label Claim and Discussion	Sponsor Perspective (Eka Nobel) EA (Larry Schmidt) CVM Perspective NADA Coordinator Perspective
3:30 - 3:45	Status of Chloramine-T Initial Label Claim All Fish Label Claim Data Gaps	Sponsor Perspective EA (L. Schmidt) CVM Perspective NADA Coordinator Perspective
3:45 - 4:15	Status of Copper Sulfate Initial Label Claim and Discussion	Sponsor Perspective (Phelps Dodge) Efficacy (D. Straus) TAS (D. Straus) EA (D. Straus) CVM Perspective NADA Coordinator Perspective

Tuesday, August 2 (continued)

4:15 - 4:30	Status of Oxytetracycline-Medicated Feed Label Expansion/Extension	Sponsor Perspective (Phibro) EA (L. Schmidt) CVM Perspective NADA Coordinator Perspective
4:30 - 5:00	Status of Potassium Permanganate Initial Label Claim and Discussion	Sponsor Perspective (Carus Chemical) Efficacy (D. Straus) CVM Perspective NADA Coordinator Perspective
5:00pm	ADJOURN !!	
6:00'ish	Bar-B-Q Picnic at Hyalite Reservoir	All + Families Welcome

Wednesday, August 3

8:00 - 8:15	Late Registration; Coffee	
Moderators - Jeff Meinertz and Dave Erdahl		
8:15 - 8:45	Discussion of Status of Priority Drugs Description of 2 - Year Work Plans	All Research Leads
8:45 - 9:30	Status of 17 α -MT Initial Label Claim	Sponsor Perspective Efficacy (Tom Bell) TAS (Anita Kelly) Tilapia Industry Perspective CVM Perspective NADA Coordinator Perspective
9:30 - 10:00	Status of Erythromycin and Discussion Medicated Feed and Injectable	Sponsor Perspective All Technical Sections (Christine Moffitt) CVM Perspective NADA Coordinator Perspective
10:00 - 10:15	BREAK !!	
10:15 - 10:30	Overview of CVM's Microbial Food Safety Evaluation	Steve Yan
10:30 - 10:45	Human Food Safety for Approval of Antimicrobial New Animal Drugs in Aquaculture	Kevin Greenlees
10:45 - 11:00	Formalin - Status of Expanding Current Label to Include use on All Fish for All Uses	Sponsors Perspective CVM Perspective NADA Coordinator Perspective

Wednesday, August 3 (continued)

11:00 - 11:15	Status of Oxytetracycline Immersion - Antibacterial Therapy	Sponsor Perspective Efficacy (Jeff Bernardy) Remediation (J. Bernardy) CVM perspective NADA Coordinator Perspective
11:15 - 11:30	Ecological Risk Assessment for Veterinary Products	Eric Silberhorn
11:30 - 12:00	Status and Discussion of Calcein Immersion and Feed Additive	Sponsor Perspective Efficacy (Dale Honeyfield, Bonnie Johnson, Tom Bell) CVM Perspective
12:00 - 1:15	LUNCH !!	
1:15 - 1:45	Open discussion - other drugs on the horizon; prioritizing new drugs of interest	All Research Leads
1:45 - 3:15	Biologics in Aquaculture User Perspective - Importance of Biologics for Disease Control in Intensive Hybrid Striped Bass Production. Industry Perspective - Vaccine Manufacturing Products & Issues Industry Perspective - Biologicals in Aquaculture Update from JSA Biologics Aquaculture Focus Group meeting held August 1, 2005	Vaughn Ostland (Ken SeaTech) Jerry Zinn (AquaHealth USA) Palma Jordan (Schering Plough) Dave Scarfe
3:15 - 3:45	BREAK !!	
3:45 - 4:15	Discuss issues related to Aquaculture Drugs and Biologics - Action Items	Dave Erdahl
4:15 - 4:30	Workshop Wrap-up; Plans for 12 th Annual Drug Approval Coordination Workshop	Dave Erdahl Jim Bowker Mark Gaikowski Jeff Meinertz
4:30	ADJOURN !!	
6:30	Dinner Reservations at Sir Scott's Oasis	

