Presentations*
from the
13th Annual Aquaculture Drug Approval Coordination Workshop
July 31- August 1, 2007
Holiday Inn
Bozeman, Montana

*** presentations and author's name in blue text indicates a presentation that may be viewed by clicking on it**

Tuesday Morning, 31 July 2007

Welcome and Opening Comments

- "Howdy, Howdy, housekeeping, agenda format, and extracurricular activities" - Dave Erdahl

Agency Perspectives on Aquatic Species Drug Approval Efforts

- **"Aquatic Species Drug Approval Efforts: A Reason to Celebrate!"**
  Dr. Bernadette Dunham
  Deputy Director – Center for Veterinary Medicine
  U. S. Food and Drug Administration
- Dr. Stuart Leon
  Division of National Fish Hatchery System – Chief
  U. S. Fish and Wildlife Service
- Mr. Steve Sharon
  AFWA, Drug Approval Working Group - Chair
  Wyoming Game and Fish Department
- Mr. Bill Knapp
  Deputy Science Advisor
  U. S. Fish and Wildlife Service
- **"USGS -UMESC Perspective on Fisheries Management Chemicals and Aquaculture Drug Program"**
  Dr. Michael D. Jawson
  Upper Midwest Environmental Sciences Center – Director
  U. S. Geological Survey – Biological Resources Discipline
- Open Forum – Perspective of others

Overview Presentations from CVM

- **"Update from CVM's Aquaculture Drugs Team" and "Public Master Files – Creation, contents, and utility"– Dr. Don Prater**
- **"Conditional Approvals" – Dr. Susan Storey**

- **"Environmental Assessment – Categorical exclusions for minor species and when is a revised EA required for additional claims of an approved drug" – Dr. Eric Silberhorn**
- **"MUMS Legislation and the OMUMS" – Dr. Bernadette Dunham**

Recent Drug Approval Success……Yes, we have reasons to Celebrate!!

- **35% PEROX AID® – Dave Lovetro, Eka Chemicals**
- **AQUAFLOR® – Palma Jordan, Schering Plough Animal Health**

Tuesday Afternoon, 31 July 2007

Approval status of original AFWA Project drugs

- **"Historical background of this fabulous partnership – from the beginning to the present" – Roz Schnick, National Coordinator for Aquaculture NADA**
- **35% PEROX-AID®** (hydrogen peroxide)
  - **"Recent Drug Approval Success 35% PEROX-AID®"- David Lovetro**
  - **"35% PEROX-AID®" - Mark Gaikowski**
  - **"A Research Protocol to Determine: Efficacy of 35% PEROX-AID® to Control Mortality due to Bacterial Gill Disease or External Columnaris in Cool- and Warmwater Finfish" – Dan Carty**
  - **"The Efficacy of Hydrogen Peroxide to Control Mortality Due to External Columnaris on Largemouth Bass" – Molly Bowman**
  - **"Designation of Cold-, Cool- and Warmwater Fish Species" – Jim Bowker**
- **AQUAFLOR®** (florfenicol)
  - **"The Efficacy of Florfenicol-Medicated Feed to Control Mortality Caused by Columnaris Disease" – Molly Bowman**
  - **"Veterinary Feed Directives: Wyoming's Approach to Distribution" – Steve Sharon**
- **HALAMID®** (chloramine-T)
  - **"Florida Bass Conservation Commission Richloam Fish Hatchery" – Michael Matthews**
  - **"Halamid®" – Mark Gaikowski**
  - **"A Research Protocol to Determine: Efficacy of Chloramine-T to Control Mortality due to Bacterial Gill Disease or External Columnaris in Cool- and Warmwater Finfish" – Dan Carty**
  - **"The Efficacy of CHLORAMINE-T to Control Mortality Due to External Columnaris on Largemouth Bass" – Molly Bowman**
- **TRIANGLE BRAND COPPER SULFATE®** (Copper sulfate)
  - **"Research Efforts on the use of Copper Sulfate as an Aquaculture Therapeutant" – Dave Straus**

Non-AFWA project and other "new" drugs

- **PORPHYRINS**
  - **"Photochemical approaches to water disinfection" – Guilio Jori**

Wednesday morning, 1 August

Approval status of original AFWA Project drugs

- **AQUI-S®**- (isoeugenol)
  - **"The Safety of AQUI-S® to Cutthroat Trout" – Dan Carty**
  - **"Status of AQUI-STM research at UMESC" – Jeff Meinertz**
- **TERRAMYCIN® 200 FOR FISH** (Oxytetracycline medicated feed)
  - **"CVM approval of Terramycin 200 for Fish®" – Paul Duquette (presented by Roz Schnick)**
  - **"TERRAMYCIN® 200 for Fish" – Mark Gaikowski**
  - **"Demonstration of Drug Efficacy on Freshwater-reared Steelhead to Satisfy Requirements for all *Oncorhynchus mykiss*" – Niccole Wandelear**
- **OXYMARINE®, OXYTETRACYCLINE HCL SOLUBLE POWDER-343®, TERRAMYCIN-343®**, and **TETROXY® AQUATIC SOLUBLE POWDER** (Oxytetracycline immersion therapy)
  - **"Oxytetracycline Immersion" – Mark Gaikowski**

Non-AFWA project and other "new" drugs (continued)

- **AQUAMYCIN 100® (Erythromycin)**
  - **"Erythromycin to Control Bacterial Kidney Disease" - Christine M. Moffitt**
- **MASCULINIZING FEED FOR TILAPIA® (17α-Methyltestosterone)**
  - **"The Efficacy of 17α-Methyltestosterone Medicated Feed to Produce Predominantly Male Populations of Tilapia" – Molly Bowman**
  - **"17α-Methyltestosterone Product Chemistry" - Terence Barry*, Padma Marwah & Ashok Marwah**
  - **"Fate of 17α-Methyltestosterone (MT) in Water/Sediment Systems" - Terence Barry*, Padma Marwah & Ashok Marwah**
- **SE-MARK®** (calcein), **OVAPRIM®** (injectable sGnRHa + additive), **OVAPLANT®** (sGnRHa implant), and **AQUACALM®** (Metomidate)
  - **"INAD Adventures at Western Chemical: Drug Development Status" – Jim Powell**
  - **"Preliminary Results from SE-MARK® Target Animal Safety Testing on Rainbow Trout and Channel Catfish" – Tom Bell**
  - **"Retention of Calcein Marks on Live Lake Trout Evaluated with the Aid of a Colorimetric Key" – Dale Honeyfield**

- **SODIUM CARBONATE PEROXYHYDRATE** (SCP) and **PYCEZE®**
  - **"Use of SCP and PYCEZE® to Control Saprolegniasis on Channel Catfish Eggs" – Brian Small**
- **CATFISH PITUITARY**
  - **"Channel Catfish Pituitary Used to Produce Hybrid Catfish (*Ictalurus punctatus* X *I. furcatus*)" – Roger Yant**

Wednesday noon, 1 August

Special presentation

- **"Using Ovaplant® in Broodstock Salmonids" – Jim Powell (Western Chemical, Inc.)**

Wednesday afternoon, 1 August

Non-AFWA project and other "new" drugs (continued)

- **SLICE®** (Emamectin benzoate in a 0.2% formulation)
  - **"Slice INAD Overview" – Dave Erdahl**
- **REWARD®** (Diquat)
  - **"Comparison of theraputants to reduce mortality in fingerling walleye caused by columnaris disease" – Alan Johnson**
- **DRAXXIN®** (Tulathromycin)
  - **"The effectiveness of to control bacterial kidney disease in salmonids" – Jed Varney**
- **"The future of this fabulous partnership" – Roz Schnick**
- **"Kona Blue: Open Ocean Aquaculture Offers Advantages and Challenges to Fish Health" – Neil Sims**

Special Session - Use of Biologics in Aquaculture; chaired by Phil Klesius

- **"Summary of the biologics questionnaire on vaccines" – Dr. Randy MacMillan**
- **"Introduction and overview of session" – Dr. Phil Klesius**
- **"APHIS licensing procedures, policies and directives" – Dr. Melisse Schilling**
- **"Assessing the safety and efficacy of vaccines" – Dr. Phil Klesius**
- **"Vaccine manufacture's viewpoint: outline of production" – John Drennan**
- **"Economic benefits of vaccination" – Kurt Schuster**
- **"Killed verses attenuated fish vaccines" – Dr. Hugh Mitchell**