U.S. Fish & Wildlife Service

The Aquatic Animal Drug Approval Partnership Program

"Working with our partners to conserve, protect and enhance the Nation's fishery resources by coordinating activities to obtain U.S. Food and Drug Administration approval for drugs, chemicals and therapeutants needed in aquaculture"

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St. Mary Lake, Glacier National Park, Montana USA

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WHAT'S SHAKIN

SLICE® approved for sea lice control in Canada: Intervet/Schering Plough Animal Health recently announced (27 July 2009) that their emamectin benzoate premix product (SLICE®) has received full approval for use against immature and adult stages of sea lice in farmed salmon. The full approval states that no withdrawal time is required for the fish following treatment. SLICE® has been available in Canada since 1999, when Health Canada authorized it for sale via veterinarians on a case-by-case basis through the Veterinary Drugs Directorate's Emergency Drug Release (EDR) program. For more information click here to read Intervet/Schering Plough's news release.

16th Annual USFWS Aquaculture Drug Approval Coordination Workshop to be held 3-5 August 2010 in Bozeman, Montana, USA: Although it may be a long way off, for those of you who like to plan ahead, the Workshop will be returning home to Bozeman, Montana in 2010. As has always been the case when it takes place in Bozeman, the Aquaculture Drug Approval Coordination Workshop will be scheduled for the week

immediately before the Sweet Pea Festival weekend. So mark it on your 2010 calendar (if you have one) and just don't forget to check the AADAP website for news of it and other upcoming workshops.

New salmon - sea lice bath treatment tested in New Brunswick, Canada: The Norwegian firm Pharmaq's deltamethrin product recently underwent net pen testing in New Brunswick, Canada. The product is currently marketed under three different trade names, dependent upon where it is approved for use; ALPHA MAX® (Norway & the Faroe Islands), AMX® (Ireland & the United Kingdom) and Deltametrina (Chile). New Brunswick's chief veterinarian and the Province's salmon growers' association executive director indicated satisfaction with the trials relative to 1) effectiveness and speed of treatment, 2) dispersion and lack of its detection in surrounding waters, and 3) lack of effects on sentinel species. Additional information can be found on Pharmaq's website (http://www.pharmaq.no/Products/Therapy/index.html), as well as that of the New

Brunswick Salmon Growers' Association website (http://www.nbsga.com/).

Encouraging studies conducted on the hemolytic parasite *Cryptobia salmositica* in Pacific salmon and rainbow trout: Researchers in the state of Washington, lead by Dr. Martin Chen, have conducted several studies to assess the efficacy of an effective African Sleeping Sickness drug to control cryptobiosis in Pacific salmonids. The etiological agent in salmonid cryptobiosis is C*ryptobia salmositica*, and is closely related to the causative agents of African Sleeping Sickness (caused by either *Trypanosoma brucei gambiense* or *T. brucei rhodesiense*). The researchers tested a commercially available product, the active ingredient of which is isometamidium chloride. For a detailed report on their findings, refer to an American Fisheries Society - Fish Culture Section Aquaculture Application Note currently available online at: http://www.fishculturesection.org/Aquanotes/AquaNotes.htm.

Update on the search for a new candidate "immediate-release" anesthetic: Since the last update in the previous edition of the AADAP Newsletter (July 2009), continued progress has been made with respect to the search for a new candidate immediate release anesthetic. As means of a very brief review: 1) the search is being "headed-up" by Association of Fish and Wildlife Agencies (AFWA) Drug Approval Working Group (DAWG); and 2) recent efforts have been focused on establishing/determining the data requirements for both eugenol and benzocaine. A summary of recent progress is provided below (not in order of importance nor chronologically).

1. In-life studies, coordinated by the USGS's Upper Midwest Environmental Sciences Center (UMESC), to establish a postsedation catchability timeframe for each of the two candidate drugs (benzocaine and eugenol) has been completed. In general, times to first feeding following sedation were less than anticipated. Five species of fish were tested under laboratory conditions, while several other species were tested under "quasi-wild" conditions (a hatchery effluent pond "stocked" with several species including brown trout). It is assumed that actual wild fish will display a much less aggressive behavior and may even hide for quite some time following sedation. The final report for these studies will be available sometime after 1 October 2009.
2. UMESC has progressed relative to the residue chemistry studies needed to address unresolved issues related to total residue depletion of eugenol. The method development phase is expected to be completed by December 2009. No timetable has been yet set for submission of the method to CVM.
3. The benzocaine genotoxicity battery of studies (funded by AFWA) has been completed and all draft study reports from the contract lab have been delivered to USFWS's Aquatic Animal Drug Approval Coordination Partnership (AADAP) Program. AADAP will compile the final reports and submit the package, with a cover letter, to CVM no later than 31 December 2009.
4. Earlier this year, AADAP collected the data and reports from a series of eugenol toxicology studies conducted by the U.S. National Toxicology Program. These were assembled and submitted to CVM requesting that they be reviewed as to their applicability and acceptability relative to the Human Food Safety (HFS) technical section of an ultimate New Animal Drug Application (NADA). CVM concurred, based on these studies, that eugenol was neither genotoxic nor carcinogenic. CVM further noted, however, that a 90-day subchronic study in a non-rodent, a two-generation reproduction study in rodents and a teratology study in rodents would still be required to complete the HFS technical section. The sponsor of the eugenol product, Aqui-S E®, submitted the same package, with the addition of one more study, and received a similar response from CVM, but noting one less study remaining.
5. The Pacific Northwest Sedative Work Group (PNSWG), reported on in the last Newsletter, completed their "support letter" gaining signatures from the "member" agency/organization leaders. The PNSWG is now in the process of assembling a funding proposal package to submit to potential benefactors within the Pacific Northwest.
6. AADAP recently submitted to CVM for review one pivotal efficacy protocol each for benzocaine and eugenol use to sedate freshwater-reared finfish to a handleable stage. Not totally unexpectedly, CVM did not concur with either protocol based on the initial submissions. However, the protocols will be revised (as per CVM suggestions) and re-submitted in the near future. Hopefully, we will have better news to reports early next year.
7. The DAWG received communications from Micro Technologies Inc. (MTI; Richmond, Maine USA) regarding a new anesthetic/sedative, Fish-eezzz™, being testing by the firm. MTI has expressed interest to the DAWG that their product be considered as a prospective immediate-release anesthetic/sedative. Discussions continue between the DAWG and MTI.

Update on the new and improved American Fisheries Society's Working Group on Aquaculture Drugs, Chemicals, and Biologics (WGADCB): It has been announced that Steve Sharon, Lester Khoo, Randy MacMillan, Jim Bowker and Mark Gaikowski will

serve as co-chairs of the WGADCB. Since the establishment of the WGADCB one year ago, the participants have strived to foster multi-stakeholder involvement in this group. To provide more formalized and consistent representation of the primary stakeholder groups involved in and affected by the aquaculture drug approval process, the organization of the WGADCB has been restructured to include 5 designated co-chair positions representing the public data-generating partners (2 positions), the private aquaculture sector (1 position), the public aquaculture sector (1 position), and the aquatic animal veterinary community (1 position). Although there will be periodic turnover among the individuals occupying these positions, our intent is that these key stakeholder groups will always be represented. We are confident that the new cross-disciplinary leadership team is well-equipped to tackle the complex issues surrounding aquaculture drug approvals, and will quickly move the WGADCB forward.

The next meeting of the WGADCB will be held in conjunction with Aquaculture America 2010 (AA2010), in San Diego, California USA. Join the leadership team in their discussions of upcoming WGADCB activities, and don't forget to pencil in the WGADCB sponsored Spawning Aids Forum, being held at AA2010, when planning your schedule for the meeting!

Text provided by Jesse Trushenski, Fisheries and Illinois Aquaculture Center, Southern Illinois University Carbondale, Carbondale, Illinois USA.

New Formulae developed for calculating the quantity of approved medicated feed: Some of us folks here at AADAP must have had some spare time on our hands, for we did a little messin' around with an old, albeit useful, formula developed by a couple of Montana treasures, Bob Piper and Jim Peterson. Their original unpublished formula was used to calculate the feed rate (i.e., percent body weight per day) to feed oxytetracycline (OTC) medicated feed to fish, depending upon the percent active ingredient in the OTC premix. From this original formula, two new formulae were developed to address aquaculturists' need to generate feed rate calculations essential for administering an efficacious dose as per label instructions.

The following two equations are intended to be of value to an aquaculture producer who purchases medicated feed prepared by a licensed feed mill or one that may legally top-coat feed using a medicated premix. The first equation applies only to oxytetracycline, while the second is applicable to Aquaflor®, Romet-30®, and presumably any other medicated feed where the approved dosage is expressed as milligrams of the active ingredient per kilogram of fish body weight.

Most typically medicated feed will be produced by a feed mill with a predetermined (i.e., set by the mill) percentage of medicated premix added, thus it will be up to the aquaculturists to adjust the feeding rate (i.e., percentage of body weight per day) to ensure that the prescribed dose is administered. The following equations provide a simplified means of calculating the percent body weight to feed per day.

Additionally, as in the case of any algebraic formula, each formula can be rearranged to solve for any of the variables.

For oxytetracycline:

$$A = \frac{22.03 \times B}{C \times D}$$

where: A = % body weight per day to feed

B = intended dose (as grams of active ingredient per 100 lb of fish per day)

C = % premix incorporated as a part of the medicated feed (e.g. 2% = 2, 2% ≠ 0.02)

D = % OTC in premix (e.g., TM200 @ 44.1% = 44.1, 44.1% ≠ 0.441)

22.03 = conversion factor constant

For all other medicated feeds:

$$A = \frac{B^*}{C \times D}$$

where: A = % body weight per day to feed

B = intended dose (as milligrams of active ingredient per kg of fish per day)

C = % premix incorporated as a part of the medicated feed (e.g. 2% = 2, 2% ≠ 0.02)

D = % active ingredient in premix (e.g., Aquaflor® @ 50% = 50, 50% ≠ 0.50)

* = If the intended dose is expressed as micrograms (µg) active ingredient per kg fish (e.g., SLICE®), merely enter the dose (e.g., if 50 µg, enter 50 for "B") and then divide the answer by 1000. If the intended dose is expressed as grams (g) of active ingredient per kg of fish, multiply the answer by 1000.

AADAP/AFS Fish Culture Section Continuing Education opportunity: Several years ago, the AADAP staff developed a 4 – 5 hr training session entitled *"Use of Drugs in Aquaculture; What Every Fish Culturist Should Know."* The session includes PowerPoint presentations on the 1) Legal and Judicious Use of Drugs in Aquaculture, 2) Introduction to AADAP's INAD Program, and 3) Skills Critical for Use of Aquaculture Drugs (treatment calculations). The session also covers information relative to what drugs are approved, legal to use but not yet approved (i.e., INADs), and unapproved drugs that can be used at the regulatory discretion of CVM. To help reinforce important points made during the training session, students were tasked with various assignments, such as 1) sharing with their classmates how they would address different aquaculture drug-related situations, such as listing one aquaculture drug-use practice at their hatchery that could be improved upon to make it more judicious, and 2) participating in an interactive lesson in which small

groups of students (3 - 4 students/group) were provided an aquaculture drug-use situation, and each group had to discuss and then describe to the rest of the class how they would have handled their assigned situation.

Over the past several years, we have presented this training session at different AFS Division meetings and as part of the 2-week Coldwater Fish Culture Course at the USFWS National Conservation Training Center (NCTC). In March 2009, the session was filmed by Brett Billings (NCTC Video Production Team) with the purpose of creating a training video that can be used in the field.

AADAP has partnered-up once again with the Fish Culture Section (FCS) of the American Fisheries Society (AFS) to launch a Continuing Education program that will allow fish culturists an opportunity to receive this type of training at their home facility and receive AFS Continuing Education Credits. Jim Bowker is working with Brett and Tom Bell to edit the video, and with Jesse Trushenski (FCS President) and Alf Haukenes (FCS Continuing Education Committee Chair) to further develop the FCS continuing education program. We hope to have the video available by the first of the year. Stay tuned.

The National Aquatic Animal Health Plan (NAAHP) published in the Federal Register (FR): Although this notice in the AADAP Newsletter is too late to allow you to officially comment, you still have an opportunity to view the FR Notice by clicking on the following link: http://edocket.access.gpo.gov/2009/E9-19702.htm. The NAAHP was "...developed by a Task Force led by USDA's Animal and Plant Health Inspection Service (APHIS), DOI's U.S. Fish & Wildlife Service (FWS) and DOC's National Marine Fisheries Service (NMFS). It is anticipated that this plan will provide a framework for how APHIS, FWS, and NMFS should develop programs for disease issues that affect the health of aquatic animals such as finfish, crustaceans, and mollusks."

As stated in the FR Notice "Disease has the potential to pose a great threat to the success of aquaculture. Developing and implementing a national aquatic animal health plan has become urgent for two reasons: the growing need to protect our domestic commerce and resources, and the advent of new health regulations by foreign governments that restrict the importation of live and processed aquatic animals from the United States."

The FR Notice also contains links to the actual NAAHP. If you would prefer not to view the FR Notice, but would like to look at the NAAHP, *per se*, click on the following link: http://www.fws.gov/fisheries/PDFs/naahp.pdf.

Minor Use Minor Species research grants awarded for FY2009: FDA recently announced that they had awarded the first two grants to support the development of new animal drugs intended for minor species or minor uses in major species (i.e., MUMS grants).

MUMS grants are one component of the Minor Use and Minor Species Animal Health Act of 2004 that was intended to make more medications legally available to veterinarians and animal owners to treat minor animal species and uncommon diseases in the major animal species. The two MUMS grants are as follows:

1) The U.S. Geological Survey's Upper Midwest Environmental Sciences Center in La Crosse, Wisconsin received funding for a study entitled *"Efficacy of 35% PEROX-AID® to control mortality caused by* Saprolegnia parasitica *or* Saprolegnia diclina *in walleye* Sander vitreum*."*

2) The Texas Agrilife Research Mariculture Laboratory in Port Aransas, Texas received funding for a study entitled *"Target Animal Safety of* Litopenaeus vannamei *treated with oxytetracycline in feed."* This study will test the safety of oxytetracycline when the drug is fed to shrimp as a medicated feed.

In accordance with the statute, a MUMS grant must be for the purpose of "defraying the costs of qualified safety and effectiveness testing expenses incurred in connection with the development of designated new animal drugs." Qualified testing occurs after the date a drug is designated under Section 573 of the act **and** before the date on which a new animal drug application for the drug is submitted under Section 512 of the act. In addition, a study for which a grant is sought must be subject to a protocol accepted by the Center for Veterinary Medicine prior to the submission of a grant application.

FDA will again announce the opportunity to apply for grant funding under this program in the near future.

> *Text excerpted from* CVM Updates *(2 November 2009). To view, refer to: http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm188653.htm.*

New national aquatic animal pathogen testing network proposed: The following has been excerpted from the American Fisheries Society - Fish Health Section Update (dated 22 October 2009).

"The US Animal Health Association (USAHA) and the American Association of Veterinary Diagnostic Laboratories (AAVLD) are national organizations that meet together once a year in a joint conference where expert committees formulate important policy recommendations for agencies like USDA. One of these committees is the USAHA/AAVLD Aquaculture Committee chaired by Kevin Snekvic (AAVLD) and Andy Goodwin (USAHA).

At the 2009 meeting in San Diego, California USA 7-14 October), Kevin and Andy presented a draft model for a new national aquatic animal pathogen testing network. This model has been under development for

several years in a process that included input from APHIS, NOAA, USFWS, university, federal and private labs, and the aquaculture industry. According to the draft, the purpose of the network would be 'To protect the health of wild and cultured fish and shellfish, to provide quality inspections in support of interstate and international trade, and to meet challenges associated with implementation of the National Aquatic Animal Health Plan.'

The draft plan envisions a lab network that uses standardized protocols developed by the joint USFWS/ AFS-FHS Inspection Committee. The network is overseen by a committee consisting of the participating laboratories, APHIS, NOAA, and the USFWS. The draft plan is modeled after the National Poultry Improvement Program. It would encourage participation by all fish health laboratories including federal, state, university, and private facilities.

Presentation of the draft plan in San Diego resulted in the following USAHA motion, 'The USAHA-AAVLD urges the USDA-APHIS-VS in partnership with the U.S. Fish and Wildlife Service and NOAA Fisheries to provide funding for, facilitate, and participate in a pilot national aquatic animal pathogen testing laboratory network as conceptualized in the USAHA-AAVLD aquaculture committee draft plan.' The next step in the process will be a formal response to the motion by APHIS."

To learn more refer to the USAHA Aquaculture Committee website: http://www.usaha.org/committees/ac/ac.shtml.

Text used with the permission of the author, Andy Goodwin; Aquaculture & Fisheries Department, University of Arkansas at Pine Bluff; Pine Bluff, Arkansas USA.

Preliminary work begins on AquaFrin™ as a microbicide for fish: Carlos Martinez of the DC Booth Historic National Fish Hatchery and Archives, along with staff from AADAP and Frontier Scientific, Inc (the pharmaceutical sponsor of the compound), recently began pilot testing a new photodynamic compound named AquaFrin™. When activated by white light, AquaFrin™ (which contains a porphyrin belonging to a class of naturally occurring photosensitizers that are related to such compounds as the pigments chlorophyll and heme) disrupts bacterial, protozoan and fungal cell walls and membranes by the local production of singlet oxygen ($^1O_2$), which is a potent oxidant. Although several photosensitizing agents have been tested for phototoxic action against various microorganisms over the years, porphyrins have emerged as superior. Their optimal photo-activation occurs in blue wavelengths most readily transmitted in water; activation can be achieved by ambient, overhead light (i.e., typical hatchery lighting) as well as by direct sunlight; and at proposed efficacious dosages they exhibit no appreciable toxicity to other than target microbes. These superior traits have made porphyrins an interesting candidate for investigation into the safety and efficacy of a novel approach for the control of saprolegnia infections. Preliminary safety and dose response tests have been conducted on rainbow trout in both South Dakota and Bozeman, and more are in the works - so, stay tuned!

***"Managing Streptococcus in Warmwater Fish"* symposium proceedings now available:** At the symposium *"Managing Streptococcus in Warmwater Fish"*, held in conjunction with the 2009 World Aquaculture Society conference in Veracruz, Mexico (September 2009), fish health experts discussed the streptococcus species and strains that affect cultivated warmwater fish, important aspects of diagnosis, prevention and treatment, and integrated health management strategies.

Intervet/Schering-Plough Animal Health was the sponsor of this educational event for the industry. The 48 page proceedings booklet contains papers authored by presenters, as well as other valuable information. It can be downloaded at the following URL: http://aqua.intervet.com/knowledge/2009-09-25.aspx.

Canada publishes draft *"Containment Standards for Facilities Handling Aquatic Animal Pathogens:"* The Canadian Food Inspection Agency (CFIA) recently published a draft set of standards, available for public comment, specifying the ultimate containment requirements for any facility that intends to handle aquatic animal pathogens. The CFIA notes "The intended scope of this document is to outline the minimum physical and operational requirements for facilities importing and subsequently working with aquatic animal pathogens or infectious materials. These facilities may include private, government, or university establishments, research laboratories and vaccine production and testing facilities. While the Containment Standards for Facilities Handling Aquatic Animal Pathogens are mandatory for facilities importing aquatic pathogens, they can also provide general guidance on the design and operating requirements for any aquatic animal containment facility." To view the draft standards refer to the CFIA webpage: http://www.inspection.gc.ca/english/sci/bio/anima/aqu/csfncich1e.shtml#a1.

The European Medicines Agency (EMEA) publishes draft guidelines for conducting finfish efficacy and target animal safety studies: The Veterinary Medicines and Inspections group of the EMEA recently (19 October 2009) published draft guidelines intended to assist prospective sponsors of new drug applications for cultured finfish within the European community. The guidance document is entitled: *"Guideline on Demonstration of Target Animal Safety and Efficacy of Veterinary Medical Products Intended for Use in*

Farmed Finfish." The document is being made available for public comment until 30 April 2010, after which time it will, with revisions based on public comments, be made final. The guidance document can be viewed at: http://www.emea.europa.eu/pdfs/vet/ewp/45986808en.pdf.

IN REMBERANCE

Betty L. Mitchell: Betty passed away on 10 July 2009, at Delta Regional Medical Center in Greenville, Mississippi USA. Betty had, for some time, been battling a relatively rare form of cancer, and for the last several months of her life she was unable to travel, even to work, with the exception of trips to her doctors.

Betty spent her entire adult life trying to promote and enhance the capabilities of the U.S. aquaculture industry. As the President of B.L. Mitchell, Inc., she played an essential role in bringing new aquaculture products to the market. She worked tirelessly with private companies such as Bayer AG in Germany; Georgia-Pacific in Salem, Oregon USA; H&S Chemical in Covington, Kentucky USA; as well as public agencies such as the U.S. Geological Survey, U.S. Fish & Wildlife Service, various state Departments of Natural Resources, the FDA and the EPA, in getting products approved to the standards required by the federal regulatory agencies.

B.L. Mitchell, Inc., through the efforts of Betty, holds several drug or chemical labels. Additionally, she had been working for the last ten to twelve years on two more, as yet to be registered/approved, aquaculture products. Her sons will continue to pursue these products, in her honor, until completion.

Text provided by Dusty M. Henson; B.L. Mitchell, Inc.; Leland, Mississippi USA

Frances M. Pell: What a beautiful difference a single life made...remembering our colleague Fran Pell. Fran passed away on 1 September 2009 at the age of 49 following a courageous three year battle against breast cancer. She graduated from Purdue University with a degree in Animal Science and went on to work for the USDA's Food Safety and Inspection Service and then the Food and Drug Administration for over 29 years. Fran served as an Investigator for the Baltimore District Office and later a Consumer Safety Officer for the Center for Veterinary Medicine.

Many of us knew Fran through her aquaculture related responsibilities and efforts to develop Agency policies for Import Tolerances. We've all enjoyed the many talks that Fran has given at industry-related meetings over the years and her enthusiasm and her ready smile brightened everyone she met. She leaves behind a loving husband Joe and three beautiful children, Mathew, Megan, and Libby. Although our hearts are saddened by Fran's passing, her spirit will continue to shine, leaving all of us an example to follow, and a remarkable life to remember.

Text provided by Deborah Cera; Team Leader, Compliance Information Management Team; Center for Veterinary Medicine, Food and Drug Administration; Rockville, Maryland USA .

We here at AADAP offer our sincere condolences to the families of Betty and Fran.

DRUG UPDATES

For the past several months AADAP has been busy drafting final study reports detailing the results of completed studies, drafting new study protocols for planned studies, wrapping up a variety of "loose ends" regarding previously completed work, and patiently waiting to hear back from CVM with respect to a number of previously submitted study protocols and final study reports. As is typically the case, we continue to move slowly forward by taking multiple small steps.

AQUAFOR® (Florfenicol) Update:

Largemouth bass and systemic columnaris final study report submitted to CVM: In the last newsletter, we reported on a study that was conducted in collaboration with our good friends in Florida at the Richloam Fish Hatchery/Florida Bass Conservation Center (FBCC). The purpose of the study was to demonstrate that AQUAFLOR®-medicated feed administered at a dosage of 10 mg florfenicol per kg fish body weight per d for 10 d effectively controlled mortality in largemouth bass caused by systemic columnaris. Since the last newsletter, we were able to confirm via PCR that the pathogen was indeed *Flavobacterium columnare*, that the concentration of florfenicol in the batch of medicated feed was within a range acceptable to CVM (i.e., 80-110% of the target dose), and that the florfenicol was mixed homogeneously throughout the batch of medicated feed. The Final Study Report was submitted to CVM's Aquaculture Team on 4 August 2009 and we anticipate hearing back from them in early February, 2010. As previously stated in the last newsletter, if this study is accepted by CVM, we anticipate that the sponsor (Intervet/Schering-Plough Animal Health) will move forward with getting a new claim for AQUAFLOR® – for the control of mortality in all freshwater-reared warmwater finfish due to systemic columnaris. We thank Mike Matthews and the staff at the FBCC for conducting the in-life phase of the study and Molly Bowman (USFWS AADAP) for being so quick on her feet and coming up with ways to provide CVM with additional data and information relative to the study.

Terramycin® 200 for Fish (Oxytetracycline dihydrate) Update:

All freshwater-reared salmonid marking final study report submitted to CVM: In the last newsletter, Dan Carty wrote the feature article describing results from a study that demonstrated that Terramycin® 200 for Fish administered in feed at a dosage of 3.75 g oxytetracycline dihydrate per 100 lbs fish per d for 10 d effectively marked skeletal tissue in rainbow trout. The Final Study Report was submitted to CVM's Aquaculture Team on 3 August 2009, and we should hear back from CVM sometime in early February 2010. If this study is accepted by CVM, we anticipate that the sponsor (Phibro Animal Health) will move forward and request that the current approval for this product to mark skeletal tissue of fish be expanded from "...use in Pacific salmon only" to "...use in all freshwater-reared salmonids." We thank Miranda Dotson (USFWS AADAP) for doing an outstanding job as the Study Investigator, and Jim Peterson (MT Fish, Wildlife, and Parks – retired) for evaluating skeletal tissue.

35% PEROX-AID® (Hydrogen Peroxide) Update:

Technical section complete for treatment of columnaris in all freshwater-reared warmwater finfish: Here's a bit of good news - in the last newsletter, we described two studies that were conducted in collaboration with Mike Matthews and the staff at the FBCC to demonstrate the effectiveness of 35% PEROX-AID® to control mortality in largemouth bass and bluegill due to external columnaris. The studies were not only accepted by CVM, but in a letter dated 26 August 2009, we were informed by CVM that the following technical section is complete: use 35% PEROX-AID® for control of mortality due to external columnaris associated with *Flavobacterium columnare* in freshwater-reared warmwater finfish when administered at a dose of 50-75 mg per L in a continuous flow water supply or as a static bath for 60 minutes per day on three alternate days. This information has been provided to the Sponsor (Eka Chemicals, Inc.) and we anticipate that the current label for 35% PEROX-AID® will soon be expanded to include this new claim.

Chloramine-T (HALAMID® AQUA) Update:

A bit of good news AND a bit of bad news: How about the good news first - in the last newsletter, we described another study that was conducted in collaboration with Mike Matthews and the staff at the FBCC. This study was to demonstrate the effectiveness of chloramine-T to control mortality in largemouth bass due to external columnaris. As expected, this study was accepted by CVM. In addition, in a letter dated 5 October 2009 we were informed by CVM that the technical section is complete for the use of chloramine-T immersion for the control of mortality due to external columnaris associated with *Flavobacterium columnare* in freshwater-reared warmwater finfish when administered at a dose of 20 mg per L in a static or flow-through water batch for 60 minutes per day on three consecutive or alternate days. We anticipate that when a sponsor is in a position to take the final steps towards an initial approval for chloramine-T for use in aquaculture, the above-described claim will be included on the label.

Now here's a little bad news: In the last newsletter we mentioned submitting a white paper argument (and associated documentation) to CVM describing that (in our opinion) sufficient data have been generated to complete the effectiveness technical section for the following claim: use of chloramine-T as an immersion bath for the control of mortality due to external columnaris associated with *F. columnare* in freshwater-reared cool– and warmwater finfish. The purpose of developing and submitting such a document to CVM was that we are having a very difficult time finding cooperators to help us conduct one last chloramine-T study on a representative coolwater fish species (other than walleye). The white paper covered various topics and referenced all data previously submitted to CVM, including INAD data that have been generated over the years. As most people know, INAD data is generated every time an investigator treats a raceway or tank of production fish. However, oftentimes in INAD field trials there is no replication, no use of controls, and various extenuating circumstances that may negatively impact the outcome of treatment. Well, in a letter dated 2 October 2009, we were informed by CVM that the effectiveness technical section for this claim (i.e., coolwater finfish) remains incomplete. So, one more study is still required to complete the effectiveness technical section for coolwater finfish. We have sent out another "call for help" and may be able to conduct a study in the future at a hatchery that rears northern pike and muskellunge. However, the reality is that the "call for help" has gone out over-and-over, and the likelihood that an effectiveness study on a coolwater fish species (other than walleye) with external columnaris will be completed within the next year is not good. As it stands, the initial approval for chloramine-T will likely be 1) to control mortality caused by bacterial gill disease in all freshwater-reared salmonids, and 2) to control mortality caused by external columnaris in walleye and all warmwater finfish.

Immediate Release Fish Sedative Update:

AQUI-S®E and benzocaine: The need for an immediate release fish sedative is still very important for fisheries professionals involved in fish culture and fisheries management. In the last newsletter, we

described some recent progress made by the AFWA Drug Approval Working Group on selecting one or more potential candidate drugs (e.g., benzocaine or eugenol). For information on more recent activities, please see "Immediate release" item in the "What's Shakin' section.

SLICE® Update:

Effectiveness study protocol not accepted by CVM: Although SLICE® (0.2% emamectin benzoate) has been on our radar screen for some time, AADAP has not yet been involved in conducting studies to evaluate its safety to fish or effectiveness to control parasitic crustaceans. In July of this year, we began to gather information and data that we believed useful for the development of a field effectiveness research protocol. After talking with a number of our colleagues who have first-hand experience with one or more species of parasitic crustaceans on their fish, including a parasitologist who specializes in *Salmincola* spp. and an expert on the use of SLICE® to control sea lice infestations, we drafted and submitted the following entitled protocol to CVM for review: *"The Efficacy of SLICE® to Control Parasitic Crustaceans on all Freshwater-Reared Salmonids."* The protocol was submitted to CVM on 5 August 2009. In addition, on 11 August 2009, we submitted a package to CVM that contained all the pertinent literature to support much of the information described in our protocol. On 5 October 2009, we received a letter of non-concurrence from CVM. To resolve some of the reasons for non-concurrence, we plan to convene a teleconference with members of the Aquaculture Team and Biometrics Team after they have had a chance to read the pertinent literature that we provided to them in August. In addition, to minimize confusion, the revised protocol will focus only on *Salmincola* spp. We hope the second time is a charm.

FINS & TAILS, BITS & BOBBERS

2010 INAD Sign-up forms are now available: Once again it is that time of year for renewal of your facility's INADs for Calendar Year 2010. All 2010 sign-up forms are available on our website at: http://www.fws.gov/fisheries/aadap/SIGNUP.htm. Please send completed sign-up forms to the AADAP Office by 31 Dec 2009. Invoices will be mailed out the end of January 2010. Note: there will now be a charge for the Diquat INAD; this change will be effective 1 Jan 2010.

Treatment use authorizations received for AQUI-S® E and BENZOAK® VET INADs: The AADAP Office has received treatment use authorizations for both the Aqui-S® E (eugenol) and BENZOAK® VET (benzocaine) INADs. The current posttreatment withdrawal period for both of these products under INAD authorization is 72 hrs. Although this withdrawal period doesn't allow for "immediate release", it is certainly a step in the right direction! If you are interested in participating under one or both INADs please be sure to sign-up for them.

End of the year INAD forms due: If you have not already done so, please send in all Form 2's (Drug Inventory Form) and Form 3's (Results Report Form) for each of the INADs that were used at your facilities for INAD Year 2009. Note: If your facility was signed-up to use an INAD, even though the INAD drug was not actually used, a Form 2 is still required showing either the amount of drug on-hand or that no use occurred.

National INAD Program (NIP) website automation (on-line data reporting) update: In the July 2008 issue of the AADAP Newsletter we reported that AADAP had begun the process of transitioning our INAD reporting procedures into the Web-age, or in other words, developing NIP website automation that would allow for the on-line reporting of all INAD-required data. We are pleased to report that we are currently in the final stages of developing this website automation program, and we anticipate that on-line reporting of INAD data will be available mid-2010!

The website automation program will allow participants to enter data via the AADAP website directly into a large database. It is hoped that the new on-line data reporting system will not only be less labor intensive (for both INAD participants and AADAP staff) than dealing with hand-entered, hard copy data, but also as a result of built-in system "crosschecks", will allow for the collection of more accurate/complete data packages. Initially, on-line reporting will be made available to only a few select facilities/agencies so that the automation program can be given a thorough "test drive" to ensure that it is fully functional. Upon completion of testing (hopefully around June 2010) it will be made available as an optional data reporting mechanism to all INAD participants. Assuming that the on-line reporting system is as successful as we hope it will be, it is anticipated that it will become a mandatory procedure for INAD reporting sometime in the not too distant future. Stay tuned...and if anyone is interested in volunteering to become a "test driver", please contact Bonnie Johnson (bonnie_johnson@fws.gov).

SLICE® (emamectin benzoate) INAD setback: Unfortunately, we have once again received word of another small setback in our ongoing efforts to establish an INAD for SLICE®. Through correspondence from FDA, we have been informed that a relatively limited amount of facility specific effluent-related information is needed for each proposed facility before an initial INAD authorization can be granted. Although we thought we had this data-gap covered…well, we didn't. All potential SLICE® participants that we are currently aware of have been

contacted and asked to fill out a SLICE® discharge table. If you have not already done so, please return this table to us so we may resubmit the information to FDA. Hopefully, by the next edition of the Newsletter we will have more positive SLICE® INAD-related information to report.

RELEVANT LITERATURE

The following is a list of journal publications with particular relevance to the broad topic of drug-use in aquaculture. This list comprises citations exclusively from 2009. Please note that this list does not include those provided in previous issues of the AADAP Newsletter.

If you have come across literature that you believe would be of interest to the readership of the AADAP Newsletter, please forward the citation to Tom Bell (thomas_a_bell@fws.gov) and we will place it in the next edition.

The inclusion of a citation within the AADAP Newsletter does not imply: (1) recommendation of the technique to any particular situation, (2) concurrence with a treatment procedure/drug, (3) acceptance by the U.S. Food and Drug Administration's Center for Veterinary Medicine of the drug's safety or effectiveness, nor (4) in any way an endorsement of a product by the U.S. Fish & Wildlife Service.

Antibiotic and Bacterial

Dang, H, et al. 2009. Molecular characterizations of chloramphenicol- and oxytetracycline-resistant bacteria and resistance genes in mariculture waters of China. *Marine Pollution Bulletin* **58(7):987-994**.

Dung, TT, et al. 2009. IncK plasmid-mediated tetracycline resistance in *Edwardsiella ictaluri* isolates from diseased freshwater catfish in Vietnam. *Aquaculture* **295(3-4):157-159**.

Fagutao, FF, et al. 2009. Differential gene expression in black tiger shrimp, *Penaeus monodon*, following administration of oxytetracycline and oxolinic acid. *Developmental & Comparative Immunology* **33 (10):1088-1092**.

Feng, JB, and Jia, XP. 2009. Single dose pharmacokinetic study of florfenicol in tilapia (*Oreochromis niloticus* × *O. aureus*) held in freshwater at 22ºC. *Aquaculture* **289(1-2):129-133**.

Fierro, J, and Oliva, D. 2009. Effect of antibiotic treatment on the growth and survival of juvenile northern Chilean scallop, *Argopecten purpuratus* Lamarck (1819), and associated microflora in experimental cultures. *Aquaculture Research* **40(12):1358-1362**.

Hoj, L, et al. 2009. Localization, abundance and community structure of bacteria associated with *Artemia*: effects of nauplii enrichment and antimicrobial treatment. *Aquaculture* **293 (3-4):278-285**.

Jia, A, et al. 2009. Simultaneous determination of tetracyclines and their degradation products in environmental waters by liquid chromatography -electrospray tandem mass spectrometry. *Journal of Chromatography A* **1216(22):4655-4662**.

Navarrete, P, et al. 2009. Oxytetracycline treatment reduces bacterial diversity of intestinal microbiota of Atlantic salmon. *Journal of Aquatic Animal Health* **20(3):177-183**.

Penesyan, A, et al. 2009. Antimicrobial activity observed among cultured marine epiphytic bacteria reflects their potential as a source of new drugs. *FEMS Microbiology Ecology* **69 (1):113-124**.

Yu, H-J, et al. 2009. Determination of erythromycin residue in fishery products by high performance liquid chromatography-tandem mass spectrometry. *Chinese Journal of Analysis Laboratory* **28(3):51-54**.

Sedation and Anesthesia

Lambooij, B, et al. 2009. Anaesthetic properties of Propiscin (etomidaat) and 2-phenoxyethanol in the common carp (*Cyprinus carpio* L.), neural and behavioral measures. *Aquaculture Research* **40(11):1328-1333**.

Park, IS, et al. 2009. Anesthetic effects of lidocaine-hydrochloride on water parameters in simulated transport experiment of juvenile winter flounder, *Pleuronectes americanus*. *Aquaculture* **294 (1-2):76-79**.

Sink, TD, et al. 2009. Stress response and posttransport survival of hybrid striped bass transported with or without clove oil. *North American Journal of Aquaculture* **71(3):267-275**.

Suquet, M, et al. 2009. Anesthesia in Pacific oyster, *Crassostrea gigas*. *Aquatic Living Resources* **22(1):29-34**.

Zahl, IH, et al. 2009. Anaesthesia of Atlantic cod (*Gadus morhua*) - Effect of pre-anaesthetic sedation, and importance of body weight, temperature and stress *Aquaculture* **295(1-2):52-59**.

Parasite and Fungus Control

Bozwell, JL, et al. 2009. Use of hydrogen peroxide to improve golden shiner egg hatchability. *North American Journal of Aquaculture* **71(3):238-241**.

Lahnsteiner, F, et al. 2009. The risk of parasite transfer to juvenile fishes by live copepod food with the example *Triaenophorus crassus* and *Triaenophorus nodulosus*. *Aquaculture* **295(1-2):120-125**.

Mitchell, AJ, et al. 2009. The effect of hydrogen peroxide on the hatch rate and *Saprolegnia* spp. infestation of channel catfish eggs. *North American Journal of Aquaculture* **71(3):276-280**.

Taylor, NGH, et al. 2009. Using length-frequency data to elucidate the population dynamics of *Argulus foliaceus* (Crustacea: Branchiura). *Parasitology* **136(9):1023-1032**.

Skeletal Marking

Caudron, A, and Champigneulle, A. 2009. Multiple marking of otoliths of brown trout, *Salmo trutta* L., with alizarin red S to compare efficiency of stocking of three early life stages. *Fisheries Management and Ecology* **16(3):219-224**.

Crook, DA, et al. 2009. Development and evaluation of methods for osmotic induction marking of golden perch *Macquaria ambigua* with calcein and alizarin red S. *North American Journal of Fisheries Management* **29 (2):279-287**.

Ellers, O., and Johnson, AS. 2009. Polyfluorochrome marking slows growth only during the marking month in the green sea urchin *Strongylocentrotus droebachiensis*. *Invertebrate Biology* **128(2):126-144**.

Kanou, K, et al. 2009. Alizarin complexone staining of the otolith and scale of largemouth bass, *Micropterus salmoides*. *Journal of Fisheries Technology (Yokohama)* **1(2):71-75**.

Spawning Hormones and Gender Manipulation

Drummond, CD, et al. 2009. Growth and survival of tilapia *Oreochromis niloticus* (Linnaeus, 1758) submitted to different temperatures during the process of sex reversal. *Ciencia e Agrotecnologia* **33(3):895-902**.

Haffray, P, et al. 2009. Genetic determination and temperature effects on turbot *Scophthalmus maximus* sex differentiation: an investigation using steroid sex-inverted males and females. *Aquaculture* **294(1-2):30-36**.

Hill, JE, et al. 2009. Survey of Ovaprim® use as a spawning aid in ornamental fishes in the United States as administered through the University of Florida Tropical Aquaculture Laboratory. *North American Journal of Aquaculture* **71 (3):206-209**.

Li, SW, et al. 2009. Analysis of differential expression and characterization of PIN in the gonads during sex reversal in the red-spotted grouper. *Molecular and Cellular Endocrinology* **309(1-2):32-38**.

Miscellaneous

Cole, DW, et al. 2009. Aquaculture: environmental, toxicological, and health issues. *International Journal of Hygiene and Environmental Health* **212(4):369-377**.

Oplinger, R, et al. 2009. Effect of sodium chloride, tricaine methanesulfonate, and light on New Zealand mud snail behavior, survival of snails defecated from rainbow trout, and effects of Epsom salt on snail elimination rate. *North American Journal of Aquaculture* **71(2):157-164**.

Velicu, M, and Suri, R. 2009. Presence of steroid hormones and antibiotics in surface water of agricultural, suburban and mixed-use areas. *Environmental Monitoring and Assessment* **154 (1-4):349-359**.

USGS's CORNER

17α-methyltestosterone: In response to comments received from FDA on the use of MT-medicated feed in tilapia, the NADA Coordinator and Upper Midwest Environmental Sciences Center (UMESC) requested that FDA reaffirm its consideration that the human food safety technical section for MT to masculinze juvenile tilapia was complete. The request was submitted through UMESC INAD 11-395 on 14 August 2009.

UMESC in collaboration with CanTest Ltd., developed a study protocol to conduct an analytical method transfer study to complete the Chemistry Manufacturing and Controls Technical Section for MT. The study protocol was reviewed by FDA and End Review Amendment comments from FDA were responded to by UMESC and CanTest. The study was funded through grants from USDA's North-Central and Western Regional Aquaculture Centers.

Hydrogen peroxide: (see What's Shakin' MUMS Grants Awarded for FY2009).

Chloramine-T: To address one of the remaining data needs for the approval of chloramine-T (Halamid® AQUA), UMESC staff modified the analytical method for para-toluenesulfonamide (ρTSA), the marker residue of chloramine-T. UMESC staff received FDA-concurrence on a study protocol to validate the new analytical method procedures. UMESC staff are presently conducing the laboratory assays to validate the new analytical method. The modified analytical method is intended to provide a ρTSA detection limit of less than or equal to 20 parts per billion, the tolerance limit now proposed by FDA for ρTSA.

Sedatives: As part of the evaluation of two new candidate sedatives (benzocaine and eugenol), UMESC, in collaboration with Viterbo University (Dr. Kim Fredricks, Biology Department Chair and Biology students Ryan Ambrose, LeAnn Jackan and Jeremy Wise), conducted studies to evaluate the time required for fish to initiate a feeding response following sedation. Several fish species were selected for inclusion in the study including rainbow trout, brown trout, yellow perch, walleye and bluegill. Responses were evaluated in fish assigned to six different treatment groups, a control, an electroshock (to simulate capture during electrofishing), electroshock plus sedation (by benzocaine or eugenol) or sedation (by benzocaine or eugenol) only. Sedation was accomplished using either AQUI-S-E® (eugenol) or BENZOAK VET® (benzocaine) at concentrations that caused fish to become handleable within two min. After recovery, defined as normal swimming movements, from either electroshock or sedation, fish were offered either a formulated pellet or live food (e.g. forage fish). Feeding responses varied among the treatment groups and species but in general sedated fish fed more rapidly than expected. For example, nearly all rainbow trout fed within 30 min of recovery from sedation. Work is presently in progress to summarize the results for submission to FDA.

UMESC developed an analytical methods development protocol to develop the analytical methods to detect eugenol residues in the fillet of freshwater fish. The proposed method is expected to utilize high performance liquid chromatography with ultraviolet detection. The study is expected to begin following completion of the ρTSA method validation work and is being funded through a Multistate Conservation Grant from the Association of Fish and Wildlife Agencies.

Viral Hemorrhagic Septicemia: In collaboration with the USFWS La Crosse Fish Health Center and the Genoa National Fish Hatchery, UMESC recently assessed the efficacy of iodophor-egg disinfection to eliminate Viral Hemorrhagic Septicemia (VHS) virus (strain IVb) from walleye and northern pike intentionally-challenged with VHS virus following egg fertilization. A USGS Fact Sheet is in preparation to summarize the study results and is expected to be available before the coolwater spawning season in 2010. The study was funded through a grant from the North-Central Regional Aquaculture Center.

Motile Aeromonad Septicemia: In collaboration with the USFWS La Crosse Fish Health Center, UMESC initiated work to identify *Aeromonas* spp. involved in outbreaks of Motile Aeromonas Septicemia in cool and warmwater fish. Several *Aeromonas* spp. isolates have been collected and challenge studies are on-going to assess the clinical signs associated with the various species and isolates. This work is a precursor to field effectiveness studies planned to be conducted in 2010 to assess the efficacy of either florfenicol or oxytetracycline-medicated feed to control mortality from MAS. The study was funded through a grant from the USDA's North-Central Regional Aquaculture Center.

Text provided by Mark Gaikowski, Fisheries Management Chemical and Aquaculture Drug Team, U.S. Geological Survey, Upper Midwest Environmental Sciences Center, La Crosse, Wisconsin, USA.

USDA's CORNER

Cooperative work with AADAP: Stuttgart National Aquaculture Research Center (SNARC) has been working with the folks at AADAP on two studies: 1) a "near" GLP compliant target animal safety study to evaluate the safety of Aquaflor® (florfenicol) administered in feed to sunshine bass and 2) a GLP compliant target animal safety study to evaluate the safety of 17α-methyltestosterone (17MT) administered in feed to tilapia.

The in-life phase of the Aquaflor® study was completed at SNARC and fish tissues were processed and evaluated histologically at AADAP. Results were excellent and the Final Study Report is being internally reviewed.

The in-life phase of the 17MT study will be completed at SNARC and is planned for January/ February 2010. A preliminary study is underway to establish a larval tilapia growth curve so that we may better predict feed amounts to be administered to fish each day of the study. Fish samples will be processed and evaluated histologically at AADAP.

Collaborating with AADAP on these studies has been beneficial for the overall drug approval projects and has helped to speed things along.

Potassium permanganate and columnaris studies: The high-density, low-flow columnaris disease-initiation method has been able to produce columnaris infections in catfish with some regularity. We have been able to demonstrate effectiveness of $KMnO_4$ to channel catfish infected with columnaris and dosed after 20 hrs with a single 8 mg per L treatment. Further experiments are planned using repeated treatments at lower doses.

Copper sulfate and channel catfish egg study: The Final Study Report for the $CuSO_4$ target animal safety study on channel catfish eggs should be submitted to FDA/CVM by the end of the year; there have been several delays with other priorities to our research mission at SNARC. A Final Study Report for the effectiveness studies of $CuSO_4$ on saprolegniasis of channel catfish eggs is being prepared.

Text provided by Dave Straus, Disease & Drug Approval Section, Harry K. Dupree – Stuttgart National Aquaculture Research Center, Agricultural Research Service, U.S. Dept. of Agriculture, Stuttgart, Arkansas, USA.

MEETINGS, ETC.

Upcoming meetings

60th Northwest Fish Culture Conference; 1-3 December 2009; Redding, California USA:

The California Department of Fish and Game is the host for this year's conference. The conference is to be held at the Red Lion Hotel in Redding, California USA. This year's theme is "Passing it On...Our Legacy." For more information refer to the conference website by clicking here.

Aquaculture 2010; 1-5 March 2010; San Diego, California USA: The San Diego meeting will be the International Triennial Meeting of the National Shellfisheries Association, the American Fisheries Society Fish Culture Section and the World Aquaculture Association. The conference is to be held at the Town & Country Resort and Conference Center. The conference is being co-sponsored by the National Aquaculture Association, the U.S. Chapter of the World Aquaculture Society and the U.S. Aquaculture Suppliers Association, with numerous associate sponsors. Early registration must be received by 25 January 2010. For further information refer to the conference website (https://www.was.org/WasMeetings/meetings/Default.aspx?code=AQ2010).

6th International Symposium on Aquatic Animal Health; 5-9 September 2010; Tampa, Florida USA: Next year's symposium, like those in the past, is being sponsored by the American Fisheries Society - Fish Health Section, with additional support from the International Association for Aquatic Animal Medicine, the National Shellfisheries Association, the Japanese Society for Fish Pathology, the European Association of Fish Pathologists, and the Aquatics Committee of the American Veterinary Medical Association.

The symposium will provide a stimulating and inclusive forum for exchange of current information on research, management and policy issues related to health and diseases of aquatic animals, whether wild, farmed, or held on exhibit. The broadest range of animals is considered,

from invertebrates, to fish, amphibians, chelonians, and marine mammals. This important international gathering will be used to facilitate discussion and action on issues of international importance. Key themes of the symposium will include (i) infectious diseases in aquaculture, (ii) planning and emergency response for aquatic animal health emergencies, (iii) interaction of diseases between wild and farmed stocks, and (iv) outcomes of environmental stress including effects of contaminants, and regional and global habitat alteration. For more information refer to the conference website: http://aquaticpath.epi.ufl.edu/isaah6/

Aquaculture Europe 2010; 5-8 October 2010; Porto, Portugal: The European Aquaculture Society is the organizing body for next year's conference. The conference is being held at the Centro de Congressos da Alfândega (web address: www.amtc.pt) – the old customs house on the quay of the Douro River in the heart of Porto and just opposite the famous port wine cellars that are synonymous with this lively city. The theme for the 2010 conference is "Seafarming Tomorrow." Further information can be found on the Society's website at: http://www.easonline.org/.

ROZ's CORNER

Chloramine-T (HALAMID® AQUA®): Update on the progress for the two initial label claims for control of mortality in 1) all freshwater-reared salmonids due to bacterial gill disease and 2) all coolwater and warmwater finfish due to external columnaris disease.

All the major Technical Sections needed for an original New Animal Drug Application (NADA) have been accepted or submitted in final form to the Center for Veterinary Medicine (CVM) for the above label claims except for a final piece for the Human Food Safety Technical Section. After the modification of the analytical method is submitted and accepted and the Chemistry, Manufacturing and Controls and the audit of the sponsor's manufacturing facilities are accepted by CVM, the National Coordinator for Aquaculture NADAs will work with Axcentive SARL, the sponsor of HALAMID® AQUA®, to complete the minor Technical Sections and then submit an Administrative NADA to CVM. Axcentive SARL's chloramine-T product, HALAMID® AQUA®, was designated to cover the above label claims under the Minor Use and Minor Species (MUMS) provision that allows for seven years of marketing exclusivity.

Formalin (PARASITE-S®): Update on the progress for one label claim for control of mortality in all freshwater-reared finfish due to saprolegniasis.

All the major Technical Sections needed for a supplemental NADA have been accepted or submitted to CVM for the above label claim. The National Coordinator for Aquaculture NADAs will work with the sponsor (Western Chemical Inc.) of the MUMS designated formalin product (PARASITE-S®) to complete the Administrative NADA.

Hydrogen peroxide (35% PEROX-AID®): Update on the progress for one label claim for control of mortality in all warmwater finfish due to external columnaris disease.

All the major Technical Sections needed for a supplemental NADA have been accepted or submitted to CVM for the above label claim. The National Coordinator for Aquaculture NADAs will work with the sponsor (Eka Chemicals, Inc.) of the designated MUMS hydrogen peroxide product (35% PEROX-AID®) to complete the Administrative NADA.

17α-Methyltestosterone (MASCULINIZING FEED FOR TILAPIA®): Update on the progress for one initial label claim for masculinization of female early life-stage tilapia.

On 14 August 2009, the Upper Midwest Environmental Sciences Center submitted to CVM the sediment transformation study completed by the University of Wisconsin at Madison. Auburn University is in the process of revising the environmental assessment that, upon acceptance by CVM, will complete the Environmental Safety Technical Section for 17α-methyltestosterone.

Immediate release sedative: Update on the progress for all freshwater finfish.

Micro Technologies, Inc., the sponsor of FISH-EEZZZ™, wants the Association of Fish and Wildlife Agencies Drug Approval Working Group to consider FISH-EEZZZ™ as an additional sedative candidate to the other two sedative candidates under consideration, benzocaine and eugenol.

MUMS Designations: The MUMS Animal Health Act of 2004 provides for sponsors to have the opportunity for marketing exclusivity for seven

years for a designated product. As of 28 October 2009, the MUMS Office has granted 83 designations, 71 of those are to aquaculture drug sponsors, many with the help of the National Coordinator for Aquaculture NADAs. The most recent MUMS designations are 1) two for AQUI-S New Zealand LTD's AQUI-S® E (eugenol) on 6 July 2009, and 2) nine for Eka Chemicals Inc.'s 35% PEROX-AID® (hydrogen peroxide) on 17 September 2009.

Of these 71 aquaculture MUMS Designations, there have been 1) one Original NADA approval for one label claim for Schering-Plough Animal Health's AQUAFLOR®, 2) one Original NADA approval for three label claims for Eka Chemicals, Inc.'s 35% PEROX-AID®, 3) two Supplemental NADA approvals for two label claims for Schering-Plough Animal Health's AQUAFLOR®, 4) one Conditional NADA Approval for one label claim for Schering-Plough Animal Health's AQUAFLOR®, and 5) one Supplemental NADA Approval for two label claims for NADA Phibro Animal Health's TERRAMYCIN® 200 FOR FISH. One MUMS Designation has been terminated at the sponsor's request - GB Research, Inc. for amoxicillin trihydrate.

Transition meeting with CVM: The National Coordinator for Aquaculture New Animal Drug Applications met with CVM on 14-16 October 2009 to work on the transition phase leading into her retirement from that position to ensure that all functions, procedures, and duties are covered by CVM and other entitles so that aquaculture drug approval successes can continue without interruption. She thanks Jen Matysczak for providing the leadership in getting 17 CVM staffers to the table to discuss how to proceed between now and 15 April 2010.

The National Coordinator for Aquaculture New Animal Drug Applications raised an issue that could help increase the number of drugs that would cover all finfish. The issue raised was the need to revisit the design and number of target animal safety and effectiveness studies needed for "all fish" label claims. Both CVM Director Bernadette Dunham and Office of New Animal Drug Evaluation Director Steve Vaughn fully endorsed moving forward with a Staff College on addressing this issue. CVM is interested in conducting this seminar as rapidly as possible.

Text provided by Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, La Crosse, Wisconsin.

CVM's NOTES

Aquaculture contact in the Office of Surveillance and Compliance: We are saddened by the loss of Fran Pell, Aquaculture Compliance Expert in CVM's Office of Surveillance and Compliance (see the tribute above). Please direct questions regarding aquaculture compliance issues to Dr. Tom Moskal (phone: 240-276-9242, email: Thomas.Moskal@fda.hhs.gov).

Transition #1: Dr. Eric Anderson, who was a reviewer on the Aquaculture Drugs Team in the Office of New Animal Drug Evaluation (ONADE), has left CVM to pursue other opportunities. We wish him the best of luck in his future endeavors.

Transition #2: Please help us welcome Dr. Eric Landis to the Aquaculture Drugs Team. He has joined our team as part of the Commissioner's Fellowship Program. This is a two year program that involves both the study of regulatory science at the Agency level and a Center-specific project. Eric will explore ways to assess the effectiveness of drugs to control parasites on fish. Eric previously was a Post-Doc at NOAA's Northwest Fisheries Science Center; his efforts there focused on identification of genetic differences between environmental and clinical strains of *Vibrio parahaemolyticus*. Before that, he studied the immune response of rainbow trout to IHN for his Ph.D. at the University of Maryland, Baltimore. Early in his career he worked in the aquaculture industry as a research scientist at a hybrid striped bass facility. We are happy to have him on board!

Text provided by Dr. Jennifer Matysczak, Aquaculture Drugs Team Leader; Office of New Animal Drug Evaluation; Center for Veterinary Medicine, Food and Drug Administration; Rockville, Maryland USA.