



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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AADAP NEWSLETTER

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Spring ice on the Yellowstone River, Park County, Montana USA

WHAT’S SHAKIN’

16th Annual USFWS Aquaculture Drug Approval Coordination Workshop to be held 3-5 August 2010 in Bozeman, Montana, USA: It’s getting closer! We here in Bozeman have started to make arrangements and other necessary preparations for this year’s Workshop. So you can as well; pencil it in on your calendar and be sure to check the [Workshop webpage](#) on AADAP’s [website](#) for news of it and other upcoming workshops. As has always been the case when the Workshop takes place in Bozeman, the Aquaculture Drug Approval Coordination Workshop will be scheduled for the week immediately before the [Sweet Pea Festival](#)



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weekend. Although final arrangements have yet to be made, we are hoping to have meetings of the [National Aquaculture Drug Research Forum](#) and AFS Fish Culture Sections’ Working Group on Aquaculture Drugs, Chemicals, and Biologics held in conjunction with the Workshop.

Update on the search for a new candidate “immediate-release” sedative: Since the last update in the previous edition of the [AADAP Newsletter](#) (November 2009), continued progress has been made with respect to the search for a new candidate immediate release sedative.

1. The benzocaine genotoxicity battery of studies (funded by [Association of Fish and Wildlife Agencies](#) or AFWA) has been completed and all final study reports have been submitted to CVM by AADAP. The submission was dated 28 January 2010, and it is anticipated that CVM should complete their review by the end of July 2010. Although CVM will, of course, have the final say, results of all studies within in the genotoxicity battery indicated that benzocaine is not genotoxic (i.e., Good News!). The genotoxicity battery was conducted by the contract research lab [BioReliance Corp.](#) and monitored by [Brock Scientific Consulting, LLC.](#)
2. The Pacific Northwest Fish Sedative Task Force (PNFSTF), reported on in the [last AADAP Newsletter](#), recently (18 February) met in Newport

Oregon. Representative from the following entities were in attendance: Oregon Department of Fish and Wildlife, Washington Department of Fish & Wildlife, Idaho Department of Game and Fish, Nez Perce Tribe - Department of Fisheries Resource Management; Columbia River Inter-Tribal Fish Commission, Northwest Indian Fish Commission, National Oceanic and Atmospheric Administration - Fisheries, US Fish & Wildlife Service, US Army Corps of Engineers, Bonneville Power Administration and the Association of Fish and Wildlife Agencies - Drug Approval Working Group. The majority of time was spent establishing, within the group, a better understanding of the sequence, timing and estimated costs for completion of all benzocaine and eugenol NADA technical section requirements, as well as exploring the potential avenues for funding remaining studies. The PNFSTF, via the co-chairs (Ed Larson - Nez Perce Tribe and Tom Bell - USFWS) will now begin the process of assembling funding proposal packages to submit to potential "benefactors" within the Pacific Northwest.

Benzocaine and eugenol INADs now available with NO enrollment fee: The prospective immediate-release sedatives BENZOAK[®] (benzocaine; INAD 11-740) and AQUI-S[®] E (eugenol; INAD 11-741) are currently available for use by interested hatchery managers, fisheries resource managers, and other individuals interested in an immediate-release sedative via the FWS's National INAD Program. Unlike participation in most other FWS-held INADs, there will be no fee for enrollment in these two INADs. Given that 1) the Association of Fish and Wildlife Agencies' Drug Approval Working Group (DAWG) is still in the process of determining which of the two drugs upon which to focus their full-attention, and 2) the vast majority of use-data available for benzocaine and eugenol are anecdotal, all field-based information/data (e.g., efficacy, safety, time to sedation, time to recovery, ease of use, etc.) that can be generated in the short-term can be incorporated into the DAWG's decision process. Therefore, we encourage as many folks as possible to sign-up for and test either or both drugs (Note: side-by-side trials would be great!). Remember, however, that the withdrawal period for use under both INADs is 72 hours...not zero hours. Although fish can not be released immediately, the 72 hour INAD-withdrawal period is considerably shorter than the 21-day withdrawal period for the approved tricaine methanesulfonate (MS-222) products currently on the market. For additional information, refer to the respective drug buttons under the "INAD Information" panel on the left-hand side of [AADAP's webpage](#). So, please consider enrolling in either (or preferably both) of the BENZOAK[®] or AQUI-S[®] E INADs.

Association of Fish and Wildlife Agencies' Drug Approval Working Group update: The Drug Approval Working Group (DAWG) of the Association of Fish and Wildlife Agencies (AFWA) met on 28 February 2010 at the AQUACULTURE 2010 conference in San Diego, California USA. As with the three previous DAWG meetings over the past eighteen months, the majority of meeting discussion focused on the DAWG's top-priority of continuing to establish a selection process for a "best candidate" immediate-release sedative. Over the last six months funding from AFWA's Multi-State Conservation Grant Program assisted in completing selected genotoxicity studies for benzocaine, capture and feeding studies following sedation for both eugenol and benzocaine, and the initial development of an analytical method to determine eugenol concentrations in freshwater fish fillet tissue.

In addition to the aforementioned progress, we are very fortunate to still have two drug sponsors each with a Minor Use Minor Species designation for an immediate release sedative; Frontier Scientific, Inc. for BENZOAK[®] (benzocaine) and AQUI-S New Zealand, Ltd. for AQUI-S[®] E (eugenol). Additionally, there is an Investigational New Animal Drug (INAD) exemption for each of the drugs (USFWS - AADAP holds the INADs), and each has a 72 hour investigational withdrawal period assigned to their use.

Although we have thoroughly evaluated both drugs with respect to the ultimate completion of all NADA technical section requirements, we have as yet been unable to identify which compound we believe is the best candidate - and for which the DAWG will actively work with the sponsor to gain an FDA approval. For better or for worse, based on currently available information both drugs "rank-out" very similar. Additionally, both drugs require a similar number of studies to be conducted in order to complete the human food safety technical section (HFSTS) of a New Animal Drug Application (NADA). In spite of the fact that the demonstration of non-toxicity via the HFSTS is critical to continuing with completion of remaining NADA technical sections, these remaining HFSTS studies require far too much of a time and funding commitment to complete before a selection is made. None-the-less, both the DAWG and the two aforementioned drug sponsors need to make key decisions soon. Hence, the DAWG must decide which drug it will focus on by our next meeting this coming September.

The DAWG clearly has a dilemma relative to its ability to move forward with one sedative! We believe that part of the solution to the dilemma is to rely on field testing input from fisheries professionals over the next six months. With such information in hand and potential other laboratory work and further information gathering completed, we are hopeful that we can make the best, informed decision possible at our upcoming meeting.



However, **we need your help!** As reported previously in the Newsletter, AADAP is managing INADs for benzocaine (BENZOAK[®], INAD 11-740, [click here](#) for fact sheet) and eugenol (AQUI-S[®] E, INAD 11-741, [click here](#) for fact sheet), and participation in the INADs is **FREE**. So, seriously consider enrolling in the sedative INAD of your choosing, or better yet, enroll in both and complete side-by-side comparative sedation trials. The more INAD trials completed this summer, the more data/information we will have to help us assess the overall utility of each sedative. If you do participate in either or both of these INADs, in addition to the routine report form submitted to AADAP, please take the time to let us/AADAP know what the pluses and minuses are for each of the drugs. For more information on the INADs, contact Bonnie Johnson (phone: 406-994-9905; email bonnie_johnson@fws.gov).

So, please take on the “Sedative Challenge” and ask your colleagues to join in. The DAWG is hopeful that we can make an informed decision at our meeting this September. With your input, we can accomplish just that.

Text provided by Steve Sharon; Wyoming Game and Fish Department and Chair, AFWA-DAWG; Casper, Wyoming USA.

AADAP nominated for U.S. Fish & Wildlife Service national award: The AADAP Program recently received official notice that it had been nominated for the Rachel Carson Group Award for Scientific Excellence for the fiscal year 2009. Although the final selection has not yet been made, in the words of the Services’ acting Director, Rowan Gould, “Regardless of the outcome, your nomination indicates that your achievements reflect science excellence and are recognized and appreciated by the Service.”

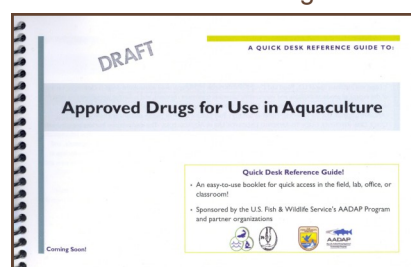
Biologics Poster being planned: The USDA - Center for Veterinary Biologics’ Dr. Melissa Schilling is heading up an effort, with assistance from AADAP and possibly other organizations, to publish a registered biologics poster. The poster, which is being planned to be similar in format to the “[Approved Drugs for Use in Aquaculture](#)” poster, will depict all biologics registered for current legal use on aquaculture species in the USA. The poster will include, product name, pathogen for which protection is being provided, manufacturer’s contact information, aquaculture species upon which it can be used, directions for use, and any associated precautionary statements. Many of the logistical details have yet to be worked out such as who will distribute, how to order one, etc. What is known, however, is that the posters will be available to end users for free! As more information becomes available it will be made public on the [AADAP website](#), so check out the site often.

Use of garlic and ginger to combat *Aeromonas hydrophila* reported: Two recent articles in the

November 2009 issue of the [Journal of Fish Diseases](#) reported beneficial therapeutic effects of two natural products. It was reported that both garlic and ginger, when added to the diets of rainbow trout, *Oncorhynchus mykiss*, provided protection from *Aeromonas hydrophila* infection. Abstracts from these article can be viewed on the Journal’s website: <http://www3.interscience.wiley.com/journal/122652629/issue>.

AADAP’s Dan Carty wins AFS award: Congratulations to Dan - at the recent Annual Meeting of the Montana Chapter of the American Fisheries Society, Dan received the Best Professional Paper award for his presentation entitled: “Efficacy of Terramycin[®] 200 for Fish (Oxytetracycline Dihydrate) for the Skeletal Marking of Rainbow Trout *Oncorhynchus mykiss*.” Anyone interested in seeing Dan’s presentation can view it by [clicking here](#). Again, a big congrats to Dan for a job well done!

AADAP developing a new information aid on aquaculture drug-use: As a companion tool to the “[Approved Drugs for Use in Aquaculture](#)” poster, AADAP is in the final stages of developing a



desk-reference booklet. The booklet (approximately 8.5” x 5.5”) will contain the same information as the poster, as

well as suggested guidance on “How to Calculate” the proper dose or concentration of approved drugs as per label instructions. Like the poster, it will be constructed of durable materials. As currently planned, the [American Fisheries Society's Fish Health](#) and [Fish Culture](#) Sections will partner-up with AADAP to maximize distribution of the booklet. The goal is to begin distribution in September 2010, or earlier if possible. Watch for an announcement of availability on [AADAP's website](#).

Progress update from the AFS/FCS Working Group on Aquaculture Drugs, Chemicals, and Biologics (WGADCB): The WGADCB held a meeting on 28 February 2010 in San Diego, California USA, in conjunction with the AQUACULTURE 2010 conference. The meeting was lead by WGADCB co-chairs Jim Bowker, Mark Gaikowski, Lester Khoo, Randy MacMillan, Steve Sharon, and Jesse Trushenski, and was well-attended by industry, academic, and agency stakeholders. The primary agenda items were projects that the WGADCB has initiated, including revising the [Guide to Drug, Vaccine, and Pesticide](#)



[Use in Aquaculture](#), participating in an [American Fisheries Society](#) (AFS) congressional briefing, and involvement with the drafting of an AFS Policy Statement.

During the previous WGADCB meeting in Little Rock, AR, the group discussed the need to revise and update the [Guide to Drug, Vaccine and Pesticide Use in Aquaculture](#) (Guide). Originally intended to be the 'bible' for end-users of drugs, vaccines, and pesticides in aquaculture, the Guide is still widely accessed, but is not providing up-to-date information in a way that resonates with 'Joe Fish Farmer.' Following a pre-meeting conference call and the ensuing discussion in San Diego, the WGADCB has decided to undertake a comprehensive revision of the Guide. The plan is to create an essentially new electronic document that will fulfill the need to provide aquaculturists with practical, pertinent information about what compounds are available to them and how they can use them legally and effectively. Co-chairs Jesse Trushenski, Randy MacMillan, Mark Gaikowski, Jim Bowker, and Lester Khoo along with Dave Straus have agreed to assist with the revision process, and this team will regroup soon to initiate action items identified during the meeting.

The AFS often gives educational seminars on issues related to fisheries and fisheries policy to provide background information and context to congressional staffers. The WGADCB, with support from the AFS - Fish Culture Section, has been approved to develop a briefing on the status of the approval process and the need for additional approved aquaculture drugs for use in the public and private sectors. The purpose of this seminar is to draw attention to the critical need for additional approved drugs, identify the major limiting factors in gaining new approvals, and propose strategies and solutions to improve the drug approval process. During the February WGADCB meeting, several major limitations were identified, including the data requirements involved in new aquatic animal drug approvals, the availability of funding to generate the needed data, and changing agency priorities and disengaging of federal entities from the approval process. During the WGADCB-sponsored "Spawning Aids Forum" which followed the "Advances in Broodstock Management" symposium at AQUACULTURE 2010, additional limitations were identified, such as the absence of a risk management-based framework for aquaculture drug approvals and failure to effectively utilize peer-reviewed literature. These issues and their consequences will be the major thrust of the briefing, which is being scheduled for later this year. Co-chairs Jim Bowker and Randy MacMillan will present the briefing, and are leading a team of

WGADCB participants to craft the message they will be delivering on our behalf on Capitol Hill.

The AFS - Fish Culture Section has initiated the development of an AFS Policy Statement on the need for an immediate release sedative/anesthetic in fisheries. AFS Policy Statements are documents that state the position of the AFS on a given issue or topic. Because they carry the weight of the 9000+ fisheries professionals that belong to AFS, they can be effective tools in informing policy-makers of issues and constraints in the fisheries disciplines. An inter-disciplinary expert panel (including several WGADCB co-chairs) has been assembled to draft a document outlining the inadequacy of current sedative/anesthetic options and the consequences of not having access to an approved compound for immediate release. The goal is to create a sound, science-based argument for the approval of one of the candidate immediate-release sedatives (benzocaine or eugenol) in an expedient manner. The document is currently being drafted, and once complete, it will be provided to the WGADCB for input and comment prior to being submitted to the AFS Resource Policy Committee for review.

It has been an active time for the WGADCB — please see the [meeting minutes](#) for more detail on these projects and other activities discussed in San Diego. We are poised to make considerable progress on each of these projects before the next scheduled meeting, during the 16th Annual USFWS Aquaculture Drug Approval Coordination Workshop. Stay tuned to the AADAP website for updates, including the WGADCB meeting date/time and agenda.

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

Review of the Aquaculture Therapeutic Drugs Session at AQUACULTURE 2010: The first Therapeutic Drug Research special session was organized and moderated by Jim Bowker (AADAP) and Dave Straus (USDA/ARS, Stuttgart National Aquaculture Research Center) and convened at Aquaculture America 2003 in Louisville, KY. Since then, the special session has been held annually, the latest being at AQUACULTURE 2010 in San Diego, California USA. At this year's session there were 12 presentations on recent research covering topics ranging from the safety of Aquaflor[®] to sunshine bass, to comparing chemical treatments for the control of fungi on catfish eggs, to evaluating the efficacy of an iodophor to control VHS on fish eggs. In addition, two excellent presentations were given by students from [Viterbo University](#) (LaCrosse, Wisconsin USA) summarizing feeding



response and catchability of fish following sedation by benzocaine or eugenol. The number of folks in the audience ranged from about 30 to 50 throughout the session. These numbers are pretty consistent with what we've seen over the last few years. Based on the interest in the session, we'll continue to organize and moderate the Therapeutic Drug Research special session at future [World Aquaculture Society](#) conferences.

Two new AADAP "Drug Research Information Bulletins" (DRIBs) published and now available:

The most recent DRIBs include:

1. "Efficacy PEROX-AID® (35% Hydrogen peroxide) to Control Mortality of Fingerling Bluegill Diagnosed with External Columnaris Disease," and
2. "Efficacy of AQUAFLO® (50% Florfenicol) to Control Mortality in Largemouth Bass Diagnosed with Systemic Columnaris Disease."

These two DRIBs, and all previously published DRIBs, can be found on the AADAP Website under Research Program/Publications or by [clicking here](#).

These short-format documents (2 pages maximum) are intended to provide readers with information about AADAP research activities in a concise format, which as such, may not normally be suitable for peer-review publication.

AFS-AADAP - Aquaculture Drug-use Guidance

Poster Update: Since 2008 when AADAP, the American Fisheries Society's (AFS) Fish Health and Fish Culture Sections, and FDA's Center for Veterinary Medicine (CVM) first began the distribution of the poster entitled: "A Quick Reference Guide to: Approved Drugs for Use in Aquaculture" approximately 1,600 posters have been placed in the hands of private and public-sector aquaculturists from the USA and several other countries. Recently a new batch was printed by CVM and distributed by CVM and AFS at AQUACULTURE 2010 in San Diego, California USA. AADAP still has approximately 100 left and would be happy to send one to anyone for the asking. These may be the last of this edition, given that we anticipate at least one new drug will be approved or one new label claim will be added to an existing approved drug in the near future. To obtain your free copy, [click here](#).

Suggested revisions to the Veterinary Feed

Directive (VFD) regulations may be sought: During the recent AQUACULTURE 2010 meeting in San Diego, California USA, comments were made by staff of FDA's Center for Veterinary Medicine (CVM) suggesting that CVM may be open to publicly-recommended revisions to the regulations governing VFD drugs. Since the Animal Drug Availability Act (ADAA) was passed as an amendment to the federal Food, Drug and Cosmetic Act

(FD&C) in 1996, difficulties have arisen especially relative to the narrowly defined legal use of VFD drugs. It appears that CVM has become aware of such concerns, and may be seeking suggestions on how best to resolve these issues. Presumably, such suggestions will be sought via a Request for Public Comment to be published in the Federal Register. Access and search the Federal Register by [clicking here](#).

AADAP DRUG UPDATES

General:

In the past, the winter season has been a time for the AADAP research team to write up final study reports for submission to CVM, prepare draft reports for publication in peer-reviewed and gray literature, and to get ready for spring and the next go-round of therapeutic drug studies. This winter has been a little different. We've been up to the top of our waders developing research protocols and conducting studies. Below is an overview of what's been happening since the last Newsletter.

17 α -Methyltestosterone (17MT) Update:

17MT Mini-session held at AQUACULTURE 2010:

As has been the case for the past couple years, the small core group of tilapia researchers, tilapia producers and funding organizations met to review the current status of 17MT activities focused on gaining U.S. Food and Drug Administration (FDA) approval for its use in tilapia production. Four of nine components of the major New Animal Drug Application (NADA) technical sections remain to be completed, with scheduled completion date for the final one in March 2011. FDA's review of these components are expected to be completed by September 2011. Several minor technical sections likewise remain to be completed, but are dependent upon the successful completion of the major technical sections. Final FDA approval hopefully will come mid to late 2012. Although work obviously remains to be completed, if viewed within the general context of the time, effort, and funding it requires to get aquaculture drugs approved, we are in fact getting very close! To view an updated tabular/graphic status report of activities, [click here](#).

35% PEROX-AID® (hydrogen peroxide) Update:

Pilot efficacy studies on the monogenetic

trematode *Gyrodactylus salmonis*: With help from Ken Peters ([USFWS Bozeman Fish Health Center](#)) and the crew at the [Ennis National Fish Hatchery](#) (Ennis, Montana USA), AADAP's Miranda Dotson has conducted a number of pilot studies to evaluate the effectiveness of hydrogen peroxide to control infestations of *G. salmonis* on rainbow trout broodfish. Virtually the entire staff, at one point or another, has traveled over to the hatchery to help Miranda evaluate hydrogen peroxide dose/duration combinations that



reduce parasite densities to zero, techniques to reproducibly enumerate parasite densities, and how best to deal with the typical logistical constraints of conducting this type of study at a hatchery. In a nutshell, groups of infested fish have been treated with 50 or 100 mg per L hydrogen peroxide for 30 or 60 min. In all trials to date, two days after a single treatment, no parasites were found on the wet mounts of skin scrapes from treated fish. The crew at Ennis has been more than helpful, has provided us with test tank space and has set aside fish for further pilot tests. We're planning on getting out to Ennis one more time to nail down the effectiveness of 50 and 100 mg per L hydrogen peroxide administered for the shorter duration (e.g., 30 min). As the current window of opportunity (at least pathogen-wise) at Ennis is beginning to wane, pivotal field efficacy trials at the hatchery are scheduled for late summer/early fall. In the meantime, Miranda has taken the lead on developing the research protocol, which is progressing like most protocols....slowly and deliberately.

AQUAFLO[®] (florfenicol) Update:

New efficacy protocol: As many of you likely know, we have been conducting pivotal field efficacy trials to evaluate the effectiveness of florfenicol to control mortality caused by a variety of pathogens in a variety of freshwater finfish species for many years. In spite of the fact that all studies have been conducted under a CVM-approved research protocol, we thought it might be a good idea to revise the protocol in order to incorporate procedures, methods, and data collection forms that have been improved upon during the last 10 yrs. To make a long story short, at the end of December 2009 we received CVM concurrence on a new/updated research protocol to evaluate the effectiveness of AQUAFLO[®] (50% florfenicol; Type A Medicated Article) administered in feed to control mortality caused by pathogens susceptible to florfenicol in freshwater fish. All AQUAFLO[®] effectiveness studies conducted in the future will be conducted under this protocol.

Warmwater efficacy studies: In the last Newsletter, we reported that we submitted a Final Study Report to CVM entitled "Use of AQUAFLO[®] to Control Mortality Caused by Columnaris in Largemouth Bass." We're happy to let you know that at the end of January 2010, CVM accepted the study as pivotal. Acceptance of this study was the first step in completing the effectiveness technical section for the following claim:

"Use AQUAFLO[®] to control mortality caused by columnaris in all warmwater finfish."

The second step in this process (i.e., an all warmwater finfish claim) was to complete a similar study to evaluate the effectiveness of AQUAFLO[®] to control mortality caused by columnaris in bluegill. The in-life

phase of this study was completed in December 2009. In this study, we were able to 1) confirm via PCR that the pathogen was indeed *Flavobacterium columnare*; 2) verify 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); 3) document that general fish behavior and feeding behavior was considered normal; and 4) demonstrate that mean percent cumulative mortality in treated tanks (19%) was significantly lower than that in control tanks (38%). The Final Study Report was submitted to CVM's Aquaculture Team on 2 February 2010, and we anticipate hearing back from them in early August 2010...hopefully with more good news!

Once again, we thank Mike Matthews and the staff at the [Florida Bass Conservation Center](#) for conducting the in-life phase of the study and Molly Bowman and Miranda Dotson (USFWS-AADAP) for taking care of all the prestudy activities and developing the Final Study Report.

AQUAFRIN[™] (lauryl methyl pyriferin) update:

Preliminary work on AquaFrin[™]: In the last issue of the AADAP Newsletter we reported that preliminary studies on AquaFrin[™], a photodynamic porphyrin compound, had been initiated. To date AADAP, with on-site assistance from Carlos Martinez ([DC Booth Historic National Fish Hatchery and Archives](#)) and Jerry Bommer ([Frontier Scientific, Inc.](#)) has completed a series of range-finding trials evaluating the effect of treatment dosage, treatment duration, and treatment light-exposure intensity on healthy rainbow trout (5-inch and 1-inch fish). Hence, these trials were in effect designed to be preliminary target animal safety trials. In short, results to date have indicated that our initially proposed target dose(s) may have been a bit on the "high-side," as a number of adverse effects of treatment, including mortality, were observed. At this time, work is being planned for additional studies to better define/establish a safe treatment regimen. Parallel studies are also being conducted by Dr. Giulio Jori at the [University of Padova](#), Padova, Italy. Once this work is completed, effectiveness studies to control saprolegniasis will be initiated.

Terramycin[®] 200 for Fish (oxytetracycline dihydrate) Update:

Skeletal marking for all salmonids: In the previous couple of Newsletters we've reported on a pivotal study conducted by Dan Carty and Miranda Dotson to demonstrate 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. Well...we heard back from CVM at the end of January 2010, and (as hoped) the Final Study Report



was accepted as pivotal. This information has been provided to the sponsor ([Phibro Animal Health](#)), and they are committed to move forward and request that the approved label claim for this product to mark skeletal tissue of fish be expanded from Pacific salmon (only) to all freshwater-reared salmonids.

Hot off the press: Recently AADAP developed a new/updated research protocol to evaluate the effectiveness of Terramycin[®] 200 for Fish administered in feed to control mortality caused by susceptible pathogens in a variety of freshwater finfish. Similar to the new AQUAFLO[®] research protocol (see p. 6), this effort was undertaken in order to incorporate procedures, methods, and data collection forms that have been improved upon during the last 10 yrs. The protocol was written by Niccole Wandelaar, followed the same format as the new AQUAFLO[®] protocol, and was submitted to CVM for review on 12 March 2010. Due to the fact that we recently obtained CVM-concurrence on the AQUAFLO[®] protocol, we anticipate that we will also obtain CVM-concurrence on the Terramycin[®] 200 for Fish effectiveness protocol (thank goodness for [End Review Amendments!](#)).

Chloramine-T (HALAMID[®] AQUA) Update:

Potential coolwater studies: Although there is nothing “solid” to report about activities related to an initial approval for chloramine-T, rest assured we are still “runnin’ the efficacy traplines.” Doug Aloisi (Project Leader; [Genoa National Fish Hatchery](#); Genoa, Wisconsin USA) has recently stepped-up and offered to help us conduct a study to evaluate the effectiveness of chloramine-T to control mortality due to columnaris in yellow perch (*Perca flavescens*) some time in June 2010. Similarly, Brian Niewinski ([Pennsylvania Fish and Boat Commission](#), [Benner Springs Hatchery](#)) has also stepped-up and agreed to launch a similar study with another (yet to be officially determined) coolwater fish species. This is big news! We have been beating the bushes for several years trying to find a collaborator(s) to help us conduct such a study on a representative coolwater fish species. If we’re able to pull off just one of these planned studies (and of course assuming we do so in a manner acceptable by CVM), we will have completed the elusive effectiveness technical section for an all coolwater freshwater finfish claim. Stay tuned.

Immediate Release Fish Sedative Update:

Pivotal protocols accepted by CVM: In previous issues of the AADAP Newsletter, we’ve described the need for an immediate release fish sedative for fisheries professionals involved in fish culture and fisheries management. In anticipation that efficacy data will be required for one or more potential candidate drugs (i.e., benzocaine or eugenol), we

developed research protocols to evaluate the effectiveness of AQUI-S[®] E (eugenol) and BENZOAK[®] (benzocaine) to sedate a variety of freshwater-reared finfish to a handleable stage. We recently heard back from CVM that they had concurred with both protocols. So...once a few more pieces are put into place (e.g., CVM-acceptance of analytical methods to verify the concentration of the active ingredient in water), we’re in pretty good shape to start evaluating the effectiveness of potential immediate-release sedatives.

SLICE[®] Update:

In the last newsletter, we described the “process” we were going through to obtain CVM concurrence for a protocol to evaluate the effectiveness of SLICE[®] (0.2% emamectin benzoate) to control infestations of the parasitic copepod *Salmincola* spp. on freshwater-reared salmonids. It turns out the second-time-around was a charm. AADAPs’ most recent SLICE[®] protocol received CVM concurrence on 24 March 2010. Now that the difficult part (obtaining protocol concurrence) is out of the way, it’s time to have some fun conducting the trials. We won’t worry about making sense out of our fun (e.g., drafting FSRs) until such time as necessary! As usual, stay tuned.

FINS & TAILS, BITS & BOBBERS

Status update for oxytetracycline (OTC) injectable (Liquamycin[®] LA-200[®]) INAD 9027:

At the encouragement of FDA, FWS-AADAP has determined that the OTC injectable (Liquamycin[®] LA-200[®]) INAD #9027 will be terminated in the very near future. Although there are a number of reasons for this decision, the bottom-line is that after 15 years of very limited use under INAD authorization, it has become difficult for FDA (and us for that matter) to visualize this investigational drug ever receiving an approved label claim for use in finfish. Furthermore, and as we were recently reminded by FDA, it is important to note that OTC injectable products can be used legally as an extra-label drug when prescribed by a veterinarian.

AQUI-S[®] E to be distributed by Western Chemical, Inc:

AQUI S[®] E (active ingredient eugenol) will be distributed by [Western Chemical Inc.](#), and will be available in either 100 ml or 1 L quantities. Please contact Jason Montgomery (phone: 800-283-5292 ext 4175; email: jasonm@wchemical.com) to order this product. For more information about participation on this INAD (i.e. study protocol, forms, etc.) please go to the AQUI-S[®] E Fact Sheet page (<http://www.fws.gov/fisheries/aadap/AQUIS-E.htm>) located on the AADAP website.

BENZOAK[®] to be distributed by Frontier Scientific, Inc./ACD Pharmaceuticals AS: BENZOAK[®] (active ingredient benzocaine) will be distributed by [Frontier Scientific, Inc./ACD Pharmaceuticals AS](#), and will be



available in either 250 ml or 1 L quantities. Please contact Ryan Parker (phone: 435-753-1901; email: rparker@frontiersci.com) to order this product. For more information about participation on this INAD (i.e. study protocol, forms) please go to the BENZOAK[®] Fact Sheet page (<http://www.fws.gov/fisheries/aadap/benzoak.htm>) located on the AADAP website.

Delay of the Website Automation Program for INAD Participants: In the last issue of the [AADAP Newsletter](#), we announced that the AADAP Office was excited about the anticipated (February 2010) test-launch of the website automation program (on-line data reporting) for National INAD Program participants. However, due to unexpected delays in the development of the foundation database for the program, the test-launch has been put on temporary hold. Unfortunately, this means that for the time being normal INAD paperwork activities must proceed as usual. Although we hesitate to make more promises we may not be able to keep, we now *anticipate* that the website automation program will be available for a test-launch in approximately 6 months. Stay tuned!

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 and 2010. 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 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 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

- Caipang, C, et al. 2009. *In vivo* modulation of immune response and antioxidant defense in Atlantic cod, *Gadus morhua*, following oral administration of oxolinic acid and florfenicol. *Comparative Biochemistry and Physiology, Part C: Toxicology & Pharmacology* **150(4):459-464**.
- Das, A, et al. 2009. Antimicrobial resistance and *in vitro* gene transfer in bacteria isolated from the ulcers of EUS-affected fish in India. *Letters in Applied Microbiology* **49(4):497-502**.

- Faroongsarn, D, et al. 2009. Hepatopancreatic and muscular distribution of oxytetracycline antibiotics in farmed pacific white shrimp (*Penaeus vannamei*): a physiological-based pharmacokinetic model approach. *Aquaculture Research* **41(1):143-152**.
- Gaikowski, M, et al. 2010. Depletion of florfenicol amine, marker residue of florfenicol, from edible fillet of tilapia (*Oreochromis niloticus* x *O. niloticus* and *O. niloticus* x *O. aureus*) following florfenicol administration in feed. *Aquaculture* **301(1-4):1-6**.
- Hesami, S, et al. 2010. Antimicrobial susceptibility of *Flavobacterium psychrophilum* from Ontario. *Journal of Aquatic Animal Health* **22(1):39-49**.
- Kayis, S, et al. 2009. Bacteria in rainbow trout (*Oncorhynchus mykiss*) in the southern Black Sea region of Turkey - a survey. *Israeli Journal of Aquaculture/Bamidgeh* **61(4):339-344**.
- Ransangan, J, and Mustafa, S. 2009. Identification of *Vibrio harveyi* isolated from diseased Asian sea bass *Lates calcarifer* by use of 16S ribosomal DNA sequencing. *Journal of Aquatic Animal Health* **21(3):150-155**.
- Ruangpan, L, and Chawepark, T. 2009. Monitoring antimicrobial usage in marine shrimp farms. *Israeli Journal of Aquaculture/Bamidgeh* **61(3):287** (abstract of oral presentation).
- Seifrtova, M, et al. 2009. An overview of analytical methodologies for the determination of antibiotics in environmental waters. *Analytica Chimica Acta* **649(2):158-179**.
- Wang, N, et al. 2009. Adverse effects of enrofloxacin when associated with environmental stress in Tra catfish (*Pangasianodon hypophthalmus*). *Chemosphere* **77(11):1577-1584**.
- Yu, D, et al. 2009. Effects of administration mode of antibiotics on antibiotic resistance of *Enterococcus faecalis* in aquatic ecosystems. *Chemosphere* **76(7):915-920**.

Parasite and Fungus Control

- Bravo, S, et al. 2010. Effectiveness of hydrogen peroxide in the control of *Caligus rogercresseyi* in Chile and implications for sea louse management. *Aquaculture* **301(1-4):in press**.
- Liu, J, and Yang, G. 2009. Changes in copper content of allogynogenetic silver crucian carp after application of copper sulfate to fishponds. *Israeli Journal of Aquaculture/Bamidgeh* **61(4):351-355**.
- Mischke, CC, et al. 2009. Impact of copper sulfate on plankton in channel catfish nursery ponds. *Journal of the World Aquaculture Society* **40(1):122-128**.
- Pedersen, LF, et al. 2009. Peracetic acid degradation and effects on nitrification in recirculating



- aquaculture systems. *Aquaculture* **296(3-4):246-254**.
- Polinski, M.P., et al. 2010. Assessment of formalin and hydrogen peroxide use during egg incubation of North American burbot. *North American Journal of Aquaculture* **72(2):111-117**.
- Shaikh, B, et al. 2009. Residue depletion of albendazole and its metabolites in the muscle tissue of largemouth and hybrid striped bass after oral administration. *Journal of Chromatography A*. **1216:8173-8176**.
- Shinn, AP, et al. 2009. Mechanical control of *Ichthyophthirius multifiliis* Fouquet, 1876 (Ciliophora) in a rainbow trout hatchery. *Aquacultural Engineering* **41(3):152-157**.
- Straus, DL, et al. 2009. Laboratory dose confirmation of copper sulfate for treating fungus on channel catfish eggs. *North American Journal of Aquaculture* **71(4):333-338**.
- Straus, DL, et al. 2009. Optimizing copper sulfate treatments for fungus control on channel catfish eggs. *Journal of Aquatic Animal Health* **21(2):91-97**.
- Wagner, EJ, et al. 2010. The safety and effectiveness of various hydrogen peroxide and iodine treatment regimens for rainbow trout egg disinfection. *North American Journal of Aquaculture* **72(2):34-42**.
- Walker, AB, et al. 2010. Surface disinfection and removal of adhesiveness from rainbow smelt eggs. *North American Journal of Aquaculture* **72(2):158-163**.
- Ikeda, Y, et al. 2009. Method of ethanol anaesthesia and individual marking for oval squid (*Sepioteuthis lessoniana* Ferussac, 1831 In Lesson 1830-1831). *Aquaculture Research* **41(1):157-160**.
- Iversen, M, and Eliassen, RA. 2009. The effect of AQUI-S™ sedation on primary, secondary, and tertiary stress responses during salmon smolt, *Salmo salar* L., transport and transfer to sea. *Journal of the World Aquaculture Society* **40(2):216-225**.
- Kilgore, KH, et al. 2009. Investigational use of metomidate hydrochloride as a shipping additive for two ornamental fishes. *Journal of Aquatic Animal Health* **21(3):133-139**.
- Meinertz, JR, and Schreier, TM. 2009. Depletion of isoeugenol residues from the fillet tissue of AQUI-S™ exposed rainbow trout (*Oncorhynchus mykiss*). *Aquaculture* **296(3-4):200-206**.
- Noble, WJ, et al. 2009. Application of anaesthetics for sex identification and bioactive compound recovery from wild *Dicathais orbita*. *Journal of Experimental Marine Biology and Ecology* **380(1-2):53-60**.
- Sattari, A, et al. 2009. Comparison of electroanesthesia with chemical anesthesia (MS222 and clove oil) in rainbow trout (*Oncorhynchus mykiss*) using plasma cortisol and glucose responses as physiological stress indicators. *Asian Journal of Animal and Veterinary Advances* **4(6):306-313**.
- Saydmohammed, M, and Pal, AK. 2009. Anesthetic effect of eugenol and menthol on handling stress in *Macrobrachium rosenbergii*. *Aquaculture* **298(1-2):162-167**.

Sedation or Anesthesia

- Anraku, K, et al. 2009. Optimum concentration of magnesium (Mg²⁺) to anesthetize octopus *Octopus vulgaris*. *Memoirs of the Faculty of Fisheries, Kagoshima University* **58:15-19** (English abstract).
- Cook, DG, et al. 2009. Effect of harvest treatment on biochemical properties of farmed Chinook salmon (*Oncorhynchus tshawytscha*) tissue during frozen and thawed storage. *Journal of Food Science* **74(7):C543-C548**.
- Crosby, TC, et al. 2010. Plasma cortisol, blood glucose, and marketability of koi transported with metomidate hydrochloride. *North American Journal of Aquaculture* **72(2):141-149**.
- Forgan, LG, and Forster, ME. 2010. Oxygen consumption, ventilation frequency and cytochrome c oxidase activity in blue cod (*Parapercis colias*) exposed to hydrogen sulphide or isoeugenol. *Comparative Biochemistry and Physiology, Part C: Toxicology & Pharmacology* **151(1):57-65**.

Skeletal Marking

- Fontagne, S, et al. 2009. Effects of dietary phosphorus and calcium level on growth and skeletal development in rainbow trout (*Oncorhynchus mykiss*) fry. *Aquaculture* **297(1-4):141-150**.
- Purcell, SW, and Blockmans, BF. 2009. Effective fluorochrome marking of juvenile sea cucumbers for sea ranching and restocking. *Aquaculture* **296(3-4):263-270**.

Spawning Hormones and Gender Manipulation

- Navarro-Martin, L, et al. 2009. Balancing the effects of rearing at low temperature during early development on sex ratios, growth and maturation in the European sea bass (*Dicentrarchus labrax*). *Aquaculture* **296(3-4):347-358**.

Miscellaneous

- Davis, MW. 2010. Fish stress and mortality can be predicted using reflex impairment. *Fish and Fisheries* **11(1):1-11**.



Oplinger, RW, and Wagner, EJ. 2009. Toxicity of common aquaculture disinfectants to New Zealand mud snails and mud snail toxicants to rainbow trout eggs. *North American Journal of Aquaculture* **71** (3):229-237.

Reimschuessel, R, et al. 2009. Residue depletion of melamine and cyanuric acid in catfish and rainbow trout following oral administration. *Journal of Veterinary Pharmacology and Therapeutics*. **33:172-182**.

Schillaci, D, et al. 2010. Antimicrobial and antistaphylococcal biofilm activity from the sea urchin *Paracentrotus lividus*. *Journal of Applied Microbiology* **108(1):17-24**.

Smith S, et al. 2009. Simultaneous screening and confirmation of multiple classes of drug residues in fish by liquid chromatography-ion trap mass spectrometry. *Journal of Chromatography A*. **1216:8224-8232**.

USGS's CORNER

17 α -Methyltestosterone (17MT): US Geological Survey's Upper Midwest Environmental Sciences Center (UMESC), in collaboration with [CANTEST Ltd.](#) is coordinating an analytical method transfer study to complete the Chemistry, Manufacturing and Controls Technical Section for 17MT. The laboratory portion of the familiarization phase was recently completed. The final report describing the results of the familiarization phase has been submitted for quality assurance review. CANTEST is now poised to conduct the definitive laboratory portion of the study which is scheduled to begin in April 2010. This study was funded through grants from the North-Central and Western Regional Aquaculture Centers.

Chloramine-T: To address one of the remaining data needs for the approval of HALAMID[®] AQUA, UMESC staff modified the analytical method for para-toluenesulfonamide (p -TSA), the marker residue of chloramine-T. UMESC staff received FDA-concurrence on a study protocol to validate the new analytical method procedures. UMESC staff completed all laboratory assays with p -TSA fortified tissue from six fish species. Laboratory assays with fillet tissue from six fish species exposed to HALAMID[®] AQUA are on-going and will be completed in April 2010. Data generated during this study will be reviewed by the FDA to determine if the detection limit of the modified analytical method is less than or equal to 20 parts per billion, an FDA proposed tolerance limit for p -TSA in fish fillet tissue.

Sedatives: A protocol describing work to develop an analytical method to detect eugenol residues in the fillet of freshwater fish has been approved. Developmental

work is underway. High performance liquid chromatography parameters to accurately determine eugenol concentrations in working solutions have been established. This study is being funded through a Multi-State Conservation Grant from the Association of Fish and Wildlife Agencies.

Hydrogen peroxide: UMESC submitted pivotal and supportive effectiveness data to FDA regarding the use of 35% PEROX-AID[®] to control *Gyrodactylus salmonis* on coaster brook trout (*Salvelinus fontinalis*). Application of hydrogen peroxide at 100 mg per L for 30 min or 150 mg per L for 15 min with or without a sodium chloride immersion bath pre-treatment significantly reduced parasite infestation density. The final study reports were submitted to FDA in February 2010.

Iodophor disinfection: UMESC and USFWS [La Crosse Fish Health Center](#) tested the effectiveness of using iodophor disinfection in walleye (*Sander vitreus*) and northern pike (*Esox lucius*) eggs and found that it eliminated active virus from fertilized eggs. Iodophor disinfectant solutions contain iodine formulated for use on fish eggs. The researchers also found that although some of the disinfection treatments reduced hatch, iodophor treatment at 90 minutes after fertilization did not alter egg hatch or fry development. For more information about this subject, as well as recommendations on the disinfection process, see the new USGS Fact Sheet on-line at <http://pubs.usgs.gov/fs/2009/3107/>. Funding for this research was provided by the USGS and the North Central Regional Aquaculture Center through grant number 2008-38500-19157 from the U.S. Department of Agriculture; Cooperative State, Research, Education and Extension Service. The iodine used during egg disinfection, OVADINE[®], was donated by [Western Chemical Inc.](#), Ferndale, Washington.

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

USDA's CORNER

17 α -Methyltestosterone (17MT) target animal safety studies: We (Harry K. Dupree – Stuttgart National Aquaculture Research Center) have finally received funding for parts of a GLP compliant target animal safety study to evaluate the safety of 17MT administered in feed to tilapia; we will again be working with the folks at AADAP on this study. A preliminary trial was completed in October and November 2009 to establish a larval tilapia growth curve to predict feed amounts to be administered to fish each day of the study. The in-life phase of the 28 day study is tentatively scheduled for May 2010. After the in-life phase, the fish tissues will be sent to AADAP to be processed and evaluated



histologically. Our collaborations with AADAP continue to be beneficial for the overall drug approval project and have helped to speed things along.

Channel catfish - columnaris studies: Research continues with the high-density, low-flow columnaris disease method and we have had reliable success in producing columnaris infections in catfish. We are preparing to devote the next few months to our egg fungus studies with various therapeutants, so our columnaris research will continue in the fall.

Channel catfish eggs - CuSO₄ studies: A Final Study Report for the copper sulfate target animal safety study on channel catfish eggs was submitted to FDA/CVM on 1 December 2009. A Final Study Report for the effectiveness range-finding (supportive) studies of CuSO₄ on saprolegniasis of channel catfish eggs is written and should be submitted in April 2010, with pivotal dose-confirmation reports to follow.

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.

Recently held meetings

Flavobacterium 2009; 21-23 September 2009; Paris, France - Proceedings available: Last year's



Flavobacterium 2009

conference brought together 84 participants from

19 countries. Fifty two oral communications were presented on a variety of topics including: fish pathology, bacterial ecology, genomics, biotechnology, and vaccinology. The organizers have made available many of the presentation in the form of expanded abstracts, and these can be accessed by [clicking here](#) or copying the following URL into your browser https://colloque2.inra.fr/flavobacterium_eng/actualites/programme_scientifique_proceedings. When viewing the Proceedings, accessible abstracts are those with the author or authors' names underlined.

Upcoming meetings

8th International Symposium on Viruses of Lower Vertebrates; 26-29 April 2010; Santiago de Compostela, Spain: This international symposium, which has been held every 3-4 years, is being hosted



this year by the [University of Santiago de Compostela](#) on its campus. The event will give scientists interested in viruses of amphibians, reptiles and fish the opportunity to discuss recent

research findings in a fruitful, friendly atmosphere. The scientific program will include sessions on virus characterization and strain differentiation,

pathogenesis, immunity, structural biology, molecular biology, virus evolution and emerging viruses of lower vertebrates, in addition the conference organizers would like to focus on validation and standardization of diagnostic methods. For complete information, including registration, hotel accommodations, planned program, local information, etc. refer to the conference website: <http://www.usc.es/congresos/8thISVLV/index.php>.

41st Annual International Association of Aquatic Animal Medicine Conference and Meeting; 8-13 May 2010; Vancouver, British Columbia, Canada:



This year's meeting is being held at the [Vancouver Marriott Pinnacle Downtown Hotel](#), with some program events being scheduled to occur at the [Vancouver Aquarium](#). Detailed information on registration, abstract preparation, hotels, associated workshops, etc. can be found

on the conference website: <http://www.iaaam.org/displayconvention.cfm>.

Aquaculture Canada^{OM} 2010 & Cold HarvestTM 2010; 16-19 May 2010; St. John's, Newfoundland,



Canada: This year's conference and tradeshow is being held at the Delta St. John's Hotel and Conference Centre. The theme is "Successful partnerships for a sustainable future." All are being invited to join this national forum on the business, science and technology of Canadian

and Newfoundland aquaculture. A comprehensive technical, industry-oriented program is being prepared and developed. Special symposia and workshops will highlight achievements by various sectors of the Canadian and Newfoundland aquaculture industries. In addition, an extensive social program will provide opportunity for valuable networking and information exchange. Tours of the local industry will be available. The conference will be co-hosted by the Province of Newfoundland and Labrador, Department of Fisheries and Aquaculture. For more information visit the conference website by [clicking here](#).

Aquaculture UK; 19-20 May 2010; Aviemore,

Scotland, UK: This year's conference is being held at the newly re-developed Macdonald Aviemore Highland Resort located in the heart of the Cairngorms National Park. Aquaculture UK 2008 attracted over 1000 visitors from 15 countries. This year's organizers are



still sourcing speakers and subject titles for the 2010 sessions, but expect a full program. Complete information on the conference including venue, accommodations, registration, etc. can be obtained on the conference website

at: <http://www.aquacultureuk.com/index.php?c=home>.



Australasian Aquaculture 2010 International Conference and Trade Show; 23-26 May 2010; Hobart, Tasmania, Australia: The theme of this

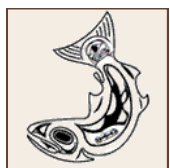


year's conference is "Keeping Pace with Change." Australasian Aquaculture 2010 is the joint international conference, trade show and series of associated events of the

[National Aquaculture Council](#) and the [Asian Pacific Chapter of the World Aquaculture Council](#). [Fisheries Research and Development Corporation](#) are sponsors of Australasian Aquaculture 2010. The conference is being held at the [Hotel Grand Chancellor](#) in Hobart. For detailed information such as registration forms, program, accommodations, etc. please refer to the conference website: <https://www.ghihotels.com/hgc/Hobart/hotels.aspx>.

35th Eastern Fish Health Workshop; 24-28 May 2010; Shepherdstown, West Virginia USA: The National Fish Health Research Laboratory (Kearneysville, WV) is proud to host the 35th Eastern Fish Health Workshop at the Clarion Hotel and Conference Center in Shepherdstown, West Virginia USA. Registration (5:30 – 8:00 PM) and evening sessions (8:00 – 10:00 PM) begin on Monday, 24 May, followed by three full day sessions, 25-27 May 2010. Our 35th Anniversary Banquet will be held on Thursday, May 27. There will also be a full day histopathology workshop on Friday, May 28 from 8:00 AM until 3:00 PM. The Workshop comprise eight special sessions, including the topics: East Meets West, Aquarium and Ornamental Animal Medicine:..., The Making of an Ugly Lobster, The Re-awakening of *Aeromonas hydrophila*..., Diseases of Coral and Other Reef Organisms, Aquatic Immunobiology..., The State of the Art of ISAV, and Cool Cases, Perplexing Problems, and Mysterious Maladies. For further information [click here](#).

2010 Western Fish Disease Workshop; 23-24 June 2010, Corvallis, Oregon, USA: This year's workshop is being held at the [LaSells Stewart Center](#) on the campus of [Oregon State University](#). On 22 June there will be a half-day continuing education class taking place over at ALS. The workshop will follow on 23 & 24 June at the LaSells Stewart Center. For more information, including hotels, registration forms, area attractions, agenda, etc. refer to the conference website: <http://oregonstate.edu/conferences/westernfishdisease/index.html>.



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/>.

2nd International Congress on Aquatic Animal Health Management & Diseases; 26-27 October 2010; Tehran, Iran: This year's congress is being held



in Tehran, Iran and is being organized by the Veterinary Council I.R. Iran. The congress will include presentations by international researchers, organized in several session topics including:

1. Diseases, Prevention and Treatment,
2. Nutritional Health Management,



3. Water Quality Management, and
4. Health Management in Farms

For more information refer to the congress website:
<http://www.icaahmd.com/index.php>.

VIII International Symposium on Fish Parasites; 26-30 September 2011; Viña del Mar, Chile: This year's Symposium will be an important forum for the discussion and distribution of new findings in this rapidly expanding field. The theme of the conference is "Fish Parasitology: from Classical Taxonomy to Holistic Approach". The organizers hope to develop an exciting

Due to the recent earthquakes in Chile, the fate of this conference is uncertain at this time.

scientific program that will provide an update in our field of research. They are sure that the diversity of themes in the dynamic field of fish parasitology will be the most favorable platform for strong and positive collaborations between fish parasitologists. An intense program is scheduled to include preliminary talks, mini symposiums, and oral presentations. Poster sessions will be an important aspect of 8th ISFP. Competitive awards for students and postdoctoral scientists from developing countries will be offered. In addition, a diverse and enjoyable program of social activities will also be provided in order to showcase the best of Chilean traditions and culture. See the conference website at: <http://www.8isfp.com/>.

ROZ'S CORNER

This is the last Roz's Corner because I am retiring on 1 May 2010 after 15 years as the National Coordinator for Aquaculture New Animal Drug Applications (NADAs).

We can all be proud of the progress we have made toward aquaculture drug approvals. In the past 15 years, we have basically equaled what we were able to accomplish in the previous 30 years of efforts. Collectively from 1995 to 2009, we gained 16 NADAs that included approvals for seven drugs (four of them new to aquaculture indicated with *) and 15 different label claims. The seven drugs that obtained original or supplemental NADA approvals include the following:

- *Chorionic gonadotropin (Chorulon[®])
- *Florfenicol (Aquaflor[®])
- Formalin (Parasite-S[®], Formalin-F[®], and Formacide-B[®])
- *Hydrogen peroxide (35% PEROX-AID[®])
- Oxytetracycline dihydrate (Terramycin[®] 200 for Fish)
- *Oxytetracycline hydrochloride (four products)
- Tricaine methanesulfonate (Tricaine-S[®])

Not only that, but we had first-time approvals for the control of mortality due to the following diseases: (1) bacterial gill disease, (2) external columnaris disease, (3) systemic columnaris disease, and (4) coldwater disease, and for the following species or groupings: (5) all freshwater-reared finfish, (6) all finfish eggs, (7) all freshwater-reared coolwater finfish and (8) all freshwater-reared salmonids.

In the near future, we should see first-time approvals for the control of mortality due to the following diseases: (1) bacterial kidney disease, (2) saprolegniasis for all freshwater-reared finfish, (3) streptococcosis, and (4) necrotizing hepatopancreatitis, for the control of sea lice control, and for production aids: (5) gender manipulation aid and (6) skeletal marking aid for all salmonids (both saltwater- and freshwater-reared), and for the following species or groupings: (7) hybrid striped bass, (8) tilapia, (9) walleye, and (10) freshwater-reared warmwater finfish. The nine drugs (five of them new to aquaculture indicated with *) nearing original or supplemental NADA approvals include the following:

- *Chloramine-T (Halamid Aqua[®])
- *Copper sulfate (Triangle Brand Copper Sulfate[®])
- *Emamectin benzoate (Slice[®])
- *Erythromycin thiocyanate (Aquamycin[®])
- Florfenicol (Aquaflor[®])
- Formalin (Parasite-S[®])
- Hydrogen peroxide (35% PEROX-AID[®])
- *17 α -methyltestosterone (Masculinizing Feed for Tilapia[®])
- Oxytetracycline dihydrate (Terramycin[®] 200 for Fish)

Under development are 15 drugs (six of them new) and 31 different label claims. The six new drugs include calcein (SE-MARK[®]), porphyrins (AquaFrin[®]), potassium permanganate (Cairox[®]), praziquantel (nondisclosable trade name), salmon gonadotropin releasing hormone analog (OVAPLANT[®]), and one sedative (either benzocaine (BENZOAK[®]) or eugenol (AQUI-S[®] E). In total, we have the opportunity of achieving additional approvals for 11 new drugs and 43 label claims if all the efforts underway result in approvals. This productivity would not have been possible without our collective efforts in response to the crisis in 1990 when FDA found drugs and chemicals at farms that were not properly labeled. We chose to find a solution and that was to gain funding for approval-oriented research on eight high priority aquaculture drugs. We proceeded to work together with FDA to determine data requirements and to help create the Minor Use and Minor Species Animal Health legislation that will form the basis of further



developments in the future to include grants to cover safety and effectiveness studies. Through the active leadership of FDA, other laws, regulations, and guidelines were put in place that help data generating entities and drug sponsors to move more actively and quickly toward aquaculture drug approvals. In addition, FDA added functions, positions, and processes that help the approval processes and progress. We also had the maturation of the data-generating partners who more fully understand the data requirements and the study designs needed for drug approvals. In addition, we were fortunate to gain 20 knowledgeable and engaged pharmaceutical and chemical company sponsors in these 15 years. In summary, we have come a long way toward gaining an adequate medicine chest for our domestic aquaculture industries.

International developments also led to clarification of the road map toward approvals. These include international harmonization of (1) study protocols through the [Organisation of Economic Cooperation and Development](#) guidelines, (2) technical requirements for drug approvals, and (3) antimicrobial sensitivity tests.

This is not to say that there have not been obstacles to these approvals. The main factor has been and always will be the lack of adequate and timely funding and/or committed sponsors to meet all the data requirements for approval. Other factors that have impeded progress toward aquaculture drug approvals include regulatory changes, study issues (e.g., unanticipated negative results, time frames, and costs), changes in study personnel and laboratory requirements, and outside forces.

Given everything, I feel I am leaving the aquaculture drug approval efforts in the United States in good hands. As for me, I have set up an LLC in case I do some consulting.

Good bye and good luck!!

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

CVM's NOTES

New Hire: We are very pleased to welcome a new member to the Aquaculture Drugs Team in the Office of New Animal Drug Evaluation at FDA's Center for Veterinary Medicine. Sarah Bembe joined the Aquaculture Drugs Team as a Consumer Safety Officer in December. Her first couple months at CVM have been quite interesting with all this snow nonsense! Sarah's background includes a Masters in Environmental Molecular Biology/ Biotechnology from the University of Maryland, other studies in

marine science, and work as a research assistant at the Center for Marine Biotechnology in Baltimore on the Chesapeake Bay blue crab restoration project.

MUMS Grants: FDA has a grants program to support the development of new animal drugs intended for minor species (which includes all finfish and shellfish) and minor uses in major species. The grant program was established by the Minor Use and Minor Species Animal Health Act of 2004. This is the second year Congress has appropriated funds for the grants. CVM hopes to be able to announce the Request for Applications for this year's funding soon on <http://Grants.gov/>. To be eligible, drugs must be designated through CVM's Office of Minor Use and Minor Species, studies must be conducted under an Investigational New Animal Drug (INAD) exemption and per a protocol (for the proposed study) that has been accepted by CVM's Office of New Animal Drug Evaluation. For further information on MUMS Grants, please click on this link (<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm064838.htm>) and/or contact Dr. Joan Gotthardt (email: joan.gotthardt@fda.hhs.gov, phone: 240-276-9331) in the Office of Minor Use and Minor Species.

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.

