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"

AADAP Aquatic Animal Drug Approval Partnership Program

Volume 6-3

AADAP NEWSLETTER

November 2010

2010 USFWS Aquaculture Drug Approval Coordination Workshop; "decompression" raft trip on the Yellowstone River

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WHAT'S SHAKIN'

2011 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 2011. All 2011 sign-up forms are available on our website by clicking here or at http://www.fws.gov/fisheries/aadap/SIGNUP.HTM. Please send completed sign-up forms to the AADAP Office by 31 Dec 2010. Invoices will be mailed out the end of January 2011. Fifteen (15) different INAD exemptions are open for enrollment.

16th Annual USFWS Aquaculture Drug Approval Coordination Workshop is history: The 2010 Workshop, held in our home base of Bozeman, Montana, hosted a few less attendees than in the past; 56 total all from the USA. Even though the numbers may have been slightly down, the representation was about as broad as one could ask for; 6 pharmaceutical firms (12 attendees), 7 state agencies, 5 federal agencies (20 attendees), 4 universities and 3 private firms. Of the pharmaceutical firms, one (Pennfield Animal Health) was a first time participant.

As in the past when the Workshop has been held in Bozeman, the attendees were offered, in addition to an excellent program of technical sessions, a variety of evening or afternoon activities, all of which would not have been possible had it not been for the generous donations of pharmaceutical sponsors. The Monday night welcome social was sponsored by Syndel Labs Ltd. and Western Chemical, Inc. Tuesday evening's picnic at beautiful Hyalite Reservoir was courtesy of Intervet/Schering-Plough Animal Health. Morning or afternoon break refreshments were provided by the support of BL Mitchell, Inc. and AQUI-S New Zealand Ltd. Thursday afternoon's raft trip was sponsored by Pennfield Animal Health and the picnic following the raft trip was sponsored by Bimeda. In addition to the aforementioned activities, which have been part of the routine when Bozeman is the venue, a new activity was added this year. The folks at Western Chemical, Inc. teamed up with Dan Carty from AADAP to host a 1/3/5 mile Fun Run/Walk (aka the "Trout Trot"). Although only about a dozen brave souls participated this year, it is sure to remain as part of the Workshop. Sorry for the name of the activity, but we just had to do it.

To all the sponsors, thank you so very much for your help!

For those not able to attend this year's event, the vast majority of the presentations from the Workshop have been placed on the web and can be accessed at the following page on AADAP's website. Additionally, on the same page, there is a collage of pictures taken at the after-session activities: http://www.fws.gov/fisheries/aadap/inadworkshop10.htm.

Update on immediate-release sedative activities: For the past two years, AADAP and other members of the Association of Fish and Wildlife Agencies' Drug Approval Working Group (DAWG) have been actively involved in the "process" of narrowing our focus of future activities to one of two potential immediate-release fish

sedatives (i.e., AQUI-S®E, active ingredient eugenol; or BENZOAK®, active ingredient benzocaine). At the most recent DAWG meeting (27 September 2010), members in attendance unanimously voted to focus future DAWG and DAWG-member activities on AQUI-S®E.

Numerous points of consideration were factored into the DAWG members' decision, including, but not limited to: 1) studies (and associated costs) remaining to be completed, 2) input from investigators field-testing either or both of the drugs (see "Sedative Challenge" note in the last issue of the AADAP Newsletter), and 3) input from the pharmaceutical sponsors of the candidate drugs. In summary, a) total remaining costs of studies are quite similar for both products, b) field investigators who tested both drugs side-by-side were almost evenly split in their preference (four in favor of AQUI-S®E and three for BENZOAK®), and c) the sponsors' drug development plans for completion of their respective New Animal Drug Application varied appreciably with the sponsor for AQUI-S®E providing a greater commitment of resources.

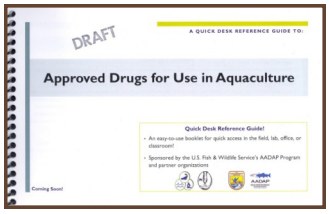
Plans are currently being formulated for the sponsor of AQUI-S®E (AQUI-S New Zealand, Ltd.) to meet with DAWG members to begin to flesh-out the product development plans; i.e., who's going to be doing what, timetables, specific resource commitments, etc. Tentatively, a meeting is planned for 9-10 December 2010 in Portland, Oregon USA, to be held in conjunction with the Northwest Fish Culture Conference.

Check AADAP's website, as well as the next issue of the AADAP Newsletter, for further developments.

Biologics Poster NOW AVAILABLE: The *"Approved Vaccines for Use in Aquaculture"* Poster (noted in previous issues of the AADAP Newsletter), which is a joint effort between the USDA's Center for Veterinary Biologics' (CVB), the US Fish & Wildlife Service's Aquatic Animal Drug Approval Partnership Program (AADAP), the American Fisheries Society's Fish Culture (FCS) and Fish Health Sections (FHS) and the American Veterinary Medical Association (AVMA) is **now available** free-of-charge in limited numbers. A second printing has been ordered. To obtain your copy or copies, either click here or go to the following webpage on the AADAP website: http://www.fws.gov/fisheries/aadap/vaccines_poster_introduction.htm. The AVMA likewise plans to make the Poster available, details of which can be found on AVMA's website (http://www.avma.org).

Note: As of 9 November 2010, all copies of the Biologics Poster first printing have been distributed. Arrangements have been made for a second printing, and copied are scheduled to be available sometime during the week of 15 November 2010. Refer to the AADAP website for availability of the second printing.

Approved Aquaculture Drugs - Desk Reference: Printing of the AADAP - AFS's " Desk-Reference booklet (details previously reported in the last issue of the AADAP Newsletter) is scheduled to be completed sometime in December 2010. It comprises all the information contained in the "Approved Drugs for Use in Aquaculture" poster, as well as a "How to Calculate" the proper dose or concentration of approved drugs as per label instructions. Once the Desk-Reference booklet becomes available, it can be ordered (free of charge) or downloaded via AADAP's website at: http://www.fws.gov/fisheries/aadap/desk-reference_introduction.htm.



Progress update from the American Fisheries Society - Fish Culture Section's (AFS-FCS) Working Group on Aquaculture Drugs, Chemicals, and Biologics (WGADCB): The WGADCB held a meeting on August 4, 2010 in Bozeman, Montana USA, in conjunction with the 16th Annual Aquaculture Drug Approval Coordination Workshop. The meeting of roughly 40 stakeholders (highest attendance for a WGADCB meeting yet!) was lead by co-chairs Jim Bowker, Mark Gaikowski, Lester Khoo, Randy MacMillan, Steve Sharon, and Jesse Trushenski. During the meeting, status updates were provided for a number of ongoing WGADCB projects and new activities were taken on. Here's what the WGADCB has been up to lately…

Revisions to the *Guide to Drug, Vaccine and Pesticide Use in Aquaculture* (*Guide*) are ongoing and significant progress is being made. Jim Bowker, Mark Gaikowski, Maren Tuttle-Lau, Dave Straus, and Jesse Trushenski have been hard at work, revising and drafting new text for the Guide. Information sheets are being developed for each of the FDA-approved, INAD exemption, and "deferred regulatory status" drugs. These information sheets provide concise, user-friendly information about the drugs themselves; indications, precautions, and calculations to administer the drugs correctly; discharge considerations; and references for those interested in finding out more. Info sheets have been completed for many drugs, and with help from co-chair Lester Khoo, the AVMA Aquatic Veterinary

Committee has been able to provide feedback on those that have been completed to date. The revised pesticides section of the *Guide* is also complete, and with help from Laura Sprague (USFWS Idaho Fish Health Center) a new section covering disinfectants and sanitizers is nearing completion. The group is confident that, once complete, the new *Guide* will serve end-users well in providing 'one-stop shopping' for information on the use of chemicals in fish culture.

The draft *"AFS Policy Statement Regarding the Need for an Immediate-Release Anesthetic/ Sedative for Use in the Fisheries Disciplines"* was brought forward at the AFS Governing Board meeting in Pittsburgh, Pennsylvania USA on September 11, 2010. The Governing Board voted unanimously to present the draft Policy Statement to the entire AFS membership for comment. An executive summary will be published in Fisheries magazine later this Fall, and after the membership has had an opportunity to comment on the draft Policy Statement, the membership will be asked to vote on the adoption of this document as AFS Policy. This effort has been incredibly well-received by the AFS leadership, and the Society leadership plans to use the Policy Statement in the context of broader educational efforts to improve the process by which drugs are approved and made available to fisheries professionals. Hearty thanks to Jesse Trushenski, Jim Bowker, Steven Cooke, Dave Erdahl, Tom Bell, Randy MacMillan, Roy Yanong, Jeffrey Hill, Mary Fabrizio, Christopher Guy, James Garvey, and Steve Sharon for drafting the Policy Statement and to AFS Resource Policy Committee Chair, Tom Bigford, for ushering the document through the review and approval process.

Following a presentation by Laurie Boulden (U.S. Department of Homeland Security; DHS) at the Annual Aquaculture Drug Approval Coordination Workshop, the WGADCB also decided to get involved in helping DHS inform the aquaculture community about Chemical Facility Anti-Terrorism Standards (CFATS) regulations. CFATS were developed by DHS to allow for cooperative monitoring and control of various chemicals that present one or more security issues if released, stolen or diverted, or could be used for purposes of sabotage or intentional contamination. CFATS regulations apply to any facility that manufactures, uses, stores, or distributes certain chemicals at or above a specified quantity. This can include aquaculture facilities that use or store formalin/ formaldehyde, hydrogen peroxide, and potassium permanganate. Because most practicing fish culturists are unaware of CFATS, Mike Mason, Jesse Trushenski, and Laurie Boulden developed an informational flyer (click here to view flyer) on behalf of the WGADCB . This flyer is being distributed electronically to fish culturists to increase awareness and compliance with these important regulations.

For more information on current WGADCB activities, please see the meeting minutes (click here to view meeting minutes), contact one of the co-chairs, or better yet, come to our next meeting! The next meeting of the WGADCB will be held in conjunction with Aquaculture America, February 28-March 3, 2011 in New Orleans, LA. Stay tuned to the AADAP website for WGADCB meeting scheduling announcements.

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

AADAP DRUG UPDATES

General: Well…the 2010 AADAP pivotal field efficacy trial train got rolling, as promised in the last issue of the AADAP Newsletter, but not surprisingly there were a few hiccups along the way. There is always a certain degree of "Murphy's Law" associated with conducting field efficacy trials, and this year was no exception. Some studies rolled on without a hitch, some required us to do a little 13th-hr head-scratching, and some planned studies simply never "left the gate" due to a lack of cooperation between the pathogen and host. Overall, it was business as usual. Sometimes things work out and sometimes they don't. Below is an overview of recent research happenings including what studies have been conducted, what data/reports have been submitted to CVM, what we've heard back from CVM regarding previous submissions, and what studies are currently in-progress.

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

Ectoparasitic monogenetic trematodes and rainbow trout efficacy studies: There is some good news to be shared relative to our efforts for expanded approval(s) for the use of 35% PEROX-AID®. A protocol entitled "The Efficacy of 35% PEROX-AID® to Control *Gyrodactylus salmonis* in Freshwater-Reared Salmonids" was submitted to CVM on 2 September 2010. On 27 October 2010, we received protocol concurrence…hurray! Although we were pretty confident that we would received protocol concurrence (**note**: we had been working very closely with CVM during protocol development), it's always nice to receive official concurrence. In fact, we were so confident that the protocol would be accepted, that a pivotal field efficacy trial was launched in mid-October at the Ennis National Fish Hatchery (USFWS, Ennis, Montana USA) to evaluate the efficacy of 50 mg per L hydrogen peroxide for 60 min on two alternate days to control an infestation of *G. salmonis* in rainbow trout

(*Oncorhynchus mykiss*) brood fish. With the help of Ennis NFH staff (Sean Henderson and Ron Lacey), AADAP's Miranda Dotson completed a study that rocked! Briefly, the mean abundance (±1 standard deviation) of *G. salmonis* determined from counting all parasites from a skin scrape prepared using a standardized procedure from 30 fish arbitrarily collected from the reference population before the start of the study was 31.20 (±38.82). At the end of the 5-d posttreatment period, the mean abundance (±1 standard deviation) of *G. salmonis* determined from counting all parasites from a skin scrape from 10 fish arbitrarily collected from the treated and control tanks was 0.10 (±0.25) and 38.5 (±78.44), respectively. We are in the process of analyzing the data and developing a Final Study Report to submit to CVM. In the meantime, Miranda is coordinating with the crew at the Ennis NFH to conduct another efficacy study to verify the reproducibility of the study outcome. Good luck Miranda and crew, and as usual, stay tuned.

AQUAFLOR® (florfenicol) Update:

Final Study Reports: Although we weren't quite as busy conducting studies to evaluate the effectiveness of AQUAFLOR® as we had hoped (read on for the details), we were able to complete a couple of efficacy studies and submit a couple of Final Study Reports (FSRs) to CVM for review. In addition, we heard back from CVM that a study conducted to evaluate the effectiveness of AQUAFLOR® at a dosage of 10 mg florfenicol per kg fish body weight per d for 10 d to control mortality in bluegill (*Lepomis macrochirus*) caused by systemic columnaris was accepted. As expected, CVM stated that to complete the effectiveness technical section for this claim for ALL warmwater finfish, additional data demonstrating the effectiveness of florfenicol to control mortality caused by systemic columnaris in channel catfish (*Ictalurus punctatus*) is needed. Efforts to provide CVM with this data are underway, and we're hopeful (as usual) that the data will be accepted by CVM and the technical section for this effectiveness claim will be completed. For more information on the bluegill efficacy study, please see AADAP's Drug Research Information Bulletin #16 entitled "Efficacy of AQUAFLOR® (50% Florfenicol) to Control Mortality in Bluegill Diagnosed with Systemic Columnaris Disease."

Chinook salmon and bacterial kidney disease efficacy studies: In the last AADAP Newsletter, we briefly described two studies that were ongoing with Doug Munson (Idaho Department of Fish and Game) to evaluate the efficacy of AQUAFLOR® at a dosage of 15 mg florfenicol per kg fish body weight per d for 10 d to control mortality caused by bacterial kidney disease (BKD; causative agent, *Renibacterium salmoninarum*) in Chinook salmon (*Oncorhynchus tshawytscha*). A Final Study Report (FSR) was submitted to CVM on 8 October 2010 summarizing the results from the first study. In this study, mean cumulative mortality in the treated tanks (14.8%, range, 11.7-18.9%) was significantly different (P = 0.020) than the mean cumulative mortality in untreated control tanks (24.3%, range, 20.9-32.0%). Although we anticipate that this study will be accepted by CVM, one never knows until CVM has reviewed the FSR. For more information on this study, please see AADAP's Drug Research Information Bulletin #18 entitled "Efficacy of AQUAFLOR® (50% Florfenicol) to Control Mortality in Chinook Salmon Diagnosed with Bacterial Kidney Disease." The second BKD efficacy study was conducted in July 2010 using Chinook salmon from a different reference population of fish to confirm that previous treatment results could be replicated. Preliminary analysis of data shows that mean cumulative mortality in treated tanks was significantly less than that in control tanks, which is good news indeed! Once we receive the original raw data from this study, we'll write it up and submit the FSR to CVM for review. At that time, we will also request that the effectiveness technical section for the use of AQUAFLOR® at a dosage of 15 mg florfenicol per kg fish body weight per d for 10 d to control mortality caused by BKD be considered complete for Chinook salmon. Stay tuned!

Yellow perch target animal safety study: Additional good news relative to AQUAFLOR® is that the FSR summarizing a study conducted last spring to evaluate the safety of AQUAFLOR® (50% Florfenicol; Type A Medicated Article) administered in feed to yellow perch (*Perca flavescens*) was submitted to CVM for review on 13 August 2010. Briefly, results from this study clearly demonstrated that the florfenicol margin of safety extends to at least 75 mg florfenicol per kg fish body weight (5X the intended dose) per d when administered for 20 d (2X the intended treatment duration). Acceptance of this target animal safety study will complete AADAP's efforts to demonstrate that 15 mg florfenicol per kg fish body weight per d when administered for 10 d is safe to fish. Additional data required to complete this technical section for ALL fish has been/is being conducted by the sponsor and other collaborators.

Channel catfish and systemic columnaris efficacy study: In the not-so-good-news column…in the last newsletter we commented that we sometimes hesitate to mention/discuss planned studies before-hand, because sometimes things just don't work out. Well, in spite of detailed planning and our best intentions, a study scheduled to be conducted this summer at the Florida Bass Conservation Center (Richloam Fish Hatchery; Richloam, Florida USA) to evaluate the effectiveness of AQUAFLOR® to control mortality caused by systemic columnaris in channel catfish (*I. punctatus*) just didn't pan-out. AADAP's Niccole

Wandelear was in frequent communication with Mike Matthews (Florida Bass Conservation Center) to get things in place to conduct this study. Medicated feed to administer to fish in treated tanks and Shieh's media for culturing the pathogen of concern were delivered to the hatchery in the event that the fish got sick. Unfortunately, the fish just didn't get sick and the proposed study was scrapped. Although we were not entirely sure that data from this study would have been required to complete the effectiveness technical section (data from an effectiveness study conducted by non-AADAP researchers has been submitted to CVM to complete this claim), we had hoped to conduct an additional study…just in case…if the opportunity arose. As usual, Mike has indicated that if additional data are required to complete the effectiveness technical section, he is willing to try it again next year. Thanks Mike!

Systemic columnaris and rainbow trout efficacy study: Lastly, we're not entirely sure where we stand with respect to a collaborative study conducted with the Bellingham Technical College's Fisheries Technology Program (Earl Steele), Bellingham State Fish Hatchery (Kevin Clark), and the Washington Department of Fish and Wildlife (Jed Varney) to evaluate the effectiveness of AQUAFLOR® to control mortality associated with systemic columnaris in rainbow trout. The study was completed on 23 July 2010. Mean cumulative mortality in treated tanks was lower than that in untreated control tanks, analytically verified concentration of florfenicol in feed was within 80 – 100% of the target concentration, and the pathogen associated with mortality was confirmed by polymerase chain reaction as *Flavobacterium columnare*. In addition, the 24 h minimum inhibitory concentration for isolates of this pathogen ranged from 0.5 to 1.0 mg florfenicol. Unfortunately, some of the raw data sent from Bellingham never arrived at AADAP. With the help of Earl and Jed, we are trying to track down the whereabouts of this missing data. Regardless of whether or not we are successful in tracking down this data, we want to thank Jed for collecting fish health data, Terry Ott and the FWS's La Crosse Fish Health Center for running PCR for pathogen confirmation, and Pat Gaunt and Mississippi State University for doing MIC work with *F. columnare*.

Channel Catfish Pituitary Update:

Waiver sought for reduced data requirements: In the last AADAP Newsletter, we mentioned that we submitted two packages to CVM requesting that no additional data be required to complete, respectively, the Human Food Safety (HFS) and Environmental Safety (ES) technical sections. On 2 August 2010, we received a letter from CVM's Division of Human Food Safety stating that the human food safety technical section is complete for the use of channel catfish pituitary in fish. That's GREAT news!! However, we have not yet heard back from the Division of Scientific Support regarding our request that the Environmental Assessment for the use of channel catfish pituitary as a spawning aid in a variety of finfish species be considered acceptable as it pertains to the completion of the Environmental Safety technical section of a New Animal Drug Application. We should hear back from CVM regarding this request in early December… so once again, stay tuned!

Immediate Release Fish Sedative Update:

Eugenol analytical method development: As anxious as we are to get the train rolling to evaluate the safety and effectiveness of AQUI-S® E, there is still work that must be done to verify that a UV-Vis spectrophotometric method developed by AQUI-S New Zealand Ltd. to measure the concentration of AQUI-S® E in water is accurate, precise, and that the linearity of the standard curve can be reproduced using various types of freshwater. After some discussions with CVM, it was tacitly decided that the linearity of standard curves should be evaluated using water from several potential study sites. As a result, standards were prepared and analyzed using water from the Fish Breeders of Idaho (Buhl, Idaho USA). As anticipated, the linearity between standards ranging from 10 to 120 mg per L AQUI-S® E was "rock solid", with the R^2 for each set of standards exceeding 0.999. In addition, a working solution of 50 mg per L AQUI-S® E was prepared and AQUI-S® E concentration measured every 2 hrs over an 8 hr period. Freshly prepared standards were used for all measurements. The end result was that there was no evidence of degradation of AQUI-S® E over the 8-hr period, the analytically verified concentration of the working solution differed little from the target concentration, and differences that were observed were attributed to slight differences in preparation of the stock and working standards (e.g., measuring 0.50 g in one stock solution, 0.51 g in the next, etc). AADAP is in the process of obtaining water from the Miles City State Fish Hatchery (Miles City, Montana USA) to further verify the repeatability of the spectrophotometric method. All the data will be summarized and submitted to CVM to support use of this method to verify the concentration of AQUI-S® E during efficacy and target animal safety studies. In addition, a Drug Research Information Bulletin briefly describing the studies and results will be developed and made available on the AADAP website.

SLICE® (emamectin benzoate) Update:

Ectoparasitic copepods and rainbow trout efficacy studies: In recent weeks, AADAP's Niccole Wandelear and Dan Carty have been busy writing up the results from two studies that were conducted to evaluate the efficacy of SLICE® at a dosage of 50 µg emamectin benzoate per kg fish body weight per d

when administered for 7 d to reduce infestations of the ectoparasitic copepod *Salmincola californiensis* in rainbow trout. One study was conducted at SeaPac of Idaho's Magic Springs Hatchery in Hagerman, Idaho USA, with the help of SeaPac's Jim Shaffer and Tom Van Tassel. At the end of the 30-d posttreatment period for this study, a significant difference ($P < 0.001$) was detected in the mean abundance of copepods in treated (3.3 copepods per fish) and untreated control (9.5 copepods per fish) tanks. In addition, the prevalence of fish with at least one copepod in treated tanks (43%) was lower than that in control tanks (91%).

The second study was conducted at Clear Springs Foods®' Research Facility in Buhl, Idaho USA with the help of Clear Springs' Scott LaPatra, Bill Shewmaker, and Robin Burkhart. At the end of the 30-d posttreatment period for this study, a significant difference ($P < 0.001$) was detected in the mean abundance of copepods in treated (1.9 copepods per fish) and untreated control (6.6 copepods per fish) tanks. In addition, the prevalence of fish with at least one copepod in treated tanks (48%) was lower than that in control tanks (98%). Niccole and Dan are in the process of developing Final Study Reports for both studies. In addition, in mid-October Niccole and Dan and the Clear Springs crew launched another SLICE® efficacy study to verify that the results observed in the first Clear Springs study are reproducible. So far, the study is progressing without any major obstacles and is scheduled to end in mid-December.

The crews at both SeaPac and Clear Springs have "bent-over-backwards" to assist us in this effort, and we are extremely grateful for their assistance/sacrifice. We are also very excited that based on the results from completed studies, we should be well on our way to completing the effectiveness technical section for the use of SLICE® for this claim. As usual, "don't touch that dial and stay tuned!"

FINS & TAILS, BITS & BOBBERS

2011 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 2011. All 2011 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 December 2010. Invoices will be mailed out the end of January 2011. 15 different INAD exemptions are open for enrollment.

Oxytetracycline hydrochloride (bath marking) INAD #9033: AADAP INAD #9033 will remain in effect for use for the skeletal marking of finfish through calendar year 2011, or until a viable FDA-approved product again becomes available. Pennox® 343 (without the fish marking claim on the label) can continue to be used under the INAD to mark fry and fingerling. Please direct any questions regarding participation in this INAD to AADAP's Bonnie Johnson (bonnie_johnson@fws.gov).

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 2010. **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 amount of drug on-hand or that no drug use occurred.

AADAP's web-based INAD Program Management System (IPMS) progressing well: The final steps in making AADAP's "long-in-coming" IPMS a reality are underway. Our webpage and database developers have been working with the "pedal to the metal" since their contract was finalized. It appears that the time we lost in getting the contract in place has nearly been made up by our contractor (Massive Studios, Bozeman, Montana USA). And as we stated in the last Newsletter, we hope to be able to have a beta version up and on-line near the end of the calendar year. If your organization has been enrolled in AADAP's INAD program and you are interested in beta-testing our web-based IPMS, please contact Bonnie Johnson (phone 406-994-9905, email bonnie_johnson@fws.gov) or Tom Bell (phone 406-994-9911, email thomas_a_bell@fws.gov). Stay tuned for new developments!

Request for amended authorization of AQUAFLOR® INAD 10-697: Working collaboratively with Intervet/Schering-Plough Animal Health (ISP), AADAP has recently requested amended authorization for AQUAFLOR® INAD #10-697 to include the treatment of freshwater-reared salmonids diagnosed with bacterial coldwater disease (CWD; causative agent *Flavobacterium psychrophilum*) at a dosage of 15 mg florfenicol per kg fish per day for 10 consecutive days. Please note that although the current authorization for INAD #10-697 includes the treatment of a variety of fish species at a dosage of 10 or 15 mg florfenicol per kg fish per day for 10 consecutive days to control mortality caused by a variety of bacterial pathogens, current authorization does **not** include the use of florfenicol for indications for which AQUAFLOR® or AQUAFLOR®-CA1 are already approved, or conditionally approved, respectively. Hence, treatment of CWD is currently **not** allowed under INAD #10-697. This request is based on clinical experience that has suggested that while the currently approved dose rate of 10 mg florfenicol per kg significantly reduces mortality caused by CWD, a higher dose (i.e., 15 mg florfenicol per kg) may be required to achieve the expected level of **long-term** control. Assuming amended authorization for AQUAFLOR® INAD #10-697 is granted by FDA, AADAP and ISP intend to work together, along with other partners, to generate the data

necessary to evaluate the efficacy of CWD-treatment at a dosage of 15 mg florfenicol per kg. Furthermore, if such data support enhanced long-term efficacy for this specific use-pattern, ISP has indicated that they will pursue an expanded label claim for the use of AQUAFLOR® at 15 mg florfenicol per kg fish per day for 10 consecutive days to control mortality caused by CWD in freshwater-reared salmonids. Stay tuned!

RELEVANT LITERATURE

The following is a list of journal publications with particular relevance to the broad topic of drugs and aquaculture species. This list comprises citations exclusively from 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

Chafer-Pericas, C, et al. 2010. Multiresidue determination of antibiotics in aquaculture fish samples by HPLC-MS-MS. *Aquaculture Research* **41(9):e217-e225**.

Dang, PK, et al. 2010. Validation of a two-plate microbiological method for screening antibiotic residues in shrimp tissue. *Analytica Chimica Acta* **672(1-2):30-39**.

Darwish, AM. 2010. Effectiveness of early intervention with florfenicol on a *Streptococcus iniae* infection in blue tilapia. *North American Journal of Aquaculture* **72(4):354-360**.

Dasenaki, ME, and Thomaidis, NS. 2010. Multi-residue determination of seventeen sulfonamides and five tetracyclines in fish tissue using a multi-stage LC-ESI-MS/MS approach based on advanced mass spectrometric techniques. *Analytica Chimica Acta* **672(1-2):93-102**.

Feng, Q, et al. 2010. Kinetic analysis of oxytetracycline residues in Chinese mitten crab, *Eriocheir sinensis*, muscle following intramuscular administration. *Journal of Fish Diseases* **33(8):639-647**.

Gonzalez, RR, et al. 2010. Depletion of veterinary drugs used in aquaculture after administration in feed to gilthead seabream (*Sparus aurata*). *Journal of Food Protection* **73(9):1664-1670**.

Harikrishnan, R, et al. 2010. Scuticociliatosis and its recent prophylactic measures in aquaculture with special reference to South Korea. *Fish & Shellfish Immunology* **29(1):15-31**.

Kitiyodom, S, et al. 2010. Characterization of antibiotic resistance in *Vibrio* spp. isolated from farmed marine shrimps (*Penaeus monodon*). *FEMS Microbiology Ecology* **72(2):219-227**.

Krupesha Sharma, SR, et al. 2010. Evaluation of immune response and resistance to diseases in tiger shrimp, *Penaeus monodon*, fed with biofilm of *Vibrio alginolyticus*. *Fish & Shellfish Immunology* **29(5):724-732**.

Lim, JH, et al. 2010. Plasma and tissue depletion of florfenicol in olive flounder (*Paralichthys olivaceus*) after oral administration. *Aquaculture* **307(1-2):71-74**.

Meng, W-N, et al. 2010. Antioxidant responses in liver of *Carassius auratus* under oxytetracycline exposure. *Journal of Agro-Environment Science* **29(5):833-838**.

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USGS's CORNER

17α-methyltestosterone: Upper Midwest Environmental Sciences Center (UMESC) submitted a letter to the U.S. FDA's Center for Veterinary Medicine (CVM) requesting that the Human Food Safety Technical section for 17α-methyltestosterone be considered complete. UMESC received notification that CVM considers the Human Food Safety Technical section for 17α-methyltestosterone complete. Contact Mark Gaikowski, mgaikowski@usgs.gov, for more information.

UMESC in collaboration with Maxxam Analytics (formerly CANTEST Ltd.) coordinated an analytical method transfer study to complete the Chemistry Manufacturing and Controls Technical Section for 17α-methyltestosterone. The laboratory portion of the familiarization phase was completed in early 2010. The definitive method transfer phase was completed in June 2010. Maxxam Analytics Quality Assurance Unit conducted inspections of the raw data and laboratory reports during July, August, and September of 2010. The Quality Assurance Unit's findings were addressed. Thereafter, Maxxam Analytics sent to UMESC final reports describing their activity and results from the study. UMESC is currently compiling a comprehensive final report for the study. This study was funded through grants from the North-Central and Western Regional Aquaculture Centers. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

Chloramine-T: To address one of the remaining data needs for the approval of Halamid®, UMESC staff modified the analytical method for para-toluenesulfonamide (p-TSA), the marker residue of chloramine-T. UMESC submitted to CVM an 866-page report containing the data that are expected to allow CVM to conclude that the analytical method to quantify p-TSA at concentrations <20 ng per g (the CVM tolerance limit for p-TSA in fish fillet tissue) is acceptable. The previous method developed by Meinertz and others had a quantitation limit of ~30 ng per g, and was developed before the CVM had determined the p-TSA tolerance in fish fillet tissue. The new method, with its lower detection limit, combined with the residue depletion data previously developed by UMESC and accepted by CVM, should complete the human food safety technical section for chloramine-T. The human food safety technical section is the last major technical section to be completed before chloramine-T may be approved to control mortality in diseased fish. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

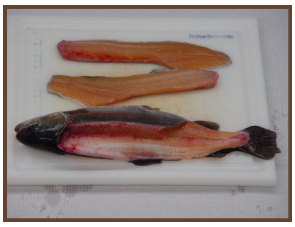
Hydrogen peroxide: The Center for Veterinary Medicine (CVM) accepted the data from a study completed by UMESC, U.S. Fish and Wildlife Service's (FWS) Iron River National Fish Hatchery, and FWS La Crosse Fish Health Center (FHC) evaluating the effectiveness of hydrogen peroxide to control external parasites on fish. The data within the final study report *"Confirmation of the efficacy of 35% PEROX-AID® to reduce* Gyrodactylus salmonis *infestation density on coaster brook trout* Salvelinus fontinalis*"* were accepted as pivotal. For more information, contact Maren Tuttle-Lau, mttuttle@usgs.gov.

The CVM accepted the data from another collaborative study completed by UMESC, Michigan Department of Natural Resources Marquette State Fish Hatchery and FWS La Crosse FHC evaluating the effectiveness of hydrogen peroxide to control external parasites on fish. The data within the final study report *"Field effectiveness of 35% PEROX-AID® to reduce* Gyrodactylus *sp. infestation density on coaster brook trout* Salvelinus fontinalis*"* were accepted as supportive. Contact Mark Gaikowski, mgaikowski@usgs.gov, for more information.

After accepting data from the previous two studies, the CVM concluded that completion of one additional pivotal study to control a *Gyrodactylus* sp. in a trout species other than brook trout, combined with evidence that all

Gyrodactylus sp. are expected to respond similarly to hydrogen peroxide, would complete the effectiveness technical section for the use of 35% PEROX-AID® to control *G. salmonis* in freshwater-reared salmonids. To address the need for an additional pivotal efficacy study, UMESC initiated a study at the Iron River National Fish Hatchery to evaluate the effectiveness of hydrogen peroxide to control external Gyrodactylus infections on juvenile lake trout. If hydrogen peroxide is found to be effective controlling the parasite in this study, these data may lead to the completion of the effectiveness technical section for the use of 35% PEROX-AID® to control *G. salmonis* in freshwater-reared salmonids. Contact Maren Tuttle-Lau, mttuttle@usgs.gov, for more information.

Sedatives: Work to develop an analytical method to detect eugenol residues in freshwater fish fillets is complete. The data generated during this body of work



indicate that the method developed by UMESC staff will accurately and precisely determine eugenol concentrations in fish fillet tissue ranging from about 0.01 to 100 µg per g. A comprehensive final report is under review. This study was funded through a Multistate Conservation Grant from the Association of Fish and Wildlife Agencies. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

Florfenicol and Oxytetracycline: UMESC submitted to the CVM a request for the review of literature and information to support the review of a clinical effectiveness study protocol submitted to INAD #11-366 to determine the field effectiveness of AQUAFLOR® (florfenicol) and TERRAMYCIN® 200 For Fish (oxytetracycline dihydrate) to control mortality in warmwater finfish due to motile Aeromonad infections. The submission was required to provide information on the Aeromonas species causing motile Aeromonad infections, the likelihood of co-infections by multiple Aeromonas species, and the likely susceptibility of Aeromonas species. Contact Mark Gaikowski, mgaikowski@usgs.gov, for more information.

UMESC coordinated a meeting with CVM in Rockville, Maryland USA on September 14, 2010 to discuss the potential of a paradigm shift in the current ideas associated with approval of an immediate-release sedative to sedate freshwater fish during fishery management or aquaculture activities. UMESC presented scientific data and other information to CVM and discussed the logic of potential changes in the methods CVM may use to conduct the human exposure risk assessment for immediate use sedatives of freshwater fish. Attendees included representatives of two fish sedative sponsors (AQUI-S New Zealand, Ltd. and Frontier Scientific, Inc.), members of the Association of Fish and Wildlife Agencies, and the U.S. Fish and Wildlife Service. Contact Mark Gaikowski, mgaikowski@usgs.gov, for more information.

Erythromycin: UMESC in collaboration with Eric S. Rosenblum (Department of Chemistry and Biochemistry, University of Colorado), and Christine M. Moffitt (US Geological Survey - Idaho COOP) submitted to the U.S. Department of Agriculture National Research Support Project No. 7 (Minor Use Animal Drug Program; NRSP-7) the report *"An Environmental Assessment of the Proposed Use of Erythromycin Thiocyanate-Medicated Feed to Control Bacterial Kidney Disease in Freshwater-Reared Salmonids"* for subsequent submission to the U.S. Food and Drug Administration's Center for Veterinary Medicine. The report summarizes the information regarding the potential environmental effects associated with the use of erythromycin thiocyanate in freshwater-reared salmonids. The work was funded through a variety of sources including NRSP-7 and the USGS. Contact Mark Gaikowski, mgaikowski@usgs.gov, for more information.

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

17α-methyltestosterone (17MT) The 17MT Target Animal Safety study with tilapia was completed early this summer and we are finalizing the Quality Assurance audit with an 'in-life study' report. We are also assisting AADAP with compiling a draft of the Final Study Report for FDA. We will present findings with respect to acute and chronic toxicity, fish growth, and feeding behavior at the upcoming Aquaculture America 2011 meeting in New Orleans. We would like to thank the Western Regional Aquaculture Center (especially Graham Young and Sarah Merlino) for funding this study.

Effectiveness Studies: We are awaiting an FDA response to our submission of a Final Study Report for the supportive effectiveness range-finding studies of copper sulfate ($CuSO_4$) on fungus of channel catfish eggs that was sent in June 2010. We continue our catfish studies with columnaris in the low-flow aquarium system with tests on potassium permanganate ($KMnO_4$) and $CuSO_4$. We have worked with the effectiveness of $KMnO_4$, $CuSO_4$ and peracetic acid on an *Ichthyobodo* spp. (Costia) infestation in catfish and in sunshine bass. We also researched the effectiveness of formalin and $CuSO_4$ on gill flukes in white bass.

Aquaculture America 2011: Finally, we have an exciting agenda lined up for the "Aquaculture Drug Research and Drug Approval Status" special session at AA 2011. As in the past, the session will provide an opportunity for those conducting studies on drugs/chemicals for use in aquaculture and fisheries to present their findings. In addition, there will be a presentation at the end of the session where we'll update attendees on the status of three (or more) drugs/chemicals important to fish culturists. This presentation will be scheduled as the last presentation to allow time for questions and answers and discussion of the status of other aquaculture drugs. We will start the session off with presentations from FDA about the approval process for animal drugs, and considerations when evaluating effectiveness trials for antiparasitic drug claims. The rest of the session will focus on technical presentations of current research, and will include presentations on: acute toxicity of diquat to freshwater prawn, comparing the efficacy of fungicides on channel catfish eggs, the safety of 17α-methyltestosterone medicated feed to tilapia, treatments of copper sulfate and formalin on gill flukes and Ich in white bass, use of peracetic acid as a fungicide on catfish eggs, use of florfenicol in recirculating aquaculture systems, effects of overdosing yellow perch with AQUAFLOR® medicated feed, controlling mortality in Chinook salmon from BKD using AQUAFLOR® medicated feed, and use of SLICE® to reduce infestations of *Salmincola* spp. in rainbow trout. The drug approval status presentations will provide an overview of activities relating to the approval of channel catfish pituitary (as a spawning aid) and AQUI-S® E, HALAMID®, and expanding label claims for AQUAFLOR®.

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

MEETINGS, ETC.

Recently held meetings

6th International Symposium on Aquatic Animal Health; 5-9 September 2010; Tampa, Florida USA: This year's symposium hosted over 300 participants, representing 24 nations - the most geographically diverse attendance at any of the Symposia. Including plenary sessions and sponsor perspectives, the Symposium comprised approximately 220 oral and poster presentations, covering 37 sessions. Abstracts from the entire Symposium, photographs and other information are now available online at: http://aquaticpath.phhp.ufl.edu/isaah6/index.html.

2010 Western Fish Disease Workshop; 23-24 June 2010 ; Corvallis, Oregon, USA: For those of you unable to attend the workshop and are interested in what was discussed in Corvallis, the complete set of abstracts from this year's meeting can be accessed by clicking here.

35th Annual Eastern Fish Health Workshop; 24-28 May 2010; Shepherdstown, West Virginia USA: As noted in the Workshop Program "Although the title of the workshop appears to be exclusive for fish..." there was represented "...broad participation in all aspects of aquatic animal health from invertebrates to mammals." Abstracts from the weeklong workshop can be viewed by clicking here. Questions regarding the workshop can be directed to Rocco Cipriano (rcipriano@usgs.gov).

Upcoming meetings

Northeast Aquaculture Conference and Expo; 1-3 December 2010; Plymouth, Massachusetts USA:

This year's upcoming conference and trade show is being held at the Plymouth Radisson. The planned agenda includes 15 session or workshop topic areas, including: Shellfish Culture, Aquaculture Education, Practical Shellfish Engineering, New Developments in Finfish Diseases, Marketing Aquaculture Products, Shellfish Diseases, Practical Finfish Engineering, Financial Resources and Risk Management, Oyster Culture, Saltwater Finfish Culture, Water Quality Management, Clam Culture, Preparation of Finfish for Disease Diagnostics Workshop, Preparation of Shellfish for Disease Diagnostics Workshop, and Ocean Acidification. Additionally a day tour is being planned for aquaculture facilities in the Cape Cod area. Information on accommodations, registration, etc. can be found on the conference website: http://www.northeastaquaculture.org/agenda.htm or by clicking here.

61st Northwest Fish Culture Conference; 7-9 December 2010; Portland, Oregon, USA: The theme for this year's conference is "Northwest Hatcheries – Focusing on the Future" and is being hosted/sponsored by the U.S. National Oceanographic and Atmospheric Administration - Fisheries Service's Salmon Recovery Division and the U.S. Geological Survey's Northwest Fisheries Science Center. The conference is being held at the Hilton Portland & Executive Tower. For more information, including registration, accommodations, etc., please refer to the conference website at: http://www.nwr.noaa.gov/NW-Fish-Culture/

71st Midwest Fish & Wildlife Conference; 12-15 December 2010; Minneapolis, Minnesota, USA: The natural resource professionals of the US Midwest have organized this year's annual meeting and have set it to take place at the Hyatt Regency Minneapolis. Examples of the 18 symposia taking place during the conference include: Influencing Shoreland Conservation Behavior; Trout and Trout Angler Symposium; Examining the Risk of Aquatic Invasive Species Transfer by Inland Waterway Transportation; Shallow Lake Ecology and Management; and Ongoing and Emerging Issues in Wildlife Health and Disease. Complete information on the conference can be found at the conferernce webpage: http://www.midwest2010.org/index.php.

Asian-Pacific Aquaculture 2011; 17-20 January 2011;Kochi India: This is the annual Conference of World Aquaculture Society's Asia Pacific Chapter (WAS-APC), and this year is hosted by the College of Fisheries, Kochi, jointly with the Kerala State Department of Fisheries. This year's conference is being held at the Le Meridien Resort and Convention Center, Kochi, India. APA 2011 is being held in conjunction with another conference Giant Prawn 2011. There are presently 21 Technical Sessions planned, as well as 7 Special Sessions. Technical sessions including one focused on aquatic animal health. For more information, including registration, accommodations, visit the conference website at: https://www.was.org/WasMeetings/meetings/Default.aspx?code=APA2011.

Aquaculture America 2011; 28 February - 3 March 2011; New Orleans, Louisiana USA: The theme of the 2011 conference is "Aquaculture on Parade," and is being held at the New Orleans Marriott. The U.S. Aquaculture Society joins with National Aquaculture Association and the U.S. Aquaculture Suppliers Association to produce the annual Aquaculture America meetings. These sponsors are joined by the annual meetings of Aquacultural Engineering Society, American Tilapia Association, Striped Bass Growers Association, US Trout Farmers Association, US Shrimp Farming Association and many more associations to make Aquaculture America 2011 the one meeting in the U.S. that you don't want to miss! The topics comprising the technical program are too numerous to count, but include those focused on drugs and therapeutants, aquatic animal health and disease, and other topics of interest to aquatic animal health professionals. For more information, including registration, accommodations, etc. visit the conference website at: https://www.was.org/WasMeetings/meetings/Default.aspx?code=AA2011.

36th Eastern Fish Health Workshop; 28 March - 1 April 2011; Mount Pleasant, South Carolina USA: The 2011 Workshop will be held at the Holiday Inn Charleston-Mount Pleasant. As always, the Workshop will provide a diverse group of Special Sessions, including 1) The evolution of Herpesviridae and fish disease, 2) Keeping 'em happy, healthy, and in those aquaria, 3) Probiotics: a SCAT-er-gun approach, 4) Just when you thought it was safe to go back: shark health, 5) Pondering the realities of antibiotic therapies, 6) The Gulf of Mexico Oil Spill and environmental health, 7) Seeing *in toto*: the ecology of disease, 8) Coral Ecosystem Health, and 9) The Aquatic

Detective: Unusual and Perplexing Case Reports. In addition to the Special Sessions, there will be a continuing education day; Histopathology, Part II: Finding and Interpreting the Overlooked. For more information refer to: http://www.fws.gov/fisheries/aadap/PDF/2011 EFHW/36 th Eastern Fish Health Workshop.pdf.

World Aquaculture 2011; 6-10 June 2011; Natal, Brazil: The 2011 annual conference of the World Aquaculture Society (WAS) will be held at the Natal Convention Center, and is being jointly hosted by the World Aquaculture Society (WAS), the Latin American & Caribbean Chapter of WAS and the Associação Brasileira de Criadores de Camarões. WA2011 is being held in conjunction with Fenacam 2011. World Aquaculture 2003 was one of the most highly attended WAS meetings ever. In 2011, WAS will once again hold WA 2011 in Brazil. This time, it will be held in Natal, Brazil and located in the midst of many kinds of aquaculture. In 2003, aquaculture in Brazil was doing well, but now the aquaculture industry is doing even better. Aquaculture now has it's own Ministry in the Brazilian Federal Government – meaning there is a lot of government support for expansion of aquaculture in Brazil. The conference comprises over 75 sessions in 9 general topic areas, including the major topic area "Aquaculture and Human Health." For more information, refer to the conference website at: https://www.was.org/WasMeetings/meetings/Default.aspx?code=WA2011.

1st Australiasian Scientific Conference on Aquatic Animal Health; 5-8 July 2011; Cairns, Queensland, Australia: The conference, being held at the Pullman Reef Hotel, provides a forum for presentation of diagnostic, research, management and policy issues encompassing all areas of aquatic animal health and bio-security. Previously, the Aquatic Animal Health Subprogram (AAHS) of the Fisheries Research Development Corporation of Australia has organized national scientific conferences (in 2003, 2005, 2007 and 2009) featuring presentations on aquatic animal health research in Australia and an international aquatic animal health expert as the keynote presenter. While the format of the 2011 conference is likewise being hosted by AAHS, it is expected to be similar to previous conferences with an international keynote speaker, presentations on a range of aquatic animal health topics, prize for best student presentation etc., a recent decision was made to expand the conference to encompass the Australasian region, attracting participants from New Zealand, SE Asia and beyond. To receive the second conference announcement which will include the draft program, registration (registration fee will be Aus$330) and abstract forms and further accommodation details please provide Joanne Slater, FRDC Aquatic Animal Health Subprogram Coordinator (email: joanne.slater@csiro.au) with an expression of interest indicating whether you plan to attend and/or make a presentation (please indicate topic). Please provide the following details: your name, institution, postal address, email address, fax and telephone numbers. Also your area(s) of interest: research/management/policy and regulation; finfish/crustaceans/molluscs/reptiles/amphibians; viral/bacterial/parasitic/fungal pathogens; and/or diagnostic test development and diagnostics.

VIII International Symposium on Fish Parasites; 26-30 September 2011; Viña del Mar, Chile: Next 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 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/.

CVM's NOTES

Animal Health Literacy Campaign: Have you visited CVM's Animal Health Literacy Campaign web site ? Some pieces added in the last year might be of interest including:

- *"From an Idea to the Marketplace: The Journey of an Animal Drug through the Approval Process."* This piece provides a plain language overview of the new animal drug approval process for the general public.
- *"Lions and Tigers and Bears! OMUMS!"* This piece explains what the Minor Use and Minor Species Animal Health Act is all about, and more

specifically, what indexing, designation, and conditional approval are.

- *"Aquaculture and Aquaculture Drugs Basics."* This piece, written by Susan Fogelson, a former CVM summer intern, provides basic information about aquaculture for the general public.
- "The Melamine Story" (video). In this video, Dr. Renate Reimschuessel from FDA/CVM's Office of Research explains what it took, in 2007, to uncover and confirm the presence of the contaminants in pet food. The search for the cause was an intense, groundbreaking, sophisticated, and collaborative effort by scientists in government, industry, and academia.

AquAdvantage® salmon: On September 19-21, 2010, FDA held two public meetings on AquAdvantage® Salmon, a genetically engineered (GE) Atlantic salmon intended to be used for food. The first event was a meeting of the Veterinary Medicine Advisory Committee (VMAC); the committee considered science-based information relevant to a potential approval, including animal health and food safety, environmental aspects, and data indicating that AquAdvantage® Salmon grows faster than conventional farmed Atlantic salmon. The second was a public hearing focused on labeling of food from the AquAdvantage® Salmon should the product be approved; FDA presented relevant legal principles for food labeling and heard comments from the public related to labeling. At the time of publication, no decision has yet been made by the agency with respect to approval.

FDA regulates GE animals under the new animal drug provisions of the Federal Food Drug and Cosmetic Act (FFDCA) and the National Environmental Policy Act (NEPA). FDA has published guidance related to GE animals, Guidance 187: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs. For the purpose of the guidance, FDA defined "genetically engineered (GE) animals" as those animals modified by rDNA techniques, including all progeny that contain the modification. Section 201(g) of FFDCA defines drugs as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." The rDNA construct in the resulting GE animal is thus a regulated article that meets the drug definition; the GE animal itself is not a drug. As a short-hand, the agency sometime refers to regulating the GE animal. All GE animals are captured under these provisions, regardless of their intended use.

The Animal Biotechnology Interdisciplinary Group at CVM reviews applications for GE Animals. Please see the CVM website for more information regarding this GE salmon (Public Meetings on Genetically Engineered Atlantic Salmon); please direct any questions to AskCVM@fda.hhs.gov.

eSubmitter: As part of a commitment with the Animal Drug User Fee Act Amendments of 2008 (ADUFA II), CVM's Office of New Animal Drug Evaluation (ONADE) initiated the CVM eSubmitter Project to develop a tool that will enable the animal drug industry to voluntarily submit Investigational New Animal Drug (INAD) file submissions as well as New Animal Drug Application (NADA) submissions electronically. The tool will also be available for Generic Investigational New Animal Drug (JINAD) files, Abbreviated New Animal Drug Applications (ANADA), Veterinary Master Files (VMFs), and General Correspondence (GC) files. The eSubmitter tool will permit drug sponsors to make submissions electronically once the tool is launched for production use in March 2011. A Federal Register Notice announced the public workshop that was held October 21, 2010, to introduce the tool ("eSubmitter"), and requested public comments on the workshop and eSubmitter.

eSubmitter was designed with the animal health industry in mind, including the aquaculture industry. It is a question based tool that helps sponsors easily identify all the information that should be included when building submissions. The eSubmitter tool will eliminate the need for paper submissions and while the use of it is voluntary, the Aquaculture Drugs Team encourages our aquaculture sponsors to use the tool when it enters production mode in March 2011. We encourage you to download the beta-test version and provide comment (information below). If you would like further information on the tool, please visit the CVM eSubmitter website.

Interested individuals may submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Electronic comments may be submitted to http://www.regulations.gov. Comments should be identified with the full title and Docket number FDA 2010-N-0481. The comment period ends December 31, 2010.

New Hire: Last, but certainly not least, we are excited to announce that Dr. David Rotstein has joined the Aquaculture Drugs Team. A veterinarian, Dave is also board certified in pathology and has a Master's in Epidemiology. His pathology work at North Carolina State University and the University of Tennessee included a wide range of cases, among them ornamental fish and marine invertebrates. Immediately before coming to CVM, Dave worked for NOAA's National Marine Fisheries Service Office of

Protected Resources, focusing on marine mammal pathology.

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