



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”



WHAT’S SHAKIN’

NTP review of isoeugenol completed: On 28 February 2008 the U.S. National Toxicology Program (NTP) publicly reviewed (and discussed) the results of the subchronic and chronic studies conducted by NTP on isoeugenol (active ingredient of AQUI-S®). Click [here](#) to view the summary report of the NTP study. Other information on AQUI-S® (and isoeugenol) is also provided in the [AQUI-S® update section](#) of this Newsletter.

14th Annual Aquaculture Drug Approval Coordination Workshop reminder: The 14th Annual Workshop will take place in Bozeman, Montana on the Tuesday, Wednesday and Thursday (29-31 July 2008) immediately before [Bozeman’s Sweet Pea Festival](#) (1-3 August 2008). Be sure, as the time gets closer, to check AADAP’s [website](#) for details.

15th Annual Aquaculture Drug Approval Coordination Workshop planned for Arkansas: Although the exact dates and venue have not been finalized, planning for the 15th Annual Workshop is already underway. The Workshop will be co-hosted by USDA’s Stuttgart National Aquaculture Research Center and USFWS’s Aquatic Animal Drug Approval Partnership (AADAP) Program, and will be held in Arkansas in June 2009. As details become available, they will be posted on AADAP’s [website](#).

AADAP’s new publication series: The USFWS’s Aquatic Animal Drug Approval Partnership (AADAP) Program recently unveiled two new publication series. Drug Research Information Bulletins (DRIBs) are short bulletins (two pages maximum) describing techniques or observations developed/made at AADAP’s facilities and/or by AADAP staff at partner facilities. DRIBs are intended to provide short study summations of drug approval-related research that fish culturists, INAD investigators, and other aquaculture folks will find useful. Unlike the DRIBs, the Drug Research Reports (DRRs) are longer publications (up to 12 pages or more). The DRRs provide a much more detailed report on studies conducted by AADAP and our partners, which typically will pertain directly to the generation of FDA-required effectiveness or target animal safety data. Access the publications series by clicking [here](#).

U.S. Fish & Wildlife Service has a new Assistant Director for Fisheries and Habitat Conservation (ADFHC):

Gary Frazer, the U.S. Fish and Wildlife Service’s recently-appointed Assistant Director for Fisheries and Habitat Conservation (FHC), brings a deep appreciation for science and natural resource stewardship to his position. Prior to assuming the reigns of FHC, Gary was the Fish and Wildlife Service’s Liaison to the U.S. Geological Survey (USGS). In that position, he led the Service’s \$7.4 million per year effort to build a nationwide early detection program for the highly pathogenic avian influenza virus. In that program and in his broader role as science liaison, Gary worked tirelessly to expand science partnerships between the Fish and Wildlife Service, USGS and state fish



and wildlife agencies, and to ensure the role of science in making informed decisions. Before becoming the science liaison to USGS in 2005, Gary was the Service’s Assistant Director for Endangered Species, where for more than five years he spearheaded the Service’s efforts to conserve biological diversity and recover threatened and endangered species. Underlying Gary’s success in each of these positions is a tremendous respect for science, an unsurpassed commitment to natural resource conservation, and a deep love of family and country. *Text provided by William Knapp, USFWS. From all of us here at AADAP, welcome aboard Gary, and we hope to see you here in Bozeman soon!!*

FDA’s Center for Veterinary Medicine

Management changes: The Center for Veterinary Medicine (CVM) recently announced changes to several middle and upper-level management positions. On 7 January 2008, Dr. Steve Sundlof (the Director of CVM since 1994) took over the leadership of FDA’s Center for Food Safety and Applied Nutrition. Dr. Bernadette Dunham was named as Dr. Sundlof’s replacement. Dr. Dunham has been with CVM for the past five years, and immediately prior to succeeding Dr. Sundlof, she held the position of

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Deputy Center Director. Within CVM's Division of Therapeutic Drugs for Food Animals (which includes aquatic species), there have also been some changes in management. On 3 February 2008, Dr. Joan Gotthardt (former Division Director) transferred to CVM's Office of Minor Uses and Minor Species. Dr. Gotthardt's successor has not yet been named. We would like to take this opportunity to congratulate Drs. Sundlof, Dunham and Gotthardt on their career moves and to wish them the very best in this new chapter of their career and lives. We would also like to personally thank them for the significant parts they have played in helping all of us move closer to our goals of obtaining new aquaculture drugs. For more information click [here](#). **Best of luck to you all !!!**

CVM publishes updated Program Policy and Procedures Manual sections on aquaculture: CVM's Program Policy and Procedures Manual provides a quick reference to the rules, regulations, and instructions pertinent to all program areas of CVM's responsibilities, including the review of new animal drug applications, and post-market surveillance and compliance activities. The sections were updated on 19 February 2008 and include Section 1240.4210 ([Extra-label Use of Approved Drugs in Aquaculture](#)), Section 1240.4220 ([Drug-Pesticide Issues](#)) and Section 1240.4230 ([Regulation of Fish Identification Products](#)). These and all other sections can be accessed by clicking [here](#), or the individual section links above.

Designation of cold, cool, and warmwater fish species proposed to CVM: On 24 October 2007, AADAP, in coordination with the National Aquaculture Drug Research Forum, submitted a proposed temperature classification system to CVM. The proposed system groups U.S. publically cultured finfish into one of four rearing temperature categories: (1) coldwater fish, those species reared at water temperatures $\leq 12^{\circ}\text{C}$; (2) coolwater fish, species reared at temperatures between $12\text{-}18^{\circ}\text{C}$; (3) warmwater fish, species reared at temperatures $\geq 18^{\circ}\text{C}$; or (4) coolwater/warmwater "crossover fish" that are reared at temperatures $\geq 12^{\circ}\text{C}$. Information collected on approximately 100 species reported in the 2005 Public Aquaculture Production Database (available on AADAP's website; click [here](#) to access) was used to determine the most common rearing water temperature range for each category. This classification system is meant to provide guidance when determining if the use of an approved drug on a specific fish species is in accordance with on-label or off-label use (e.g., 35% PEROX-AID[®] approved for use in all freshwater, coolwater finfish), and developing data requirements for future drug approvals. Click [here](#) to view the complete

proposed temperature classification system. Stay tuned to learn what CVM's opinion will be!

Live-Attenuated Vaccine for *Streptococcus iniae* in advanced development stages: Researchers at the University of California San Diego and Aqua Bounty Technologies, in collaboration with Kent Sea Tech Corporation have been testing, with encouraging results, a live-attenuated injectable vaccine for *S. iniae*. The hope is that the vaccine will work equally well when delivered in feed. Click [here](#) for detailed information on the vaccine.

National Aquaculture Drug Research Forum update from February 2008 meeting:

The 6th meeting of the National Aquaculture Drug Research Forum (NADRF) was held in conjunction with Aquaculture America 2008, held in Lake Buena Vista, Florida, USA. The meeting convened at the conclusion of the Therapeutic Drug Research Special Session on Sunday, March 10, and was well attended by aquaculture drug researchers, research coordinators, drug and pharmaceutical sponsors, and members of CVM's Aquaculture, Environmental, and Toxicology Teams. The following agenda items were covered:

- Dr. Steve Yan (Center for Veterinary Medicine; CVM) discussed general data requirements for microbial food safety (Guidance For Industry ([GFI #152](#)) and microbiological Acceptable Daily Intake (ADI; [GFI #159](#)) assessment in order to expand the use of approved antimicrobial drugs for aquatic species. Dr. Yan stated that although both documents pertain to antimicrobial drugs and related microbiological considerations, the guidance documents each serve a different purpose. GFI #159, which is part of the toxicology assessment, is used to determine whether a microbiological ADI is needed for an antimicrobial drug for its intended use in aquatic or other food animal species. GFI #152, a requirement overseen by the Microbial Food Safety (MFS) Team, provides guidance on preparing a qualitative risk assessment relative to the drug's potential to induce antimicrobial resistance in human pathogens of concern.
- Mark Gaikowski (U.S. Geological Survey - Upper Midwest Environmental Sciences Center; UMESC) discussed feed method trial requirements and disseminated a draft feed method position paper he developed that summarizes current CVM thinking and CVM's guidance document [GFI #136](#). Mark's document is entitled "Developing Method Transfer Studies for Type C Medicated Feed

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Assay Methods – A Review,” and it describes: 1) selection of participating laboratories, 2) method demonstration, 3) transfer study feed sample sets, 4) establishing reference concentrations, 5) transfer study methods, and 6) analyzing and reporting results.

- Jim Bowker (U.S. Fish & Wildlife Service - Aquatic Animal Drug Approval Partnership; AADAP) discussed establishing a more functional Education and Outreach Team, incorporating an extra-curricular training session to be held in conjunction with the USFWS's annual Drug Approval Coordination Workshop, and identifying potential training topics. At this time, tentative plans are underway to put together a training session led by representatives from CVM's Aquaculture and Biometrics Team to discuss conducting studies to evaluate the effectiveness of parasiticides. Other outreach venues suggested included hosting Webinars, recording training sessions and disseminating by CD or DVD at a later date, WebEx Seminars, and recording technical presentations with audio that could be viewed by others at a later date
- Mark Gaikowski also drafted a “Survey of Parasitic-Related Aquatic Animal Health Issues.” The intent of the survey is to identify priority aquatic health issues caused by external and internal fish parasites. Survey results will help aquaculture drug researchers better prioritize drug approval efforts to treat priority parasite problems. The survey is currently undergoing review by select fish health biologists and aquaculture drug researchers.
- Jim Bowker provided excerpts from a CVM-accepted protocol that describes in detail methods to count or weigh fish into tanks at the start of a study, and count or weigh fish out of test tanks at the end of a study. The AADAP staff had worked with CVM's Aquaculture and Biometrics Team to resolve this issue and how it relates to fish discovered missing at the end of a study.
- Mark Gaikowski and Jim Bowker briefly discussed establishing a NADRF product peer-review process. The extent of such a process will be evaluated and instituted in the near-future.
- The fate of the NADRF was discussed in the context of the fact that the U.S. Joint Subcommittee on Aquaculture's Working Group on Drugs, Biologics, and Pesticides may soon cease to function as it has in the past (i.e., direct

involvement of non-federal representatives). There was group consensus that the NADRF is a functional group made up of federal and non-federal participants that has generated quality products that will help CVM with pre- and post-approval decisions, and that a new home for this Forum will be found in the event that it can no longer be associated with the JSA.

- The next meeting of the NADRF will be held in conjunction with the 14th Annual Aquaculture Drug Approval Coordination Workshop to be held in Bozeman, Montana, USA; 29-31 July 2008.

Aquaflor® (florfenicol) update:

No order too small for Veterinary Feed Directive drugs: Recent approvals for AQUAFLO[®] (florfenicol) for use in catfish and freshwater-reared salmonids have provided much-needed antimicrobial treatments for salmonid and catfish producers. However, the Veterinary Feed Directive (VFD) drug classification for AQUAFLO has created some challenges to feed companies and growers — particularly when only small batches of medicated feed are required.

“Fortunately, the vast majority of prescribed VFDs typically deal in tons of feed shipped and can easily be filled directly by the feed company,” says Steve Sharon, Fish Culture Supervisor, Wyoming Game and Fish Department. “However, the requirement for a feed mill to receive a VFD directly from a veterinarian prior to shipment in a specific prescribed amount can be very problematic if the infected fish lot is small in number, or if the feed poundage prescribed does not fit within 40- to 50-pound increments that a feed company typically ships.”

The Wyoming Game and Fish Department has established its own feed distributorship, which allows the state agency to receive medicated feed directly from the mill and then deliver it to its fish culture facilities as ordered by a veterinarian through a VFD.

A company or a wildlife agency can receive fish feed in 40- or 50-pound increments as a feed distributor without the requirement of a VFD order. In turn, the feed distributor can maintain a feed inventory and distribute the exact prescribed amount to a fish-culture facility upon receiving a valid VFD order. According to Sharon, this arrangement has allowed them to fulfill small VFD orders, keep VFD feeds on hand for cyclical fish-health issues and deliver feed quickly to a fish-culture facility after receiving a VFD.

To become a feed distributor, a company or wildlife agency must notify FDA of its intent to become a feed distributorship for VFD feeds and must develop an agreement with a feed company to become a VFD feed distributor as regulated by federal law, Sharon says. It also must establish the feed-distribution point at a

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location where fish are not reared. The distributor must maintain inventory control, original VFDs and supporting documentation for a minimum of 2 years.

For further information on how to obtain Aquaflor® click [here](#) or contact Kasha Cox, US Territory Manager (kasha.cox@spcorp.com) or 662-907-0692.

Text provided by Schering-Plough Animal Health; Summit, New Jersey, USA.

Aqui-S® updates:

Target Animal Safety studies: In January 2008, CVM reviewed AADAP's Final Study Report (FSR) on the safety of 40 mg/L AQUI-S® to small fingerling cutthroat trout and found that, "This study demonstrated that there is an adequate margin of safety above 40 mg/L AQUI-S® (i.e., the label dose) for sedation of cutthroat trout to handleable." Pending acceptance of the validation of the dose verification method, the accepted cutthroat FSR, along with previously accepted rainbow trout FSRs will complete the target animal safety technical section for all freshwater-reared salmonids.

National Toxicology Program Study Review Completed: On behalf of AQUI-S New Zealand, Tom Goodrich attended the National Toxicology Program's Technical Reports Review Subcommittee meeting held 27-28 February 2008 at the National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina. Among the compounds reviewed was isoeugenol (TR551), which is the active ingredient in the sedative/ anesthetic AQUI-S®. The subcommittee was presented with the combined findings of the 90-day (acute) and 2-year (chronic) carcinogenicity studies that had been contracted by NTP/NIEHS between the years 1998-2004. Following the presentation, three designated reviewers provided comments and critiques of the report. In addition, Tom Goodrich and Dr. Mark Toneby (MIT miljölab, Sweden) gave presentations discussing study-conduct issues and the lack of genotoxicity associated with isoeugenol, respectively. The acceptance of the report conclusions was put to a vote of the committee and was passed "as written" in the draft report. For AQUI-S®, the only significant conclusion was the finding of "clear evidence of carcinogenicity" in the male mouse model.

What does this finding conclusion mean for AQUI-S®? For European registration, nothing; the male mouse only finding is not considered relative to, or predictive of, carcinogenicity in humans, and since their registration process is based on risk assessment, an MRL (maximum residue level) will be assigned to isoeugenol and registration will

proceed. Under the U.S. FDA system, this finding may mean the end to the registration process for AQUI-S® for use on food fish, although further discussions with the FDA will ensue to explore any avenue that may remain open. As it relates to the study-conduct of the NTP studies, there remain unanswered concerns relative to the GLP (good laboratory practice) validity of the 2-year study. While the future may be clouded, AQUI-S NZ remains dedicated to the process and will continue its efforts until resolution is attained. *Text for this section of the AQUI-S® update was provided by Tom Goodrich, U.S. Agent for AQUI-S NZ, Redmond, Washington, USA.*

AADAP's perspective on the NTP findings: The conducted NTP studies demonstrated clear evidence of carcinogenic activity of isoeugenol in male mice. Although no official comments regarding these results have been offered by U.S. FDA's Center for Veterinary Medicine (CVM), earlier discussions with CVM suggested that **if** the NTP studies resulted in clear evidence of carcinogenic activity in any rodent study, this would more than likely be considered evidence of cancer in animals and would probably result in the regulation of isoeugenol as a carcinogen at such time that it were the subject of an Investigational New Animal Drug (INAD) exemption or a New Animal Drug Application.

Regardless of what method one may choose to slice, dice or view the findings of the NTP study as described above, it is clear that these findings have dealt a very serious blow to recent collaborative efforts to pursue FDA-approval of AQUI-S® for use as a zero-withdrawal anesthetic in aquatic species. Without a doubt, the immediate outlook for continued efforts towards an NADA for AQUI-S® in the U.S. would appear bleak. None-the-less, at this point in time it is still too early to fully comprehend all ramifications of the NTP findings, or to say "...OK, that's it for AQUI-S®!!" Rest assured that in the next several weeks there will be considerable discussion between members of the Association of Fish and Wildlife Agencies' Drug Approval Working Group, CVM, and Aqui-S New Zealand to determine 1) what, if any, options exist for continued work on AQUI-S®; and 2) if AQUI-S® is indeed unapprovable, what potential "replacement compounds" exist towards which we may realistically focus new efforts for a zero-withdrawal anesthetic. In the next issue of the Newsletter, we will fully explore the past, current, and future status of our quest for a zero-withdrawal anesthetic for use in aquatic species.

Calcein (SE-MARK®) updates:

SE-MARK® for marking calcified structures of young fish: Aquatic Life Sciences, Inc.'s (ALS)

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INAD work is continuing with AADAP and collaborators in several hatcheries and agencies building the data for target animal safety and effectiveness. ALS is also working on the Human Food Safety component of the data package.

Text provided by James Brackett, President; ALS, Inc., Ferndale, Washington, USA

Copper sulfate (Triangle Brand Copper Sulfate[®]) update:

Status of New Animal Drug Application (NADA) Technical Sections: Refer to [USDA's Corner](#).

Halamid[®] (chloramine-T) updates:

Research Activities: A field study to demonstrate the effectiveness of 20 mg/l chloramine-T for 60 min on three consecutive days to control mortality due to external columnaris in fingerling walleye has been accepted by CVM. The study was conducted at the Iowa Department of Natural Resources Rathbun Fish Culture Research Station (Moravia, Iowa) by Alan Johnson and AADAP staff in June 2006. Acceptance of this study completes the effectiveness technical section for external columnaris in walleye.

Review is pending on two chloramine-T pivotal field effectiveness studies conducted at Richloam Fish Hatchery (Florida Bass Conservation Center) for the control of mortality due to external columnaris on largemouth bass. Stay tuned.

Recently published journal articles pertaining to chloramine-T use in aquaculture: Following are two abstracts of articles recently authored by AADAP staff and published in the *North American Journal of Aquaculture*.

Bowker JD, DG Carty and MP Bowman. 2008. Inexpensive apparatus to rapidly collect water samples from a linear-design, plug-flow hatchery raceway. *North American Journal of Aquaculture* **70**:8-11.

Abstract — In July 2001, we conducted a study to determine whether a target concentration of chloramine-T (a waterborne chemical) could be achieved and maintained for 60 min in linear-design, plug-flow hatchery raceways (devoid of fish) via a charged “flow-through” treatment methodology. In each of four independent trials, a raceway was charged to achieve the target concentration by turning off the inflow water (creating a static bath) and manually mixing in a premeasured volume of chloramine-T stock solution. Water inflow was then turned on, and the target concentration was maintained by metering

additional chloramine-T stock solution into the inflow water with a calibrated chicken-watering system. To help verify chloramine-T concentrations during treatment, we built an apparatus to rapidly collect many water samples from throughout a raceway. The apparatus comprised three fixed sampling stations, each of which was equipped 9 water collection devices (i.e., 60-mL plastic syringes fitted with fixed-length “suction needles” made of ridged polyvinyl chloride pipe threaded with flexible vinyl tubing) and 9-11 plastic bottles for storing the collected samples. During each of the four 60-min trials, water samples were collected at elapsed times of 0, 30, and 60 min; thus, 12 sampling events were conducted during the study. During each sampling event, three people (working simultaneously but independently) collected a total of 29 water samples (27 for chloramine-T dose verification and 2 for quality control). The time for one person to collect 9-11 water samples (50-60 mL per sample) from one sampling station averaged 1.5 min (SD = 0.382 min; n = 36) and ranged from 0.9 to 2.5 min). The apparatus was inexpensive, easy to build and use, and portable; it ultimately helped us verify the spatial and temporal distribution of chloramine-T in linear design, plug-flow hatchery raceways during 60-min charged flow-through treatments.

Bowker JD, DG Carty, L Telles, B David and D Ovideo. 2008. Efficacy of chloramine-T to control mortality in freshwater-reared salmonids diagnosed with bacterial gill disease. *North American Journal of Aquaculture* **70**:20-26.

Abstract — Bacterial gill disease (BGD), caused by *Flavobacterium branchiophilum* and other species of yellow-pigmented, filamentous bacteria, is a common and potentially catastrophic disease of hatchery (freshwater)-reared fish. Chloramine-T (Chl-T) is a biocide proven effective for controlling mortality in freshwater-reared fish diagnosed with BGD. However, Chl-T is not approved by the U.S. Food and Drug Administration for such use. To generate data in support of a U.S. approval, we evaluated the effectiveness of Chl-T (administered at 12 mg/L of static bath water for 60min/d on three alternate days) to control mortality caused by BGD in freshwater-reared chum salmon *Oncorhynchus keta*, Apache trout *O. gilae apache*, and rainbow trout *O. mykiss*. For each species, mean percent total mortality in Chl-T-treated tanks (N = 3) was significantly less than that in control tanks (N = 3): chum salmon = 8.9%

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versus 99.7%, Apache trout = 39.2 % versus 97.9%, and rainbow trout = 5.7% versus 25.8%. Because the Chl-T regimen administered was efficacious for each species, we conclude that our findings support the approval of Chl-T for use in the USA to control mortality in freshwater-reared salmonids diagnosed with BGD.

Metomidate (Aquacalm®) update:

Aquacalm® for sedation and anesthesia: INAD work has focused over the last couple of years on ornamental and aquarium fish. However, work on food fish has been carried out in other countries. Further work on food fish is anticipated by Aquatic Life Sciences, Inc. (ALS).

Text provided by James Brackett, President; ALS, Inc., Ferndale, Washington, USA

Oxytetracycline (OTC) updates:

Human Food Safety Technical Section: On 21 December 2007, CVM approved Phibro Animal Health's 2 July 2007 request for a Human Food Safety Technical Section complete letter. CVM's letter contained some errors in the FOI, which were corrected and a new Human Food Safety Technical Section complete letter was issued on 6 February 2008.

Medicated Feed Labels: On 28 December 2007, CVM responded to Phibro Animal Health's 23 July 2007 request for review of Type A, B and C labels for Terramycin® 200 for Fish. CVM's response requested minor changes in the submitted labels. Phibro Animal Health made all requested changes and resubmitted the labels to CVM on 30 January 2008.

Environmental Safety Technical Section: On 21 February 2008, USGS's Upper Midwest Environmental Sciences Center (UMESC) received official notice from CVM that the UMESC-prepared Environmental Assessment was acceptable and hence, the Environmental Safety Technical Section for Terramycin® 200 for Fish was considered complete. See [USGS's Corner](#) for more details.

2008 Approval On Track: Two new label claims 1) a claim for coldwater disease in all freshwater-reared salmonids, and 2) a claim for systemic columnaris in all *Oncorhynchus mykiss*; and two label revisions/updates 1) addition of the approved Pacific salmon skeletal marking claim, and 2) removal of the water temperature restriction under the current salmonid claim are expected to be approved in 2008. As of the date of this newsletter, Manufacturing, Human Food Safety,

Environmental Safety, Animal Safety and Effectiveness Technical Sections are complete. The Label and All Other Information Technical Sections are currently under CVM review, with acceptance expected within 3 - 6 months. CVM is compiling the Freedom of Information summary and expects to complete this task when outstanding technical section reviews are complete.

Text provided by Paul Duquette; Phibro Animal Health, Ridgefield Park, New Jersey, USA.

Ovaprim® (LHRHa + domperidone) update:

Ovaprim® INAD work: Work on Ovaprim® (used to assist in spawning) by Aquatic Life Sciences, Inc. (ALS) has focused on ornamental and aquarium fish.

Text provided by James Brackett, President; ALS, Inc., Ferndale, Washington, USA

Ovaplant® (sGnRHa) update:

Ovaplant® INAD work: Work on Ovaplant® (used for advancing, compressing and synchronizing spawning) by Aquatic Life Sciences, Inc. (ALS) has focused on developing target animal safety and effectiveness study protocols. Supportive studies have been completed under the INAD and in other countries. Ongoing discussions are underway with CVM regarding the potential for classifying broodstock as non-food animals.

Text provided by James Brackett, President; ALS, Inc., Ferndale, Washington, USA

Potassium permanganate update:

Status of New Animal Drug Application (NADA) Technical Sections: Refer to [USDA's Corner](#).

17 α -methyltestosterone (17MT) updates:

Research/Approval status update meeting held at Aquaculture America 2008: In early February, key players in generating requisite data, and assembling and submitting the New Animal Drug Application (NADA) for 17MT, met to discuss the current status of activities and to plan future activities. The greater part of the meeting involved (1) formulating a plan to complete the target animal safety technical section, (2) discussing ongoing activities to complete the environmental assessment and (3) activities required to validate the transfer of the analytical method (to a private lab) for detection of 17MT in feed.

The USDA's Stuttgart National Aquaculture Research Center has agreed to conduct the target animal safety studies, and activities are underway to acquire partial funding for this work.

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Preliminary work is ongoing to allow for a new revision of the environmental assessment to incorporate the probable requirement to mitigate 17MT discharge to public surface waters.

The research lab that developed the detection method for feed, a private contract lab and the drug sponsor are currently working toward completing the necessary documentation to demonstrate successful method transfer.

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

Research Protocol: After making a few changes and edits to the pivotal efficacy protocol entitled, "The Efficacy of 35% PEROX-AID® to Control Mortality Due to Bacterial Gill Disease or External Columnaris in Cool and Warmwater Finfish", AADAP received a concurrence letter from CVM in February 2008. So, we're ready to roll with 35% PEROX-AID® pivotal efficacy studies just in time for the upcoming disease season!

FINS & TAILS, BITS & BOBBERS

SE-MARK® Detector Loaner: If you are enrolled in AADAP's INAD for calcein (SE-MARK®) or have hesitated to enroll in the INAD because of the high cost of a detector, help is now available. AADAP has an extra detector and is making it available for use by any calcein INAD investigator. If you are not enrolled and the cost of the detector has been holding you back from doing so, you've no excuses now. If you are interested in borrowing it, please contact Tom Bell (thomas_a_bell@fws.gov). Once you borrow it, you can keep it for as long as you need it, as long as someone else has not already reserved it for that time slot. Your only costs for using it are to replace batteries with fresh ones, replace any bulb that burns out and pay for shipping to the next user.

RELEVANT LITERATURE

The following is a list of journal publications with particular relevance to the broad topic of chemotherapy in aquaculture. This list comprises citations from 2007 and 2008. We plan to maintain this feature in future editions of the AADAP Newsletter. If you have come across literature that you believe would be of interest to the readership of the AADAP Newsletter, please forward the citation to Tom Bell (thomas_a_bell@fws.gov) and we will place it in the next edition.

The inclusion of a citation within the AADAP Newsletter does not imply: (1) recommendation of the technique to any particular situation, (2) concurrence with a treatment procedure/drug, (3) acceptance by 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.

Barrero M, BC Small, LR D'Abramo, GC Waldbieser, LA Hanson, and AM Kelly. 2008. Effect of carp pituitary extract and luteinizing hormone releasing analog hormone on reproductive indices and spawning of 3-year-old channel catfish. *North American Journal of Aquaculture* **70**:138-146.

Darwish AM. 2007. Laboratory efficacy of florfenicol against *Streptococcus iniae* infection in sunshine bass. *Journal of Aquatic Animal Health* **19**:1-7.

Gaikowski MP, WJ Larson and WH Gingerich. 2008. Survival of cool and warm freshwater fish following chloramine-T exposure. *Aquaculture* (in press, no issue number or page numbers available).

Russo R, EW Curtis and RPE Yanong. 2007. Preliminary investigations of hydrogen peroxide treatment of selected ornamental fishes and efficacy against external bacteria. *Journal of Aquatic Animal Health* **19**:121-127.

Samanidou VF and EN Evaggelopoulos. 2007. Analytical strategies to determine antibiotic residues in fish. *Journal of Separation Science* **30**:2549-2569.

Straus D. 2007. Copper sulfate: liquid or crystals? *The Catfish Journal* **21(11)**:17.

Williams RE, I Ernst, CB Chambers and ID Whittington. 2007. Efficacy of orally administered praziquantel against *Zeuxapta seriolae* and *Benedenia seriolae* (Monogenea) in yellowtail kingfish *Seriola lalandi*. *Diseases of Aquatic Organisms* **77**:199-205.

USGS's CORNER

Upper Midwest Environmental Sciences Center (UMESC) expands environmental safety

assessment capabilities: In an effort to expand our environmental safety capabilities, we are investigating methods to chronically expose juvenile mussels to pharmaceutical drugs used in aquaculture. According to published reports, of the nearly 300 taxa of freshwater mussel populations in North America, 70 species (23%) are listed as endangered or threatened and another 40 species (14%) are candidates for listing as endangered or threatened. The causes for the gradual loss of unionid (freshwater mussels) abundance and diversity have not been well characterized. We felt that it was prudent for us to ensure that newly developed aquaculture drugs discharged from aquaculture facilities will not augment mussel population declines. Therefore we are developing methodology to assess the chronic toxicity of aquaculture drugs with juvenile mussels, an organism sparingly used as a test organism. This methodology will potentially provide to researchers the

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ability to enhance future environmental assessment submissions with unique data supplying environmental assessment reviewers pertinent information that will aide in justifying their decisions.

It is generally understood that the earliest life stages of aquatic organisms are regarded as the most sensitive life stage. Our pilot study was designed to assess the survival and growth of newly transformed mussels in a flow through test system through an 8-week period.

Largemouth bass (*Micropterus salmoides*) were infested with glochidia from plain pocketbook mussels (*Lampsilis cardium*). One day after transformed mussels were siphoned from the bottom of aquarium, juvenile mussels (40 per chamber) were transferred to test chambers containing 200 mL of well water and 4 mm of silica sand. The test system consisted of 60 chambers evenly divided into 5 or 10 mL/min water flow rate groups. Each chamber received 1 of 6 food types (type 1 - Nannochloropsis 3600 Instant Algae[®]; type 2 - Shellfish diet 1800[®] Instant Algae[®]; type 3 - UMESC daphnia diet; type 4 - Nannochloropsis 3600 Instant Algae[®] x Shellfish diet 1800[®] Instant Algae[®]; type 5 - Nannochloropsis 3600 Instant Algae[®] x UMESC daphnia diet; and type 6 - Shellfish diet 1800[®] Instant Algae[®] x UMESC daphnia diet). The nominal water temperature was 21°C. Survival was assessed on day 56 post-stocking and retained for growth measurements.

Flow rate did not appear to affect survival. By day 56, chambers receiving food types 3 and 6 held no live mussels. Only 4 chambers of food type 2 and 2 chambers of food type 5 held live mussels. All chambers receiving food type 1 (48% survival) and food type 4 (27% survival) held live mussels. The mean length of 1 day old mussels was 267 µm. After 56 days, the mean length of mussels offered food type 1 at 5 mL/min was 927 µm and at 10 mL/min was 991 µm. Growth rates were 11.8 µm/day and 12.9 µm/day, respectively. The mean length of mussels offered food type 4 at 5 mL/min was 888 µm and at 10 mL/min was 1054 µm. Growth rates were 11.1 µm/day and 14.1 µm/day, respectively.

In our test system, the Nannochloropsis 3600 Instant Algae[®] food type resulted in the greatest survival and growth rates similar to rates previously published for similar species reared in laboratory environments. (contact: Jeff Meinertz; jmeinertz@usgs.gov)

TM-200[®] For Fish Type A Medicated Article (oxytetracycline dihydrate) environmental assessment accepted!!!! UMESC received notification from CVM's Environmental Safety Team that the environmental assessment (EA) prepared by UMESC was adequate to assure that oxytetracycline dihydrate use in aquaculture would not be expected to

have a significant impact on the human environment. CVM signed the technical section complete letter 21 February 2008. CVM issued a Finding Of No Significant Impact (FONSI) associated with the administration of oxytetracycline-medicated feed at 82.5 mg/kg bodyweight for 10 days to control mortalities associated with (1) columnaris disease in all freshwater-reared finfish; (2) bacterial hemorrhagic septicemia and pseudomonas disease in scaled warm freshwater-reared finfish; (3) bacterial hemorrhagic septicemia, furunculosis, and pseudomonas disease in cool freshwater-reared finfish; and bacterial coldwater disease in freshwater-reared salmonids. CVM's acceptance of the EA completes one of three outstanding requirements to amend the TM-200[®] For Fish label. (Mark Gaikowski; mgaikowski@usgs.gov)

Fish culture transition: Jim Luoma, UMESC's Fish Culturist, recently transferred to the Genoa National Fish Hatchery to take the Assistant Hatchery Manager position. Although we miss Jim's knowledge and experience, we wish him well in his new endeavors and challenges at GNFH. While in the process of recruiting for a new Fish Culturist, Sue Schleis and Maren Tuttle are taking turns caring for our fish. We presently have a vacancy announcement advertized on USAJOBS (<http://www.usajobs.opm.gov>) and through USGS's on-line recruitment system (<http://www.usgs.gov/ohr/oars/index.html>). Interested individuals are encouraged to apply. (Mark Gaikowski; mgaikowski@usgs.gov)

UMESC recently published manuscripts on chloramine-T and hydrogen peroxide: Both manuscripts summarize data submitted to FDA that were critical in completing the animal safety technical section or the environmental safety technical section for the respective drug.

Gaikowski MP, WJ Larson, and WH Gingerich. 2008. Survival of cool and warm freshwater fish following chloramine-T exposure. *Aquaculture* (2008), doi:10.1016/j.aquaculture.2007.12.017

Meinertz JR, SL Greseth, MP Gaikowski, and LJ Schmidt. 2008. Chronic toxicity of hydrogen peroxide to *Daphnia magna* in a continuous exposure, flow-through test system. *Science of the Total Environment* 392:225-232

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

Aquaculture America 2008 report: The Stuttgart National Aquaculture Research Center (SNARC) crew is back from Aquaculture America 2008 in Lake Buena Vista, FL where we made presentations in the

(Continued from page 8)

Therapeutic Drug Research special session organized and moderated by Jim Bowker, Mark Gaiowski and Dave Straus. Presentations made were: 1) "Improved method for minimum inhibitory concentration testing of *Flavobacterium columnare*" by Ahmed Darwish, 2) "Trials and tribulations of dose confirmation: using copper sulfate for fungus control on channel catfish eggs" by Dave Straus, and 3) "Comparison of tank treatments of copper sulfate and potassium permanganate on sunshine bass infested with Ichthyobodosis (Costiosis)" by Drew Mitchell. Please email us if anyone wants more information (Dave.Straus@ars.usda.gov).

Ongoing research: We have/are conducting various disease research projects which focus on toxicity and effectiveness of several compounds and management strategies. These projects include demonstrating the efficacy of Diquat to control *Flavobacterium columnare* in channel catfish and determining the effectiveness of Diquat and hydrogen peroxide in controlling Saprolegniasis on channel catfish egg masses.

Other news from SNARC:

Copper sulfate label: SNARC is partnering with Phelps Dodge Refining Corporation to draft a label for their product. When the label is acceptable to FDA/CVM, Phelps Dodge will then assume remaining approval activities through their channels and will formally submit the label. SNARC submitted the first draft and will address FDA/CVMs comments soon.

Copper sulfate human food safety (HFS): Several years ago, CVM issued a HFS technical section complete letter for all finfish, but the letter was sent to the Quality Assurance unit on the study instead of to the drug sponsor. Recently the sponsor asked for this letter to be addressed to them. However, in CVM's recent iteration of the letter the technical section was noted to be complete only for channel catfish. Currently, FDA/CVM requires a hazard characterization (Guidance for Industry #152) to be submitted and accepted before the HFS technical section can be considered complete. Once the GFI #152 is submitted and accepted, the HFS technical section should be complete for all finfish. The National Coordinator for Aquaculture New Animal Drug Applications has prepared a template to expedite the process. This is a good example of the need to get these approvals finished before the bar changes!

Copper sulfate Environmental Assessment (EA): An EA was prepared for copper sulfate use in earthen ponds and submitted to FDA/CVM. CVM responded with a request that we

resubmit the EA after addressing their comments, which will happen soon.

Copper sulfate effectiveness – fungus on channel catfish eggs: The protocol for this study has reached FDA/CVM concurrence and we've completed a laboratory dose-confirmation experiment. A field experiment will be completed at a nearby hatchery at the beginning of this year's spawning season for independent substantiation of the dose (10 mg/L). A Final Study Report will be prepared for both of these experiments.

Copper Sulfate Target Animal Safety – Channel Catfish Eggs: The protocol for this study has reached FDA/CVM concurrence and this GLP study is planned for mid-June.

Potassium Permanganate Human Food Safety: The HFS technical section complete letter for all finfish was received in 1999. In light of what happened with the HFS technical section for copper sulfate, a hazard characterization is being prepared (i.e., response to Guidance for Industry #152).

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.

33rd Eastern Fish Health Workshop; 31 March – 4 April 2008; Atlantic Beach, North Carolina, USA:

This year's annual workshop is being held at the Oceanfront Sheraton Inn and Conference Center, and as always is being hosted by the U.S. Geological Survey's National Fish Health Research Laboratory (Kearneysville, West Virginia).

Some important dates to remember: hotel reservation must be made by 1 March 2008 and full presentations received by 15 March 2008. Special session titles include: 1) New perspectives in coral disease; 2) A spoonful of Finquel helps the medicine go down: fish medicine and surgery; 3) Emergent diseases: betanodaviruses, rickettsial-like/*Francisella* organisms; 4) Letting the catfish out of the bag: updates from the South; 5) What's abnormal in fish histology and histopathology; 6) Molluscs and their critters; 7) Crustacean health; and 8) The aquatic detective: unusual case studies. For more information, contact Dr. Rocco Cipriano at 304-724-4432 or via email at rcipriano@usgs.gov. Click [here](#) for a registration form.



Aquaculture Canada^{OM} 2008; 11-14 May 2008; Saint John, New Brunswick, Canada:

The theme of this year's conference is "Growing Quality Seafood through Innovation." The conference is being held at the Delta Brunswick Hotel; Saint John, New Brunswick. The conference will not only include technical and industry

sessions, a full industry trade show, special topic sessions and workshops, but will also comprise several thematic areas, including, but not restricted to: freshwater hatchery and grow-out issues; market strategies and developments; sturgeon aquaculture development - sustainability and innovation; advances in shellfish production and economics; DFO Aquaculture Collaborative Research and Development Program Overview; developments in aquatic animal health management; biosecurity issues and management; developments in broodstock technology and management; advances in salmon production; and advances in aquaculture physiology and nutrition. For detailed information on registration, accommodations, etc. refer to the conference website by clicking [here](#).

World Aquaculture 2008; 19-23 May 2008; Busan, Korea:

The theme of this year's annual international World Aquaculture Society conference is "Aquaculture for Human Wellbeing - The Asian Perspective." It is being co-hosted by the Korean Aquaculture Society & KBMBX. The conference is being held at the Busan Exhibition and Conference Center, in Busan, South Korea. Scheduled sessions are too numerous to print here, but include Fish Health and Genetic, Functional Foods and Nutraceuticals, and Environmental and Health Management. The deadline for abstract submission was 1 November 2007. Please refer to the [Conference Website](#) for more information.

Aquaculture UK 2008; 21-22 May 2008; Aviemore, Scotland, United Kingdom:

This is a new conference taking place in the heartland of the Scottish aquaculture industry. The conference is being held at the Macdonald Aviemore Highland Resort. The conference will comprise seminar and workshop sessions concentrating on four themes, which include: 1) Shellfish – a new future?; 2) New Species - Are they a real opportunity or a diversion?; 3) Getting Started - Is aquaculture only for multinationals?; and 4) Operational Issues Workshop. For more information click [here](#) to view the conference website.

Diseases of Warmwater Fish Course; 2-13 June 2008; Ruskin and St. Augustine, FL, USA:

The University of Florida, has collaborated with the USDA Animal and Plant Health Inspection Service, State of Florida's Conservation Commission, the Whitney Laboratory of Marine Bioscience and several U.S.

public aquaria to organize and conduct this hands-on course. Diseases of Warmwater Fish is an intensive two-week class designed to provide instruction in the methodology of diagnosis and treatment of parasitic, bacterial, viral, nutritional, and environmental diseases of warmwater food fish and aquarium species. This course is open to students, veterinarians, fisheries biologists, aquaculturists, and professional aquarists. For information on registration, course topics, instructors, etc. access their course website by clicking [here](#).



Seventh Symposium on Diseases in Asian Aquaculture; 22-26 June 2008; Taipei, Taiwan:

The Fish Health Section (FHS) of the Asian Fisheries Society (AFS) is holding its Seventh Symposium on Diseases in Asian Aquaculture (DAA VII). It is being held in Taipei, Taiwan from the 22nd through the 26th of June 2008. The DAA Symposia are a series of triennial meetings of the world's leading scientists and students working in aquatic animal health, where all participants share their latest research findings, exchange ideas and establish new collaborations. To meet the current interest in disease control, DAA VII will also offer two "extra curricular" seminar/workshops on risk analysis and on recent advances on fish and shellfish immunology. Complete Conference information can be found on their [brochure](#).



49th Annual Western Fish Disease Workshop; 23-25 June 2008; Ocean Shores, Washington, USA:

This year's meeting is being co-hosted by The Northwest Indian Fisheries Commission and the Washington Department of Fish and Wildlife. The meetings are scheduled to be held at the Shilo Inn Suites Hotel in Ocean Shores, Washington. A block of rooms are being held at a special conference rate until 23 May 2008. Click [here](#) for the workshop's second announcement, and/or [here](#) for the conference website.



2008 American Fisheries - Fish Health Section Annual Meeting; 9-12 July 2008; Charlottetown, Prince Edward Island, Canada:



This year's meeting is being hosted by the Atlantic Veterinary College – University of Prince Edward Island, and will mark only the second time in history the FHS annual meeting has been held in Canada. Anticipated session topics include: epidemiology and clinical trials; infectious

salmon anemia; viral hemorrhagic septicemia in North America; diseases of marine finfish; diagnostic test validation; diagnostic electron microscopy; interactions of aquaculture and the environment; finfish immunology and vaccination; general finfish and shellfish pathology; and bacteriology and virology. For more detailed information, including on-line registration visit the conference website by clicking [here](#).

Symposium on Immunity and Disease Resistance in Fish; 28 July - 1 August 2008; Portland, Oregon, USA:

This symposium is being held as part of the 8th International Congress on the Biology of Fish. The symposium is being organized by Drs. Stephen Kaattari (Virginia Institute of Marine Science, College of William and Mary, Gloucester Point, VA), and Gregory Wiens (U.S. Department of Agriculture, National Center for Cool and Cold Water Aquaculture, Kearneysville, WV). The symposium is described as such: "Critical to the survival of any species is the optimal operation of their immune defense systems. Although fish



have set the evolutionary paradigm for the evolution of all vertebrate immune systems, they possess and retain mechanisms unique to their own physiology, anatomy and environment. Facets of immune function span and integrate a variety of disciplines from endocrinology and neurophysiology to toxicology and microbiology. The last two decades have demonstrated the extraordinary nexus that immunology serves within these sub-disciplines of ichthyology. This section will focus on the current molecular, cellular, and genetic means of understanding and enhancing fish immunity, both as a basic science and for the improvement of aquaculture." More detailed information on the International Congress and the symposium, including registration, accommodations, etc., can be accessed by clicking [here](#).

Australasian Aquaculture 2008 International Conference & Trade Show; 3-6 August 2008;

Brisbane, Queensland, Australia: Australasian Aquaculture 2008 is the joint international conference, trade show and series of associated events of the National Aquaculture Council, the Asian Pacific Chapter of the World Aquaculture Council and the Australian Prawn Farmers Association. Skretting and the Fisheries Research and Development Corporation are co-sponsors of the event. The conference takes place in the Brisbane Convention & Exhibition Centre. Detailed information regarding the conference and trade show can be found by clicking [here](#).



International Conference on Fish Diseases and Fish Immunology; 6-9 September 2008; Reykjavik, Iceland:



The understanding of infectious fish diseases and the causative agents, like viruses, bacteria and parasites, has been growing fast lately in the international scientific society. In parallel there is an increasing knowledge on host-pathogen interaction, including fish immunology and genome analysis of pathogens and several fish species. The aim of the meeting is to gather scientists from Europe and other parts of the world to discuss the recent developments in the field. Sessions will include fish immunology, viral diseases of fish and causative agents, bacterial diseases of fish and causative agents, fish parasitology, communication networks in marine bacteria and diseases in coldwater fish species. For more information refer to the conference website, by clicking [here](#).

International Council for the Exploration of the Sea - Annual Science Conference; 22-26 September 2008, Halifax, Nova Scotia, Canada:

The theme for Session "D" of the conference is: New Trends in Diseases of Marine Organisms: Causes and Effects. Abstracts for oral and poster presentations will be considered for Theme Session D on the following



and other relevant subjects: a) causes and effects of emerging diseases (including parasites) in wild fish, shellfish and other marine organisms; b) causes and effects of new diseases (including parasites) in farmed fish and shellfish; c) the use of diseases and parasites of wild marine organisms as indicators in integrated ecosystem health monitoring and assessment; d) new trends in the disease interactions between wild and farmed fish and shellfish; e) effects of introduced species on the health status of native fish and shellfish stocks; and f) new methodologies related to disease diagnosis and control. On-line abstract submission is now available at the ICES ASC website: <http://www.ices.dk/iceswork/asc/2008/index.asp>. Abstract are due: 21 April 2008. For further information contact: Sharon MacLean (sharon.macleam@noaa.gov), Thomas Lang (thomas.lang@vti.bund.de) or Sharon McGladdery (mcgladderys@inspection.gc.ca).

Aqua 2008 - 10th Congress of Equadorian Aquaculture and Trade Show; 6-9 October 2008; Guayaquil, Ecuador: This three-day conference and trade show is being held at the new Convention Center ExpoGuayaquil. Technical sessions include those on: aquaculture diversification, shrimp health and diseases, shrimp culture and markets. Detailed information on registration, accommodations, etc. can be found on the conference website or by clicking [here](#).



5th International Symposium of the Japanese Society of Fish Pathologists; 18-19 October 2008; Tokyo, Japan: The theme of this year's international symposium is "The role of fish pathology in sustainable aquaculture." This year's symposium is being held at The University of Tokyo's Yayoi Auditorium in



Bunkyo, Tokyo, Japan. The official language of the symposium is English. Keynote topics include: emerging diseases, international trade of aquatic organisms, international epidemiology and disease control. The deadline for submission of abstracts and early registration is 31 May 2008. For registration, accommodation and all other detailed information, click [here](#) to access the conference website.

ROZ's CORNER

For a summary of recent activities of the National Coordinator for Aquaculture New Animal Drug Applications (NCANADA) [click here](#) [editor's note].

Drug Approval Progress Matrices Updated: The NCANADA recently (4 March 2008) updated the detailed drug approval matrices. These matrices, in a tabular form, outline the current status of progress toward completion of the major NADA technical sections for priority drugs for aquatic species in the U.S. Click [here](#) to view these matrices.

Candidate zero withdrawal sedatives for aquatic food animals: The NCANADA began working in February 2008 with CVM, potential sponsors, and involved researchers to determine a course of action for a replacement candidate for a zero withdrawal sedative based on the peer review finding that the National Toxicology Program study results [on AQUI-S®/ isoeugenol] for the male mouse carcinogenicity study still stand, i.e., that there is clear evidence of carcinogenicity. She prepared tables on 29 February 2008 that illustrate the preliminary status of the technical sections for possible candidate zero withdrawal sedatives for food fish.

Aquaculture America 2008 Producer Session: The NCANADA convened a producer session at Aquaculture America 2008 on 12 February 2008. The

session covered the overall progress toward aquaculture drug approvals and included status of approvals for oxytetracycline dihydrate (TERRAMYCIN® 200 FOR FISH), hydrogen peroxide (35% PEROX-AID®), potassium permanganate (CAIROX®), and a number of drugs under development by Aquatic Life Sciences, Inc. CVM provided an update on its aquaculture drug approval activities. Researchers from the Aquatic Animal Drug Approval Partnership Program, the Harry K. Dupree National Aquaculture Research Center, and the Upper Midwest Environmental Sciences Center provided updates on their research activities toward aquaculture drug approvals.

New funding for oxytetracycline work: The North Central Regional Aquaculture Center is funding the Upper Midwest Environmental Sciences Center to conduct pivotal effectiveness studies on TERRAMYCIN® 200 FOR FISH (oxytetracycline dihydrate) and AQUAFLO® (florfenicol) for control of mortality due to *Aeromonas* sp. in warmwater and coolwater fish species produced in the North Central region. The project will start in late summer 2008.

Formation of a new industry-based group: Because of a potential concern that the Joint Subcommittee on Aquaculture Working Group on Aquaculture Drugs, Biologics, and Pesticides may be acting as a Federal Advisory Committee, an informal meeting was convened on 9 February 2008 to solicit input from non-federal stakeholders on future roles and direction. The new group is tentatively named the National Aquaculture Industry Therapeutic Agent Program (NAI-TAP) and is a coalition of aquaculture industry stakeholders and invited non-industry entities [exclusive of federal entities] who support the development and approval of drug, biologic, nutritional, and other therapeutic agents that affect the health and production of aquatic animals. The first organizational meeting of NAI-TAP will be to set its mission and objectives and discuss how to continue similar functions and activities of the Working Group on Aquaculture Drugs, Biologics and Pesticides. This meeting will be convened on 1 August 2008 from 1 to 5 PM in Bozeman, Montana, which is immediately following the 14th Annual Drug Approval Coordination.

MUMS "designations:" The designation provision of the Minor Use and Minor Species Animal Health Act of 2004 (MUMS) gives sponsors seven years of marketing exclusivity. As of 24 January 2008, the MUMS Office has granted 53 designations, 46 of those are to aquaculture drug sponsors, many of whom have received extensive help from the NCANADA. The most recent MUMS designations are 1) Western Chemical Inc.'s PARASITE-S® (formalin), and 2) Western Chemical Inc.'s TRICAINE-S® (tricaine methanesulfonate). There has been one original NADA approval for three label claims with MUMS designations for Eka Chemicals, Inc.'s 35% PEROX-AID®, and two

NADA supplemental approvals and one conditional NADA approval with MUMS designations for Schering-Plough Animal Health's AQUAFLO[®].

MUMS “indexing:” The final regulations for indexing (i.e., legal marketing of unapproved drugs) was published 6 December 2007. These provisions should allow companies to provide legally marketed drugs to our non-food fish industries (e.g., bait fish, ornamental fish). Companies began to submit requests on 19 February 2008. Dr. Joan Gotthardt, formerly the Director of the Division of Therapeutic Drugs for Food Animals, will be in charge of implementing these regulations.

MUMS “tax credits:” The U.S. Congress is addressing the possibility of adding the MUMS tax credit provision under the current Farm Bill. This provision would provide additional incentives for companies to pursue aquaculture drug approvals.

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

CVM's NOTES

Previous editions of the [FDA Veterinarian](#) newsletter and the [AADAP newsletter](#) have highlighted CVM's visits to the [catfish industry in Mississippi](#), [ornamental fish industry in Florida](#), and [fish facilities and hatcheries in Montana](#). Such opportunities have provided CVM staff with valuable insight into standard aquaculture practices.

Additionally, CVM is fortunate to have a program called Staff College which provides scientific, technical (veterinary medicine regulatory law and writing), and leadership education that supports our Center's mission. Staff College has supported various fish health courses. The most recent was a seminar on fish parasites taught by Dr. Ed Noga. Dr. Noga is a Professor of Aquatic Medicine at North Carolina State University's College of Veterinary Medicine and the author of *Fish Disease: Diagnosis and Treatment*. Dr. Noga discussed the biology of common fish parasites and implications for the design of studies of the effectiveness of antiparasitic drugs. Via webconferencing, AADAP, Upper Midwest Environmental Sciences Center, Stuttgart National Aquaculture Research Center, and FDA's Center for Food Safety and Applied Nutrition and CVM's Office of Research were able

to participate. Veterinary staff from the National Aquarium in Washington, D.C. and the National Aquarium in Baltimore also attended on-site.

We are looking forward to another Staff College seminar this spring focused on trout husbandry and diseases. Also successful is a monthly aquaculture journal club with participants from CVM's Office of New Animal Drug Evaluation (ONADE), Office of Surveillance and Compliance, and Office of Research.

While the majority of our time in ONADE is spent reviewing submissions, we are able to create opportunities with the aim of keeping current on evolving aquaculture practices and developments in aquatic animal medicine. We use this knowledge to help make educated, science-based decisions in the context of our regulatory framework.

Dr. Jennifer Matysczak, Aquaculture Drugs Team, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, Food and Drug Administration.



Hosted by the
USFWS's Aquatic Animal Drug Approval Partnership Program



14th Annual Aquaculture Drug Approval Coordination Workshop July 29—31, 2008 Bozeman, MT



Photo: Workshop attendees at the Icebreaker BBQ, Hyalite Reservoir, Aug. 2007

Just a quick announcement to let everyone know that the **14th Annual Drug Approval Coordination Workshop** will be held **July 29—31, 2008 in Bozeman, MT**. As in previous years, we will continue to discuss the approval status of priority aquaculture drugs and emerging biologics, focusing primarily on those drugs and biologics in which there has been active progress. We are fortunate that once again we will have representatives from both CVM and many drug companies in attendance. This Workshop is a tremendous opportunity for those of us in field-related aquaculture to be able to discuss with CVM, and each other, progress and strategies with respect to INAD/NADA activities.

Please visit our website for more detailed information on the Workshop, including other meetings scheduled to be held in conjunction with the Workshop, extra-curricular activities, lodging, maps and directions, and tentative agendas: www.fws.gov/fisheries/aadap



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