



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”



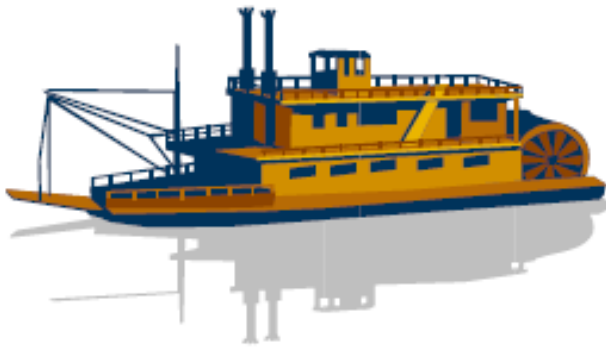
Volume 2-3

AADAP NEWSLETTER

June 2006

WHAT’S SHAKIN’

2006 Drug Approval Coordination Workshop: This year’s annual Workshop is being held in La Crosse, Wisconsin on 1-2 August 2006 at the Radisson Hotel. The workshop is being hosted by the U.S. Geological Survey’s Aquaculture Drug Research and Development Project in cooperation with the University of Wisconsin-La Crosse Continuing Education and Extension.



As has been the case for the past 11 years, the Workshop will showcase an excellent suite of presentation and discussion sessions covering the complete spectrum of the work being done on, and the status of, aquatic animal drugs. Similar to last year’s Workshop, the JSA’s National Aquaculture Drug Research Forum will be held in conjunction with the Workshop, this year on Thursday, 3 August.

The Workshop organizers have been hard at work scheduling other activities to make your stay even more enjoyable. An “Ice Breaker” is planned at Ebenezer’s Wood-fired Pizza and Grille the evening before (Monday, 31 July) the Workshop. On Tuesday evening a river boat cruise and light meal is scheduled. And if that ain’t enough, you can spend a wonderful evening Wednesday night on the shores of beautiful Lake Onalaska at a hog-roast picnic.

For detailed information regarding amenities, accommodations, agenda, events, registration (online), maps and contacts see http://www.umesc.usgs.gov/dacw/dac_workshop.html.

Summer Intern Position at the Iowa DNR Rathbun Fish Research Station: Congratulations to Alan Johnson, at the Rathbun Fish Culture Research Facility (RFCRF), and the Iowa DNR for taking a giant step to establish a new aquatic animal drug field efficacy program at the RFCRF. Alan initiated action to recruit a summer intern for a 10-wk period this summer with the goal of having this individual dedicated to drug approval-related efficacy testing. He then partnered up with the USFWS’s AADAP Program and Schering-Plough Animal Health (SPAH) Corp.

(Union, NJ) to help fund this position. Funding was contingent upon addressing the following two priority areas. First, AADAP’s highest priority is to have studies conducted to demonstrate that chloramine-T is effective in controlling mortality in a coolwater fish species (other than walleye) caused by bacterial gill disease or other external flavobacteria associated with the gills. Secondly, SPAH’s highest priority is to have one or more studies conducted to demonstrate that florfenicol-medicated feed is effective in controlling mortality in channel catfish caused by columnaris. After some discussion, it was agreed upon that these studies would be the primary focus of this intern’s efforts. Furthermore, AADAP has agreed to provide on-the-ground support during the studies and will analyze the data and develop Final Study Reports for submission to FDA’s Center for Veterinary Medicine. SPAH has agreed to provide medicated feed analytical support. Without going into too much detail, these are missing pieces to the drug approval puzzles for chloramine-T and florfenicol. Successful completion of these studies will allow “us” to plug these pieces into the puzzle to gain broader approval claims. “Big Ups” to Alan and the Iowa DNR for steppin’-up in a big way.

Aquaculture Drug Researchers receive FDA Award: FDA recently presented awards to several associated with aquaculture drug research. See photo below & [ROZ’s CORNER](#) for details.



Figure 1: “FDA Honor Awards” recipients and presenters (left to right): Dr. Steve Sundlof, Director CVM; Dr. Don Prater, CVM Aquaculture Team Leader; Dr. Susan Storey, CVM Aquaculture Team; Mr. Chuck Eirkson, CVM Environmental Safety Team Leader; Dr. Eric Silberhorn, CVM Environmental Safety Team; Dr. Steve Vaughn, CVM Director of the Office of New Animal Drug Evaluation; Dr. Stuart Leon, USFWS (accepting for Dr. David Erdahl, USFWS-AADAP); Dr. Bill Gingerich, USGS-ADRDP Leader; Ms. Roz Schnick, National Coordinator for Aquaculture New Animal Drug Applications; Dr. David Straus, USDA-ARS; Dr. Kevin Greenlees, CVM Toxicology Team; and Dr. Janet Woodcock, FDA Deputy Commissioner for Operations. Photo courtesy of CVM.

JSA’s Research Forum information: The JSA - Quality Assurance in Aquaculture Production Working Group’s National Aquaculture Drug Research Forum (NADRf) now has an extensive list of Standard Operating Procedures (SOPs) and Study Protocols available online. Refer to the [Feature Article](#) for more details on this and the NADRf in general.

The Food and Agriculture Organization of the United Nations' publication on prudent use of aquaculture antibiotics:

The FAO recently published "FAO Fisheries Technical Paper #469 – Responsible Use of Antibiotics in Aquaculture." This thorough and lengthy (97 pages) document is available on FAO's website (<http://www.fao.org>), as well as on AADAP's site (<http://www.fws.gov/fisheries/aadap/a0282e00.pdf>).

AADAP ...on the road again... at Penn Aqua Conference

2006: Part of the AADAP crew will provide another Workshop covering INADs and how they fit into the aquaculture drug approval process. The Pennsylvania Aquaculture Association has invited AADAP to provide a Workshop at their annual meeting to be held at the Holiday Inn Harrisburg-West in Mechanicsburg, Pennsylvania. The Penn Aqua Conference 2006 is scheduled for 20-23 September and is being jointly organized by The Aquaculture Advisory Committee, Pennsylvania Department of Agriculture, the United States Trout Farmers Association and the Pennsylvania Fish and Boat Commission. The INAD Workshop is scheduled for Friday, 22 September from 8:00 am until noon. For details contact Charles Conklin, Pennsylvania Aquaculture Coordinator (phone: 570-629-0427 or 460-0804; email: charlieconklin@verizon.net).

Calcein (SE-MARK[®]) update:

Western Chemical meeting: Western Chemical's new owner and general manager, Mr. Steve Becker, initiated a meeting with AADAP staff to discuss product development plans for their calcein marking agent (SE-MARK[®]). Western has expressed interest in calcein both as an immersion and feed-based product. Mr. Becker envisions Western Chemical as a new and agile leader in the aquaculture drug arena, and his enthusiasm is contagious!

Aquaflor[®] (florfenicol) update:

Bellingham Technical College: In our (AADAP's) world, it's always exciting to start-up new field efficacy trials, particularly when they are with new partners. That was the case in April 2006 when we headed out to Bellingham, Washington to work with Earl Steele, head of Bellingham Technical College's aquaculture program. What made this event even more exciting was that we had an opportunity (or at least we thought) to conduct a trial to demonstrate the effectiveness of florfenicol to control mortality caused by systemic columnaris in chum salmon. Successful completion of this study, when combined with the accepted study on coho salmon, would have been the final piece of the puzzle to complete the florfenicol/columnaris/all freshwater-reared salmonids claim for Aquaflor[®]. Dr. Jed Varney, DVM (Washington Department of Fish & Wildlife) contacted us with one of those late night calls and informed us that Earl had sick fish and that if we got moving, we had a chance to start a pivotal study before mortalities mushroomed out of control. Molly Bowman hustled out to Bellingham, and working closely with Earl, his students and Dr. Jed set the study up, and got things rolling. Then the "Bowker Effect" kicked in, and the fish spontaneously recovered...another opportunity lost. Not to be deterred, we arranged to have rainbow trout eggs from the J. Perry Egan State Fish Hatchery (Bicknell, UT) shipped to the Technical College to give it another try. So far all fish remain healthy and happy...oh well...but we're keeping our fingers crossed that they'll get sick. However, we would not have gotten this far without help from a few folks, and we want to say "many thanks" to Earl and his dedicated students for their hard work and willingness to give it another try. If nothing else, we'll see you next spring Earl.

17- α methyltestosterone update:

T minus 30 and holding: The initiation of efficacy and target animal safety studies on 17MT for tilapia is currently kind-of on hold. Although the analytical method needed for dose-verification has been approved by CVM, at the eleventh hour it was discovered that a contract needed to be let for manufacturing of the internal standard (IS) necessary for the analyses. Way back in February a custom order was placed with Steraloids, Inc. (Newport, RI) by AADAP and CanTest Ltd. (Burnaby, BC, Canada) to produce sufficient IS for the next couple years. Finally on 12 June, CanTest received IS shipped from Steraloids. CanTest has estimated that the analytical procedure will be transferred and ready for samples to be submitted no later than one month from their receipt of the IS. Hence, CanTest should be ready to receive feed samples for analysis by the 2nd week in July.

Research: It's taken awhile to get to this point, but FDA-CVM finally accepted our (AADAP's) MT-medicated feed field efficacy research study protocol. As usual, it took several revisions and many conversations with the CVM Aquaculture Team to get concurrence. During the review process, Tom Bell (AADAP) and the folks at Steraloids (Newport, RI) were working to manufacture the internal standard needed as part of the dose verification methodology, which had been previously developed by the University of Wisconsin - Madison. Now that the internal standard is available, we will soon be able to start our first efficacy trial at SeaPac of Idaho in Buhl, ID. We've made a couple of site visits to the fish farm and have gotten down to the nitty-gritty of study implementation. Working closely with the SeaPac crew, we have worked out the logistics at the farm, and we will plan to get this 4-5 month study up and running by mid-July. Many thanks to all those that have helped get "us" to the this point, including Dave Brock (Rangen Feeds, Inc.) and Ken Ashley, Ray Gill, and Patty Sheen (SeaPac of Idaho). We'll keep you posted as the study progresses and results become available.

AQUI-S[®] update:

Research: The Final Study Report for the pivotal AQUI-S[®] target animal safety study that we (AADAP) conducted on rainbow trout *Oncorhynchus mykiss* in March 2005 was submitted for review to CVM in April 2006. In this study, four replicate groups (n=20 fish per group) of "new" (previously unused) rainbow trout (3.8 cm) were exposed to 0 (control), 20, 40, or 80 mg/L AQUI-S[®]. We tested AQUI-S[®] concentrations of 20 and 40 mg/L because they are the lowest and highest concentrations currently being proposed for efficacious use in the U.S., and we tested 80 mg/L AQUI-S[®] as the study's "overdose" concentration. Each concentration was tested at four exposure durations, and the sets of four exposure durations assigned to each concentration were intentionally structured to generate survival data that ranged from 50 to 100%. Therefore, 16 unique exposure regimens (exposure concentration X exposure duration) were tested in the study. Each exposure event was followed by a 24-h recovery period.

Our study objective was to empirically identify an exposure duration (minutes) margin of safety for each of the AQUI-S[®] concentrations tested. Identification of "safe" exposure durations was based mostly on the survival data generated (acceptable if mean survival of n=4 replicates was $\geq 95\%$). However, we also considered the histology and behavior data generated. Results indicated that after rainbow trout

become sedated to handleable at 20, 40 or 80 mg/L they can be safely overexposed for an additional 17.0, 4.4, and 1.2 min, respectively.

We have revised the rainbow trout pivotal AQUI-S® target animal safety research protocol to include procedures for testing coolwater and warmwater fishes. In April 2006 we submitted the revised protocol to CVM for review. CVM will likely complete their reviews of both the rainbow trout final study report and the revised AQUI-S® target animal safety protocol within the next few months.

Publications: The March 2006 issue of *Fisheries* (Vol. 31, No. 3, pages 122-126) contains an article written by Roz Schnick. The article is entitled: Zero Withdrawal Anesthetic for Finfish and Shellfish: Need and Candidates.

INAD INFORMATION & STATUS

INADs and National INAD Program Map: Hey!!...we just wanted to take this opportunity to throw in a short “plug” for good ol’ INADs and everyone’s participation in the FWS’s National INAD Program (NIP). In the glitzy world of high-powered drug research, statistically significant events, technical section complete letters, and NADAs, the important role that INADs play in overall aquatic species drug-approval efforts is often under appreciated. And, the fact that participation in INAD-authorized drug-use requires a fair amount of “extra” work for all involved doesn’t help to bolster their reputation or garner respect. However, it is important to note that not only do INADs provide fishery managers with valuable treatment options otherwise not available; they also contribute very important production-scale (i.e., real-life!) efficacy and safety data that FDA seriously reviews and considers when making a final decision on a new or expanded NADA label claim. So...to all of you dots on the map below, keep up the good work and rest assured that by your extra efforts you are providing a valuable contribution to our partnership drug approval efforts!!

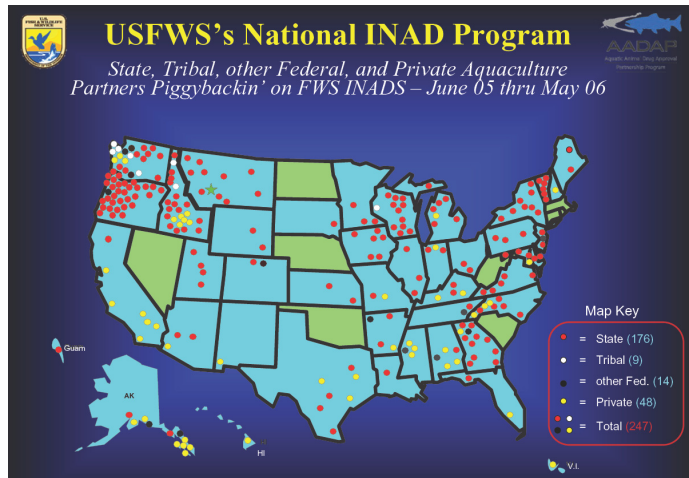


Figure 2: Non-USFWS participants in AADAP's National INAD Program. Within the Map Key, the numbers within parentheses represent the number of participating facilities.

Bonnie's Maternity Leave: Speaking of the NIP...this is a “heads-up” to all of you that are currently participating. Program Coordinator Bonnie Johnson is expecting a baby to arrive on her doorstep shortly (child #1 and we think it is a girl !!), and consequently will be on maternity leave for ~3 months starting on or about 4 July 2006. During the first month of Bonnie's leave please contact Dave Erdahl for assistance with any INAD-related questions, and please fax all study worksheets to the AADAP Office instead of mailing or emailing them in.

However, starting 1 August Bonnie will be working part-time on Mondays, Wednesdays, and Fridays, and be available to check email and phone messages, send out study numbers, and answer questions you may have. Please note that if you have any particularly pressing matters during this three month period you should call Dave Erdahl at 406-994-9904. Dave has promised to track down Bonnie for help when needed!

FEATURE ARTICLE

The National Aquaculture Drug Research Forum

*Jim Bowker; U.S. Fish & Wildlife Service;
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 4050 Bridger Canyon Road;
 Bozeman, Montana 59715*



It can take years (not to mention a whole lot of money) to gain U.S. Food and Drug Administration (FDA) approval of a New Animal Drug Application (NADA) for the initial or expanded use of a test article (i.e., drug or chemical) on an aquatic animal. Regardless of the test article under consideration, the public and private entities involved in the approval process face many similar challenges with respect to planning, coordinating, and conducting the research needed to demonstrate manufacturing consistency, user safety, human food safety, environmental fate, target animal safety, and efficacy. These challenges have been, and will continue to be, addressed via development of “road maps” by individual researchers at a variety of public agencies and universities working somewhat independently. After all, focused creativity is the heart of research, and there is often more than “one way” to generate the different types of data needed for FDA approval of a NADA! However, there is also great value in (1) exchanging information about what “has worked” and what “has not worked” in aquaculture drug research and (2) making this information available to all interested parties. To these ends, the National Aquaculture Drug Research Forum (NADRF) was formed under the auspices of the Joint Subcommittee on Aquaculture (JSA) Working Group on Drugs, Biologics, and Pesticides (WGDBP).

The NADRF first convened in August 2004 at the 10th Annual Drug Approval Coordination Workshop in Bozeman, MT. The Forum's mission is to identify and resolve issues and challenges facing researchers working to gain FDA approval of drugs for use in aquaculture and fisheries management. The Forum's goals are to (1) establish a national forum to facilitate coordination, cooperation, and communication among researchers in academia, government, and industry; (2) create a mechanism to broadly disseminate information relative to drug approval research activities; and (3) develop a strategic plan to address and resolve issues specific to technical projects. There are four Technical Project Teams: (1) Efficacy and Target Animal Safety, (2) Antimicrobial Resistance, (3) Environmental Safety, and (4) Human Food Safety. The latter team comprises four sub-teams: (a) analytical methods development and validation, (b) total residue depletion, (c) marker residue depletion, and (d) toxicology. There is also an Education and Outreach Team to disseminate information generated by the NADRF. Participation in the NADRF is voluntary, and anyone involved in aquaculture drug research is encouraged to become a member.

Many thanks to all those who helped establish the NADRF and to those who are currently in leading organizational positions: Mark Gaikowski (USGS, Upper Midwest Environmental Sciences Center) deserves special recognition for helping to draft the group's mission statement, strategic plan, and goals. The NADRF Co-Chairs are Renate Reimschuessel (FDA, CVM Office of Research), Dave Straus (USDA, ARS Stuttgart National Aquaculture Research Center), Jeff Meinertz (USGS, UMESC), and Jim Bowker (USFWS, AADAP). The Technical Project Team Co-Leaders for the environmental, antimicrobial, analytical methods, and efficacy teams, respectively, are Mark Gaikowski and Chuck Eirkson (USFDA, CVM), Christine Moffitt (USGS University of Idaho) and Steve Yan (CVM), Jeff Meinertz and James Nitao (CVM), and Jim Bowker and Don Prater (CVM). The Co-Leaders of the Education and Outreach Team are Gary Jensen (USDA, CSREES) and Susan Storey (CVM). Special thanks to those at FDA's Center for Veterinary Medicine who have acknowledged the value of the NADRF and have agreed to provide suggestions and advice to the Technical Project Teams (note: special consideration needs to be taken when working with FDA in this environment because they cannot provide guidance...only advice or suggestions). Finally, thanks to Gary Jensen, Kevin Greenlees (FDA, CVM), Don Prater, and Dave Erdahl (USFWS, AADAP) for helping to guide the NADRF in the "right direction" during our first meeting.

For more information about the Forum, click the JSA Research Forum navigation button on the AADAP website (<http://www.fws.gov/fisheries/aadap>). If you are interested in participating, please contact any NADRF member. The next meeting of the NADRF will be held on 3 August 2006 in conjunction with the 12th Annual Aquaculture Drug Approval Coordination Workshop, 1-2 August, 2006, LaCrosse, WI (for more information about the Workshop, visit www.umesc.usgs.gov/dacw/dac_workshop.html).

FINS & TAILS, BITS & BOBBERS

National Aquaculture Production Database: The most current information on fish production (numbers and weights) by Federal and State hatcheries is now on AADAP's website. [Click here to view](#). An updated version of the Database is planned for the end of 2006.

STOP THE PRESSES!!! National INAD Participants - do you know that all of the INAD forms are now available on the AADAP website in both PDF and MS Word formats? Check out the following link for all of the current INAD forms: <http://www.fws.gov/fisheries/aadap/signup.htm>.

Do you need help on calibrating or operating new test equipment or instruments?: Check out the JSA National Aquaculture Drug Research Forum (NADRF) button on our website for links to a huge collection of Standard Operating Procedures (SOPs), or [just click here to view](#).

Do you need to consult with an expert in some area of drug approval related research? The NADRF also has generated a subject expert directory, which can be viewed by [clicking here](#).

Do you need help calculating how much Aquaflo[®] premix to add to your feed? [Click here for a "cheat-sheet" to help you](#).

Does your facility produce more than 100,000 pounds of fish annually? If it does, you might find EPA's new (March 2006) aquaculture effluent compliance guidance document for permit writers and producers a valuable resource. [Click here to view](#).

Do you need/want to do a little extra reading on a specific INAD drug? AADAP is starting to add a section to each drug page with citations and/or links to specific drug-related articles. [Click here to see](#) a couple publications on the use of calcein for marking finfish. If you have any publications relevant to any of the INAD drugs that could be made available, please contact us.

PARTNERS' CORNER

Tropical Aquaculture Laboratory, Department of Fisheries and Aquatic Sciences, University of Florida:

"The Ornamental Aquaculture Industry Meets AADAP and the FDA." Aquarium-keeping remains one of the top-ranked hobbies nationally. The fish sold in the hobby are both imported and farmed domestically, with the ornamental fish industry a major component of aquaculture in the U.S.

Unlike the channel catfish and the salmonid industries, each of which is based primarily on one or two major species, the ornamental fish industry comprises thousands of finfish species, with hundreds produced domestically. Florida's industry accounts for the majority of domestic production and other states also raise a significant volume of koi and goldfish. This species diversity provides both economic robustness and logistical challenges for drug approvals.

Funding required for FDA-approvals of drugs for the catfish and salmonid industries has been considerable, and AADAP has greatly facilitated the process. However, by comparison, incentives for private companies to pursue FDA-approval of ornamental finfish drugs, given species number and differences in infrastructure, have been non-existent.

With the passage of the Minor Use Minor Species (MUMS) Act and increasing attention to drug and chemical use nationally, the prevailing regulatory climate has changed. In addition to added incentives for development of aquaculture drugs, new and innovative methods have been proposed to facilitate science-based legalization of drugs for aquarium species.

The learning curve has been steep for both sides of the regulatory aisle: the aquarium fish industry, and its research and extension support as well as those in the FDA. As faculty and staff at the University of Florida's Department of Fisheries and Aquatic Sciences (UF-FAS), we are the primary source of ornamental aquaculture extension and research support for Florida's tropical fish farmers. Legal drug and chemical availability is an identified industry priority, important for disease therapy, production, reproduction, and transport. Working with a number of private companies, we have begun using the experience and expertise of AADAP collaborators to assist with INAD protocols and NADA development. AADAP's 2005 Drug Approval Coordination Workshop in Bozeman, MT helped us to better understand and speak "the language," and provided us with numerous helpful contacts.

The FDA-CVM Aquaculture Drugs team has also been very helpful and open in its willingness to learn more about the industry. Ornamental aquaculture production and industry needs differ significantly from those of catfish and salmonids. Recently, at the request of FDA-CVM, a series of educational workshops were held to help get the FDA-CVM staff up to speed on ornamentals. Faculty from UF provided classroom and laboratory sessions at FDA on the ornamental industry, including production, transport, diseases, and industry needs. A number of FDA staff then followed-up by spending several days in Florida for additional lectures from UF faculty, USDA-APHIS-Veterinary Services and Wildlife Services, and Florida's Department of Agriculture and Consumer Services, Division of Aquaculture.



FDA staff also met with members of the Florida Tropical Fish Farms Association and visited a number of ornamental fish facilities of varying sizes and production system designs. These discussions and visits provided FDA with a first hand look at reproduction and production methods, including growout, harvesting, grading, and transport, water treatment, and shipping. The visit to Florida was equally informative for the producers, who learned more about the logistics involved for approvals.

We are now more optimistic that, with continued assistance from many supporters including AADAP, the ornamental aquaculture industry is much better positioned to obtain legal access to badly needed drugs. **Roy P.E. Yanong, VMD; Associate Professor/Extension Veterinarian; Tropical Aquaculture Laboratory, Department of Fisheries and Aquatic Sciences, University of Florida, Ruskin, FL 33570.**

USGS's CORNER

12th Annual Aquaculture Drug Approval Coordination Workshop in La Crosse: The U.S. Geological Survey's Aquaculture Drug Research and Development Team at the Upper Midwest Environmental Sciences Center will co-host the 12th Annual Drug Approval Coordination Workshop with the U.S. Fish and Wildlife Service's Aquatic Animal Drug Approval Partnership program. The Workshop will be held 1 & 2 August 2006, and is guaranteed to be both informative and entertaining. This year's Workshop will be held in the South Hall Ballroom of the La Crosse Center featuring a beautiful view of the Mississippi River. The Workshop format will be similar to the format from previous Workshops and will include presentations and discussions concerning the status of aquaculture drugs in the approval process. Representatives from FDA's Center for Veterinary Medicine will be attending to discuss INAD/NADA requirements and related issues. For additional information, including instructions to register, view the Workshop website http://www.umesc.usgs.gov/dacw/dac_workshop.html. **Contact Jeff Meinertz: phone 608-781-6291, email jmeinertz@usgs.gov.**

Center for Veterinary Medicine Considers Chloramine-T Target Animal Safety Technical Section Complete: The vision for a broad approval of chloramine-T use in U.S. aquaculture came a little closer to realization this spring when the USGS's Upper Midwest Environmental Sciences Center received word from the Center for Veterinary Medicine that the Target Animal Safety Technical Section is considered complete for all freshwater-reared finfish. The acceptance of the technical section was based on CVM's review of data provided by the FWS's Aquatic Animal Drug Approval Partnership Program, and the Aquaculture Drug Research and Development Team, Upper Midwest Environmental Sciences Center, USGS, La Crosse, Wisconsin. Completion of the Target Animal Safety Technical Section for all freshwater-reared finfish is viewed as a major milestone on the path for the eventual broad approval of chloramine-T use in U.S. aquaculture. **Contact Bill Gingerich at (608-781-6225), bgingerich@usgs.gov.**

MEETINGS, ETC.

Upcoming meetings

10th International Congress on International Society for Developmental and Comparative Immunology; 1-6 July 2006; Charleston, South Carolina, USA: This international conference will be held at the Charleston Place Hotel. The international program, with plenary lectures, contributed sessions and workshops will cover the latest research on mechanisms of



immunity, host/pathogen relationships, and environmental impacts on immune function across the phylogenetic spectrum. For more information see their website: <http://www.isdci.org/congress/index.shtml>.

6th International Conference on Recirculating Aquaculture; 21-23 July 2006; Roanoke, Virginia, USA: All aspects of recirculating aquaculture will be covered at this annual conference. This year the conference is at the Roanoke Hotel and Conference Center. Detailed information can be obtained via email at aqua@vt.edu or at the conference website: <http://www.conted.vt.edu/aquaculture/r-aqua/>.

International Symposium on Veterinary Epidemiology and Economics; 6-11 August 2006; Cairns, Australia: This 11th triennial symposium is being sponsored by: Biosecurity Australia, Department of Agriculture, Fisheries and Forestry; Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease; New Zealand Food Safety Authority; and Murdoch University School of Veterinary and Biomedical Sciences (Australia). Epidemiology and animal health economics are disciplines which depend on integrating expertise from a wide range of people, from virologists to sociologists and many in between. For more information refer to their website: <http://www.isveexi.org/content.php?page=home>.



Skretting Australasian Aquaculture 2006; 27-30 August 2006; Adelaide, South Australia: Skretting Australasian Aquaculture 2006 is a joint international conference, trade show and series of associated events of the National Aquaculture Council, the South Australian Aquaculture Council and the Asia-Pacific Chapter of the World Aquaculture Council. It is being hosted by Primary Industries and Resources, South Australia and the South Australian Tourism Commission. A large variety of sessions are planned including one on "Health in Aquaculture - vaccines and new technologies." Detailed information at: <http://www.australian-aquacultureportal.com/austaqua/aa06.html>.



5th International Symposium on Aquatic Animal Health; 2-6 September 2006; San Francisco, California, USA: The 5th ISAHA is being sponsored by the Fish Health Section of the American Fisheries Society and will be held at the San Francisco Marriott Hotel. The program includes 12 plenary lectures, more than 200 oral presentations, and up to 150 posters. Plenary lectures by outstanding speakers of international stature will address topics of broad interest. Detailed information, including hotels, registration forms, can be found at: http://www.fisheries.org/fhs/Meeting_Files/ISAHAbrochure4.pdf.



American Fisheries Society, 136th Annual Meeting; 10-14 September 2006; Lake Placid, New York, USA: The annual meeting of the American Fisheries Society will be held in Lake Placid, New York in the Olympic Village, site of the 1980 Winter Olympics. The meeting theme is "Fish in the Balance," during which attendees will explore the interrelationship between fish, aquatic habitats and man. The meeting will highlight challenges facing aquatic resource professionals and the methods that have been employed to resolve conflicts between those that use or have an interest in our aquatic resources. There are 34 scheduled symposia, including one entitled: "Whirling Disease: what's going on and what can we do about it?" Details can be found at: <http://www.afslakeplacid.org/>.



Aquaculture Canada^{om} 2006; 19-22 November 2006; Halifax, Nova Scotia, Canada: This year's conference is being co-hosted by the Aquaculture Association of Canada, the Aquaculture Association of Nova Scotia and Nova Scotia Fisheries and Aquaculture. The conference will take place at Westin Nova Scotian Hotel. Detailed information can be found at:



<http://www.aquacultureassociation.ca/AC06/index.html>.

7th Nordic Symposium on Fish Immunology; 17-20 June 2007; University of Stirling, Stirling, Scotland: The seventh international symposium on fish immunology, organized by the Nordic Society for Fish Immunology (NOFFI), will be held in June 2007, at the University of Stirling, Scotland. This event is held every three years and as with previous meetings, scientists from around the world are invited to attend to discuss recent advances in fish immunology. The conference will last for three and half days and will consist of plenary and keynote lectures, and oral and poster presentations covering both basic and applied fish immunology. There will also be a workshop on the day prior to the conference aimed at PhD students and young researchers which will focus on new, cutting-edge technologies in fish immunology. Registration fee will be £75 less for NOFFI members. To join NOFFI please contact the treasurer, Dr. Jarl Børgwald, Norwegian College of Fishery Science, University of Tromsø, N-9037 Tromsø, Norway. E-mail: jarlb@nfh.uit.no. For further details contact Janina Costa or Kim Thompson, Institute of Aquaculture, University of Stirling, Stirling, Scotland FK9 4LA Fax: 0044 1786 472133 Tel: 0044 1786 467912 Email: noffi@stir.ac.uk. Conference updates may be viewed at NOFFI's website: <http://www.noffi.org>.

Recently held meetings

Eastern Fish Health Workshop; 27-31 March 2006; Charleston, South Carolina, USA: True to form, the USGS's National Fish Health Research Laboratory (Leetown, West Virginia) sponsored 31st Annual Eastern Fish Health Workshop was, by all accounts, a big success. The workshop was well attended by folks from all sectors of the aquatic animal health arena. Part of the program was a special session focusing on the aquatic animal drug approval process. During this special session a series of excellent presentations were offered which outlined not only the current status, but also provided an understanding of what it takes to obtain a final approval from CVM and what are some of the hurdles encountered on the way. Presentations in the drug approval special session were: Dr. Don Prater (CVM), Ms. Roz Schnick (National Coordinator for Aquaculture New Animal Drug Applications), Mr. Jeff Meinertz (USGS - LaCrosse) and Mr. Jim Bowker (USFWS - AADAP). Presentations from the drug approval special session will be available soon for viewing on AADAP's website.

Western Division – American Fisheries Society; 15-19 May 2006; Bozeman, Montana, USA: Over 400 aquatic resource professionals convened on the campus of Montana State University for 176 presentations and 36 posters all relating to the meeting's theme of "Natives and Newcomers." Session titles included topics on sturgeon, bioassessment, bull trout, fish ecology, fish conservation and management, warmwater/prairie streams, chinook salmon culture, and natives and newcomers. Continuing education courses were held on; current knowledge of *Didymosphenia geminata* research and management, hydroacoustic tools for fish and habitat assessment, and study design and applied statistics for fisheries biologists which were

all very well attended. Presentation abstracts may be obtained by contacting Dr. Al Zale (zale@montana.edu) or Dr. Chris Guy (cguy@montana.edu).

ROZ's CORNER

Eka Chemicals, Inc. submitted the remaining technical sections (All Other Information and Labeling) in March 2006 for approval of three label claims for PEROX-AID[®] (hydrogen peroxide). The environmental assessment is in the final stages of acceptance by the Center for Veterinary Medicine (CVM). The label claims include the control of mortality due to (1) saprolegniasis on all freshwater-reared fish eggs, (2) bacterial gill disease on all freshwater reared salmonids, and (3) external columnaris disease on all coolwater fish and channel catfish.

As of 5 June 2006, the Office of Minor Use and Minor Species Animal Drug Development (MUMS) granted 22 Designations, 19 for aquaculture drugs. These Designations included 29 label claims for aquaculture applications. "MUMS Designation" means that sponsors will gain seven years of marketing exclusivity and have the possibility of receiving grants for safety and effectiveness testing. Aquaflor[®] (florfenicol) was the first animal drug to be approved under MUMS Designation in October 2005. The other aquaculture drugs designated so far (with number of designations in parentheses) include: florfenicol (6), hydrogen peroxide (3), calcein (1), 17 α -methyltestosterone (1), isoeugenol (2), amoxicillin (1), and oral oxytetracycline (5).

At an Honor Awards Ceremony on 5 June 2006, CVM presented awards for "...outstanding collaboration with state and federal agency partners developing data to support aquaculture drug approvals..." to the Aquaculture Working Group and the Drug Approval Coordination Workshop that included six CVM employees and their external data generating partners. The CVM employees included Chuck Eirkson III, Kevin Greenlees, Don Prater, Eric Silberhorn, Susan Storey, and Steve Yan. The external partners included Dave Erdahl (US Fish and Wildlife Service), Bill Gingerich (US Geological Survey), Roz Schnick (National Coordinator for Aquaculture New Animal Drug Applications), and Dave Straus (USDA Agricultural Research Service). A heartfelt thanks and congratulations are offered to all those recognized and their respective organizations. **Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, La Crosse, Wisconsin.**

CVM's NOTES

Food fish vs. Non-food fish: From time to time FDA/CVM receives questions about what species we consider to be food fish vs. non-food fish. With respect to enforcement priorities for aquaculture drugs, FDA/CVM has developed the following definitions. Additional information can be found on our website (<http://www.fda.gov/cvm/aqualibtoc.htm>) via links to our Policy and Procedures Manual sections 1240.4200 and 1240.4260.

Food fish and shellfish for human consumption - An aquaculture species is presumed to be a food species if it is reasonably likely that (a) a significant percentage of the species population will be consumed directly or indirectly by humans for food, or (b) the species is consumed by an identifiable human population.

Food fish and shellfish for animal feed - Fish used in whole or in part as a component of any animal feed will be considered a food fish species.

Non-food fish - An aquaculture species is presumed to be a non-food species if it is reasonably likely that (a) no significant

percentage of the species population will be consumed directly or indirectly by humans for food or (b) the fish species is not known to be consumed by an identifiable human population.

The following definitions are provided for categories of non-food fish.

Ornamental and aquarium fish - In general, ornamental and aquarium species are non-food species. Ornamental and aquarium fish are defined as fish that are produced and maintained solely for exhibit purposes in home or public aquaria, or in ornamental garden ponds.

Baitfish - Fish commercially raised to be used as bait in sport or commercial fishing e.g., fathead minnows, golden shiners and goldfish. A baitfish species will be considered a food fish if humans will consume any significant part of the species directly or indirectly.

Home aquarium - An aquarium in a private residence or exhibited in a business for hobby or decorative purposes.

Ornamental garden pond - Pond on the property of a private residence or for display in a business for hobby or decorative purposes.

Commercial pond – Pond or raceway where the fish are grown ultimately to be sold to individuals at pet stores or for some other commercial use.

For further information contact Dr. Donald A. Prater, Leader, Aquaculture Drugs Team at 301-827-7567 or dprater@cvm.fda.gov.

