



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 2-2

AADAP NEWSLETTER

March 2006

WHAT’S SHAKIN’

AADAP on the road: Part of the AADAP crew recently provided two Workshops covering INADs and how they fit into the aquaculture drug approval process. The organizers of the Southern Division – American Fisheries Society (AFS) and Colorado-Wyoming Chapter – AFS invited AADAP to provide Workshops at their annual meetings early February in San Antonio, Texas and early March in Cheyenne, Wyoming, respectively. See the “INAD Information & Status” Section of this Newsletter for details on the Workshops.

National INAD Program 2006 Sign-up — Just a reminder.... NOW is the time to sign-up for 2006 participation in the National INAD Program. Sign-up forms are available on the AADAP website (<http://www.fws.gov/fisheries/aadap/signup.htm>) or by contacting Bonnie Johnson at bonnie_johnson@fws.gov.

Also, all 2005 participants please send in all Form 2’s (Drug Inventory Form) and Form 3’s (Results Report Form) for each of the INADs that were used at your facility for **INAD Year 2005**.

Quarterly INAD Investigator/Monitor Award: A tip-of-the-hat and a pat-on-the-back to Bill Couch of the Georgia Department of Natural Resources and Bill Davin of Berry College School of Mathematical and Natural Sciences located in Georgia, for their continuing involvement in generating high quality efficacy data under the AQUIS® INAD for cool- and warmwater fish species.

Can you help us, please: Not that we are averse to writing the text for the Newsletter, but we truly appreciate “outside” contributions. If you have any information you believe our readership would be interested in knowing, don’t hesitate to give us a call or drop us an [email](#). For each quarterly Newsletter, we also try to find one facility, agency, organization, or individual that would like to contribute to our “Partner’s Corner” section. Although we would like to see a little more than a paragraph, we still are not asking for that much. For the “Partner’s Corner,” we only ask that you meet two requirements: 1) the article not exceed 300 words, and 2) the article contain information that our readership would find interesting or valuable, and pertains to activities within the U.S. drug approval arena.

USFWS Fisheries and Habitat Conservation personnel changes: The Fisheries and Habitat Conservation (FHC) Program and its Division of the National Fish Hatchery System (DNFHS), under which AADAP is a Branch, recently underwent several significant changes in leadership and staff. The long-vacant positions of Deputy Assistant Director of FHC, Division Chief of DNFHS and DNFHS National Aquatic Animal Health Coordinator were recently filled by Mr. Everett Wilson, Dr. Stuart Leon and Dr. Robert Bakal, respectively. About the same time, the highly respected Mr. Buddy Jensen retired from his position as the DNFHS Branch Chief for Hatchery Operations and Maintenance. We welcome the new arrivals and look

forward to working with them. We wish Buddy the very best in his new “job;” he’ll be sorely missed.

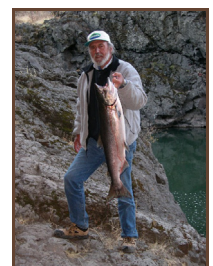
Charlie Smith inducted into NWFCC Hall of Fame: On 8 December 2005, while attending the 56th Northwest Fish Culture Conference (NWFCC) in Boise, ID, a GREAT HONOR was bestowed on one of “AADAP’s own.” On that date, Charlie Smith was inducted into the NWFCC Hall of Fame....and became only the 17th inductee to be so honored.

As many of you probably already know, Charlie has been an active, positive, and productive force in the fish culture and fisheries management arenas for 50 years. During a long and storied career with the U.S. Fish and Wildlife Service (FWS), Charlie was at the cutting edge of scientific efforts to help move fish culture (and our credibility) into the 21st century. Although Charlie’s list of credits and achievements is long, he is likely best known by most folks for his expertise and accomplishments as a certified fish histopathologist.

Charlie officially retired from the FWS way back in ‘93. However, through his myriad of “consulting” and *gratis* activities his involvement in, and contributions to, aquaculture has barely skipped a beat. For the last several years, those of us in AADAP have had the good fortune to have had access to Charlie’s histopathology expertise on a contract basis. A number of years ago Charlie was inducted into the AFS Fish Culture Section Hall of Fame....and now ol’ Chuck has received similar recognition by the NWFCC. WOW!!.....Congratulations Charlie.....and please don’t slow down or really retire!



Laurie Fowler (at left - retired FWS) presenting award to Charlie



Charlie with the one that didn’t get away

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 co-hosted by the U.S. Geological Survey’s Aquaculture Drug Research and Development Project, and the U.S. Fish & Wildlife Service’s Aquatic Animal Drug Approval Partnership Program in cooperation with the University of Wisconsin-La Crosse Continuing Education and Extension.

A [workshop flyer](#) is available with details. A more detailed announcement will be made available in April 2006 at <http://www.umesc.usgs.gov/dacw/> as well as on the AADAP website.

A “new” engaged sponsor is on the scene: AADAP recently met with the new management of Western Chemical, Inc. Mr. Steve Becker, General Manager, announced Western’s renewed commitment to gaining approval for SE-MARK® (calcein) as a marking agent. Current investigational activities have focused on SE-MARK® being administered via an immersion bath. Mr. Becker expressed Western’s desire to also investigate, and hopefully bring to approval, SE-MARK® administered via feed. Pilot work by AADAP, USFWS’s Lamar and Bozeman Fish Technology Centers, USGS’s Northern Appalachian Research Laboratory and Mr. Ron Secor (former owner of Western Chemical) have demonstrated that SE-MARK® administered via feed has real potential as a marking agent.

Western Chemical Inc. combines forces with Syndel Laboratories, Ltd.: As of 21 February 2006 Western Chemical Inc. of Ferndale, Washington and Syndel Laboratories Ltd. of Vancouver, BC Canada became sister companies under the U.S. company Aquatic Life Sciences, Inc. The union of these two leaders in aquatic animal health products should greatly increase potential new drug approvals for aquatic species. See Syndel’s [press release](#) for further details.

JSA’s Biologics Focus Group meeting: As a follow-up to the August 2005 JSA special meeting on Biologics, a special session on vaccines and immunostimulants was held at Aquaculture America 2006 in Las Vegas. A few [presentations](#) from the special session are now available, and as permission is granted for the others, they will also be made available. For more information about the special session see this edition’s “Feature Article.”

JSA’s Research Forum information: The JSA - Quality Assurance in Aquaculture Production Working Group’s National Aquaculture Drug Research Forum (NADRF) has met three times in the last 18 months. In addition to meeting notes, the NADRF has published a directory of experts involved in the aquatic animal drug approval arena. For the time being, all NADRF products and other associated information are available on the AADAP website under the [JSA Research Forum](#) menu button.

sGnRHa - Ovaplant INAD 11-375 is now available: This is a pellet implant product available through Syndel International, Inc. for use to induce final gamete maturation in a variety of species. **Please note if you are currently using implants under the LHRHa INAD, that you will need to switch to the sGnRHa INAD as implant use is no longer authorized under the LHRHa INAD.** sGnRHa Study protocols should be ready to send out within the next few weeks. Please contact Bonnie Johnson or Dave Erdahl if you have questions.

Aquaflor® (florfenicol) update:

Request for “Technical Section Complete” letter: As noted in the last edition of the Newsletter, AADAP requested that CVM consider all pivotal studies complete to support the following claim: “use of florfenicol-medicated feed administered at a dosage of 10 mg active drug per kg of fish per day administered for 10 consecutive days to control mortality in all freshwater-reared salmonids caused by furunculosis.” Unfortunately, we can not provide any further information at this time; we are still awaiting CVM’s reply.

17- α methyltestosterone update:

Efficacy Research: The AADAP office received a letter from CVM dated 1/27/06 outlining a few minor deficiencies with our pivotal effectiveness research protocol. The protocol has been revised and resubmitted to CVM. To

demonstrate the effectiveness of administering MT-medicated feed to tilapia fry to produce a predominately male population, we will conduct a “multi-site” study at three sites. We will start the first trial, to be conducted at a commercial farm in Buhl, ID, once the last few details have been ironed out with respect to analyzing feed to verify the dose being administered to test fish. We anticipate a “start date” within the next month or two.

AQUI-S® update:

Research: The AADAP research group has spent considerable effort developing data to support the following proposed label for use of AQUI-S® as a fish anesthetic in the U.S.:

“Use AQUI-S® to sedate all freshwater fishes for management and handling purposes. No withholding period required: treated fish may be assimilated into the food chain at any time.”

Recently, we were informed (verbally) by CVM that a sufficient number of pivotal efficacy studies have been conducted (and Final Study Reports submitted to CVM) to complete the effectiveness technical section. Although all Final Study Reports have not yet been officially reviewed, it certainly sounds like that assuming we don’t encounter some sort of un-natural disaster, the efficacy technical section will soon be complete for all freshwater fish! In summary, we have completed pivotal studies on rainbow trout, chinook and kokanee salmon, walleye, largemouth and smallmouth bass, channel catfish, tilapia, and hybrid striped bass. In all studies, “individual fish” were sedated to the handleable stage of anesthesia using 20, 40 or 60 mg/L AQUI-S® or 80 mg/L MS-222. In addition, we completed a small suite of studies to demonstrate that there is no significant difference in treatment effect between sedating individual fish (i.e., 1 fish) and small groups of fish (i.e., 10 fish per group).

AADAP has also completed the first of six required target animal safety studies to demonstrate that the highest proposed efficacious dose of AQUI-S® to sedate all freshwater fish to handleable is safe. In this initial study, rainbow trout (RBT) were overexposed (i.e., extended duration) to 20 or 40 mg/L AQUI S®, which are the lowest and highest proposed efficacious dosages. As per CVM requirements, we also exposed fish to an overdose concentration, which in the RBT study, was determined to be 80 mg/L AQUI-S®. As one would logically expect, effectiveness and safety of an anesthetic is a function of both dose and duration. Hence, our objective was to demonstrate that test fish could be overexposed at each of the dosages tested for a “safe” duration. A determination of “safe” exposure duration was based primarily on acceptable survival (i.e., $\geq 95\%$) and findings of no AQUI-S® - induced pathologies or adverse behavior. Results from this study show that after rainbow trout had become sedated to handleable at 20, 40, or 80 mg/L, they could be safely overexposed for an additional 17.0, 4.4, and 1.2 min, respectively. A Final Study Report has been drafted and is currently being audited by our Quality Assurance Officer.

SE-MARK® (calcein) update:

Feed Studies: As part of a USGS-funded Science Support Program (SSP) project, studies were initiated during November 2005 at the Bozeman Fish Technology Center (BFTC) to evaluate the effectiveness of calcein-medicated feed to mass-mark calcified tissue of shovelnose sturgeon



and Snake River cutthroat trout (*note*: 2 of 6 species to be tested under the SSP project). Studies with additional fish species are scheduled to begin soon at the Lamar Fish Technology Center (LFTC), Lamar, PA and the Northern Appalachian Research Lab, Wellsboro, PA. All fish in the BFTC study received a “standard dose” of calcein (40 mg calcein/kg of fish/d). Calcein was incorporated in feed in either an encapsulated or straight pre-mix form (non-encapsulated), and groups of fish were fed for either 5, 10, or 15 d durations. Fish were also marked via calcein immersion to provide a positive control.

Shovelnose sturgeon readily consumed encapsulated and non-encapsulated calcein-medicated feed, and fluorescent marks (on fins, scutes, and other calcified tissues) were readily visible during evaluation with the SE-MARK[®] detector for all treatment groups. In fact, marks on fish fed a calcein medicated diet for a duration of 10 or 15 days, were virtually identical in intensity to the immersion marked positive controls! The shovelnose sturgeon are currently being regularly sampled, euthanized, frozen and shipped to the LFTC for evaluation using fluorescent microscopy to determine the duration of mark retention. Mark retention evaluation will continue for the next 3 years.

Unfortunately, calcein medicated feed palatability issues were noted in the trial with Snake River cutthroat trout, and only low-level marks were observed. To address this issue, future trials with cutthroat trout (and other species) will likely involve evaluation of a lower calcein dosage(s).

Nonetheless, we were encouraged by the results of this preliminary trial, and eagerly await the results of the other trials to be conducted under the SSP project. The development, and approval, of a method for mass marking fish via medicated feed would indeed be another useful tool/drug to include in our aquatic species medicine chest!

FEATURE ARTICLE

Aquaculture American 2006 Highlights



Aquaculture America 2006, the World Aquaculture Society's U.S. Chapter annual meeting was held this year in Las Vegas, Nevada from 13 through 16 February. As in the past, there were numerous concurrent sessions (approximately 60). The sessions were extremely varied, ranging from aquaculture engineering to shrimp health to organic aquaculture and everything in between. There were several sessions that dealt directly or indirectly with activities pertaining to aquatic animal drug approvals. We've tried to very briefly summarize the aquatic animal drug-related sessions.

17- α methyltestosterone: Approval Status and Activities

Overview Session: The timeline for completion of NADA technical section components was reviewed by Roz Schnick. The following is a condensed summary of the technical sections and their respective anticipated completion dates (including review by CVM): feed studies (analytical method development, homogeneity, stability and segregation) – September 2006; water analytical method development – October 2006; biodegradation studies – September 2006; environmental assessment – June 2007;

target animal safety studies – June 2007; pivotal and supportive efficacy studies – June 2007. Jim Bowker (USFWS), Terry Berry (University of Wisconsin – Madison) and Anita Kelly (Southern Illinois University) provided a detailed progress report on efficacy, analytical methods and feed studies, and target animal safety, respectively. The analytical feed method was recently accepted by CVM, and we now await the transfer of the method to a commercial laboratory. The conduct and completion of both efficacy and target animal safety studies are directly dependant upon the analytical feed method for dose verification. The method transfer is expected to occur late April to early May. Several session [presentations](#) are now available, and they can be viewed on AADAP's website under “What's Shakin'/Recently Held Meetings”; additional ones will be added as they become available.

Therapeutic Drug Research: For the fourth year in a row, Dave Straus (USDA/ARS Stuttgart National Aquaculture Research Center) and Jim Bowker (USFWS - AADAP) hosted and moderated a special session on Therapeutic Drug Research. The session was held on the first day of the Conference right after the plenary session, and was very well attended. At this year's session, there were 11 presenters who covered a variety of topics including: effectiveness or environmental fate of therapeutants, anesthetics, and marking agents, developing disease models, and evaluating of the use of live attenuate vaccines in catfish pond culture. At the conclusion of this session, a short meeting of the JSA National Aquaculture Drug Research Forum (NADRF) was convened, and several topics were discussed and resolved, including posting NADRF-related information on the AADAP website, finalizing the Subject Matter Expert Directory, and developing a process to begin posting research study protocols and associated standard operating procedures on the AADAP site. Information relative to the NADRF can be accessed by clicking on the JSA Research Forum navigation button on the AADAP website. As soon as presentations from this session are made available, they can be viewed on AADAP's website; look for them to show up under [What's Shakin'/Recently Held Meetings](#).

Vaccines & Immunostimulants: Use and Development of Disease Prevention in Aquatic Animals: This session was somewhat of a follow-up to last August's biologics special session held in Bozeman, Montana. This year's session was organized by Drs. Phil Klesius (USDA Agriculture Research Service), Melisse Schilling (USDA – Center for Veterinary Biologics), John Hawke (Louisiana State University) and Randy MacMillan (Clear Springs Foods, Inc. and the National Aquaculture Association). The session was well attended, with estimates of over 100 attendees. The morning segment focused on producers' perspectives, while the afternoon focused on research progress. A portion of the [presentations](#) have been made available, and can be viewed on AADAP's website under “What's Shakin'/Recently Held Meetings”. As the other session presentations are made available, they too will be accessible on AADAP's website.

Aquaculture Drug Approval Successes: This session, hosted by Ms. Roz Schnick for 9 years running, has in the past typically been billed as a producer session. However, this year more than half of the attendees and presenters were representatives from the pharmaceutical industry. Prior to the actual presentations, Ms. Roz Schnick and Dr. Palma Jordan (Schering Plough Animal Health) officiated

over an awards ceremony. A plaque was given to each of several people expressing Schering Plough Animal Health's appreciation for that individual's contribution to the Aquaflor® (florfenicol) approval package and for continuing work to expand the label beyond the initial claim for ESC in catfish. Presentations at the session were given by representatives from the companies pursuing approvals for chloramine-T, hydrogen peroxide, AQUI-S®, oxytetracycline (feed additive) and oxytetracycline (marking). Several session [presentations](#) are now available, and they can be viewed on AADAP's website under "What's Shakin'/Recently Held Meetings"; additional ones will be added as they become available.

INAD INFORMATION & STATUS

Aquatic Animal Drug Approval Workshop: The Southern Division – American Fisheries Society (SD-AFS) and the Colorado – Wyoming Chapter of AFS (CW-AFS) invited AADAP to conduct a Workshop at each of their recent annual meetings. The SD-AFS Workshop was held on Friday, 10 February and was attended by approximately 20 people. The CW-AFS was held on Monday, 6 March, with 23 in attendance. The requested emphasis was on AADAP's National INAD Program (NIP) and how attendees might become involved. Additionally, the workshop provided other information to assist attendees in understanding how INADs and participation in INADs fits into the overall aquatic animal drug approval process.

From our perspective, the Workshops were a tremendous learning experience; they elucidated several ways in which AADAP can better align our program with the needs of our resource agency and private aquaculturist partners. We are also confident that many attendees went away better equipped to make decisions regarding their future involvement in INADs, which in turn should help all of us to gain the data needed for expanded label claims.

Both workshops were multi-media and interactive sessions. The topics covered included: (1) an overview of the drug approval process, acronyms and definitions, and AADAP's mission; (2) legal use of drugs; (3) judicious use of drugs; (4) an overview of AQUI-S® and an associated video; (5) a video on the Service's INAD program; (6) the drug approval process and how INADs fit into it; (7) an overview of calcein and an associated video; (8) a how-to session on participation in AADAP INADs; and (9) progress status of drugs for which new approvals are being sought.

For anyone interested in more details about the topics covered at the workshop, all the [PowerPoint presentations](#) have been archived on AADAP's website.

FINS & TAILS, BITS & BOBBERS

National INAD Program: Thanks to many of you, record participation in the National INAD Program is anticipated for calendar year 2006. In part, this happenstance is likely the result of a major change to the Pennsylvania Fish & Boat Commission's (PFBC) INAD program, that became effective 1 January 2006. Due to a reduction in time available for the PFBC INAD Coordinator to devote to their INAD efforts and increasing FDA reporting requirements, it became necessary for the PFBC to discontinue their practice of permitting other agencies to participate on PFBC INADs. An email was sent out to all affected participants advising them to contact the AADAP Office for enrollment in the FWS's National INAD Program (NIP). If you are an ex-PFBC INAD participant and are interested in

participating under the NIP, please contact Bonnie at bonnie_johnson@fws.gov for more information.

PARTNERS' CORNER

Wisconsin Department of Natural Resources – Wild Rose State Fish Hatchery: The Wild Rose State Fish Hatchery (SFH) is centrally located in Wisconsin and participates in the Service's LHRHa INAD to synchronize ovulation in free ranging adult female lake sturgeon. Historically, lake sturgeon had self-sustaining populations in several large lakes and all of the larger river tributaries to Lake Michigan, Lake Superior and the upper reaches of the Mississippi River. The construction of dams and other factors have caused lake sturgeon populations to decline over the past 100 years, and today only remnant populations exist in many parts of the state.

Part of Wisconsin's sturgeon management plan is to restore lake sturgeon throughout their historic range by stocking. Our goal is to retain whatever genetic "uniqueness" remains in each remnant population. Thus, lake sturgeon eggs collected from wild broodfish from a particular river system will be used only for stocking in that same river system. Each year, progeny from up to five river systems are reared at the Wild Rose SFH and are stocked above dams in their parental watershed. Restoration efforts are ongoing in the Wisconsin, Flambeau, Menominee, and Upper St. Croix watersheds and in Lake Michigan tributaries. Surplus eggs are usually available to other agencies for other restoration projects.

Infrequent spawning, late maturity (female lake sturgeon spawn once every 3 to 5 years only after they are 25 years old) and limited spawning habitat (usually tail waters of dams during spring high water flow) make it challenging to find adult females in the act of spawning. By capturing females before they have ovulated and injecting them with LHRHa (males in the same tank with ripe females produce tremendous amounts of viable sperm) we have been able to increase the number of adults used as founders in these remnant populations. As a result of our successes with LHRHa, we are "on target" to meet the stocking goals of our management plan. **Steve Fajfer, Hatchery Supervisor, Wild Rose SFH, Wild Rose, WI 54984, and Sue Marcquenski, Fish Health Specialist, Wisconsin DNR, Madison, WI 53707.**

USGS's CORNER

AQUI-S®: The Upper Midwest Environmental Sciences Center (UMESC) successfully competed for research funds from the North Central Regional Aquaculture Center to validate the analytical method for the marker residue of AQUI-S® in tissues of cool and warm water fish. Once validated, the method will be used to conduct marker residue depletion studies on selected cool and warm water fish to fulfill a part of the human food safety technical section for AQUI-S® as a short or zero withdrawal anesthetic for all freshwater fish. **Contact Jeff Meinertz, phone 608-781-6291; e-mail bjgingerich@usgs.gov.**

Chloramine-T: The UMESC submitted a revised draft of the environmental assessment for chloramine-T to the Center for Veterinary Medicine on 9 February 2006. The environmental assessment was written to cover all cultured U.S. freshwater fishes. The Product Chemistry technical section, the only outstanding technical section for chloramine-T, is being prepared by the sponsor. **Contact Bill Gingerich, phone 608-781-6225; e-mail bjgingerich@usgs.gov.**

External Columnaris Disease Model: Good progress has been made in the development of an external columnaris disease



model for cold, cool and warm water fish. Two geographically isolated strains of *Flavobacterium columnare* were tested for infectivity against rainbow trout, walleye, channel catfish, yellow perch and hybrid striped bass. Within fish species, severity of the infection was controlled by concentration of bacteria in the exposure baths, temperature of exposure baths and time of exposure. Reproducible mortality/morbidity patterns have been observed for both strains of bacteria among the species of fish tested. **Contact Bill Gingerich, phone 608-781-6225; e-mail bjgingerich@usgs.gov.**

Retirement: Longtime USFWS and USGS chemist Larry J. Schmidt retired from federal service on January 3, 2006. Most recently Larry was responsible for drafting the UMESC environmental assessments for chloramine-T, hydrogen peroxide, and oral oxytetracycline. We wish Larry a long and fulfilling retirement. **Contact Bill Gingerich, phone 608-781-6225; e-mail, bjgingerich@usgs.gov.**

MEETINGS, ETC.

Upcoming meetings

Eastern Fish Health Workshop; 27-31 March 2006; Charleston, South Carolina, USA: USGS's National Fish Health Research Laboratory (Leetown, West Virginia) will be hosting the 31st Annual Eastern Fish Health Workshop. The workshop will include special sessions focused on several themes, including: imminent threats affecting our coral reefs, advances in crustacean health and disease, clinical approaches in pet fish medicine, practical vaccination in aquatic animal health management, health management and clinical conundrums in public aquaria, case diagnostics, and the INAD/NADA process. For further information contact Rocco Cipriano, email rcipriano@usgs.gov, phone 304-724-4432, FAX 304-724-4435.

Aquaculture Today 2006; 28-30 March 2006; Edinburgh, Scotland: This is the second annual Aquaculture Today conference. This year's meeting is being hosted by the aquaculture magazine *Fish Farmer*. One half-day session is devoted to fish health and veterinary medicine. More details can be found on their website: <http://www.aquaculturetoday.co.uk/>.

Aqua 2006; 9-13 May 2006; Florence, Italy: The next annual meeting of the World Aquaculture Society and the European Aquaculture Society is scheduled for the 9th through the 13th of May 2006 in Florence, Italy. The themes for the conference are "Linking Tradition and Technology" and "Highest Quality for the Consumer." Planned topics for the conference include: sustainable environment; society and aquaculture; consumer issues; economics and business; shrimp; juvenile fish production; juvenile invertebrate production; nutrition, health and welfare; and production systems. Information available on their website (<http://www.was.org/meetings/WasMeetings.asp>) or by contacting the Director of Conferences at (phone) 760-432-4270, (FAX) 760-432-4275.

Western Division – American Fisheries Society; 15-19 May 2006; Bozeman, Montana, USA: The Montana Chapter of AFS is hosting the next divisional meeting to be held on the Campus of Montana State University in Bozeman, Montana. Scheduled symposia include: sturgeon; chinook salmon culture; reservoir forage fish; bull trout; biological assessment and prairie/warmwater streams. Details can be found at: <http://www.fisheries.org/AFSmontana/2006AFSWesternDivisionAnnualMeeting.htm>.

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>.

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 meeting 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 interrelation between fish, aquatic habitats and man by highlighting 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/>.

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. Detailed information, including hotels, registration forms, can be found at the AFS-FHS website: http://www.fisheries.org/fhs/Meeting_Files/ISAHAbrochure4.pdf.

Recently held meetings

JSA's National Aquatic Drug Research Forum; 14 February 2006; Las Vegas, Nevada: Jim Bowker and Renate Reimschuessel (CVM's Office of Research) moderated a meeting of the National Aquaculture Drug Research Forum (NADRf). The major accomplishments of the meeting include: (1) finalizing the Subject Matter Expert Directory, (2) announcing that all printed information relative to the NADRf will be posted on the AADAP website and can be located by clicking on the JSA Research Forum navigation button, and (3) a plan has been developed to post pertinent research study protocols and associated SOP's on the site. Scientists and biologists just getting involved in aquaculture drug approval research, and even those that have experience in drug approval research but are beginning to work on a "new" drug or "new" technical section, have found that using a CVM-accepted protocol as a template has greatly reduced the time required to develop their own CVM-accepted protocol and associated SOP's. Visit the [AADAP website](#) to learn more about the NADRf; located under the navigation button entitled "JSA Research Forum."

AQUI-S[®] meeting with FDA's Center for Veterinary Medicine; 7 February 2006; Rockville, Maryland: Jim Bowker attended a meeting at CVM to discuss issues relative to the approval of AQUI-S[®]. The meeting was requested by Tom Goodrich and Jan Holland from AQUI-S New Zealand Ltd. to discuss progress and status of the research to complete the efficacy, target animal safety (TAS), human food safety, and environmental safety technical sections. Also attending the meeting were Don Prater and Jen Matysczak from CVM's Aquaculture Team, Joan Gotthardt, CVM's Director of Division of Therapeutic Drugs for Food Animals, Julia Oriani and Kevin Greenlees from CVM's Division of Human Food Safety, Jeff Meinertz and Bill Gingerich from USGS's Upper Midwest Environmental Sciences Center, and Roz Schnick, Aquaculture NADA Coordinator. Results from



the meeting that directly affect the AADAP research group include: (1) the addition of a second salmonid species that must be tested to complete the TAS technical section for all freshwater salmonids and (2) the revision of the TAS research protocol to include other fish species and a scheme to sample and examine fish for AQUI-S® - induced pathologies.

Coolwater Fish Culture Workshop; 8-10 January 2006; Wisconsin Dells, Wisconsin: This year's 2-day workshop comprised 27 presentations organized into five topic-specific sessions, including one on fish health/INADs/markings. Organizers of the workshop will be making all the presentations available for posting on AADAP's website. Within the next month they should be accessible; look for them to show up under [What's Shakin'/Recently Held Meetings](#).

Western Fish Disease Workshop; 28-29 June 2005; Boise, Idaho: The meeting was well attended and the organizers have made a copy of the proceedings available on-line at: <http://www.fws.gov/fisheries/aadap/recentlyheldmeetings.html>).

ROZ's CORNER

Schering-Plough Animal Health (SPAH) obtained an approval for Aquaflor® (florfenicol) for control of mortality associated with enteric septicemia in catfish on 25 October 2005. SPAH recognized the contributors to the approval at Aquaculture America 2006 during my producer session entitled "Aquaculture Drug Approval Successes".

On 5 January 2006, 37 of the 38 state natural resources agencies that financially supported the Federal-State Aquaculture Drug Approval Partnership Project (known as the IAFWA Project) filled out the "Survey on Unmet Label Claim Needs for the IAFWA Project Exit Strategy". The states were offered the opportunity to let the IAFWA Drug Approval Working Group (DAWG) know if it has met or are meeting the states' needs for the legal use of drugs in hatchery or fish management operations. The DAWG wanted to be sure that each state has the tools needed to control mortality from diseases in or on cultured fish species and to sedate or anesthetize fish for immediate release or slaughter. The responses to this survey will help the DAWG assess progress to date and to determine what data need to be generated in the future to meet any of the states' unmet label claim needs. I have tabulated and analyzed the responses on 10 January 2006 for a March 2006 DAWG meeting.

Under the auspices of the Joint Subcommittee on Aquaculture, Working Group on Quality Assurance in Aquaculture Production, I developed the "[Internet-Based Drug Matrix Database](#)". These matrices provide detailed information and status on the data and information being developed for the approval of high priority drugs in the United States aquaculture industries. The matrix or matrices for each drug are web pages that can be downloaded and will be updated periodically. **Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, La Crosse, Wisconsin.**

CVM's NOTES

New Judicious Use of Antimicrobials Booklet: A new booklet describing principles of judicious use of antimicrobials for aquatic veterinarians was released this month at Aquaculture America 2006. The booklet, *Judicious Use of Antimicrobials for Aquatic Veterinarians*, is a collaborative effort between the Aquatic Veterinary Medicine Committee of the American Veterinary Medical Association (AVMA) and the Aquaculture Working

Group of FDA's Center for Veterinary Medicine (CVM). The booklet is the first guide produced for a minor species.

The work is intended as a reference and educational resource for practitioners administering antimicrobials primarily to food fish, although the application of judicious and prudent use of antimicrobial drugs applies to the treatment of other types of aquatic animals, as well.

Currently, three antimicrobials are approved to treat various bacterial diseases in fish: sulfadimethoxine/ormetoprim, oxytetracycline and florfenicol. All are administered as medicated feed. Oxytetracycline (Terramycin® 100 for Fish) and sulfadimethoxine/ormetoprim (Romet® 30) are approved for over-the-counter use.

Under FDA's [Compliance Policy Guide 615.115, Extralabel Use of Medicated Feeds for Minor Species](#), veterinarians may use oxytetracycline and sulfadimethoxine/ormetoprim to treat additional diseases or additional species, provided the medicated feed is produced in accordance with approved label directions (i.e., extra-label use).

In October 2005, florfenicol (Aquaflor®) was approved as a veterinary feed directive (VFD) drug for the control of mortality in catfish due to enteric septicemia of catfish. VFD drugs are available only upon the order of a licensed veterinarian and extralabel use of VFD drugs is strictly prohibited.

VFD categorization of Aquaflor® is consistent with CVM's policy for approving new antimicrobials for use in medicated feeds. VFD status limits access to the antimicrobial and places it in the hands of prescribers with training and experience in the diagnosis and treatment of disease in populations of animals.

The booklet describes concerns for the development of antimicrobial resistance and outlines principles for the use of antimicrobials in veterinary practice. The veterinary profession shares the concerns of the public, governmental agencies, and the public health community regarding the broad issue of antimicrobial resistance and specifically the risk of resistance developing in animals with subsequent transfer to humans.

The 15 principles described in the booklet are followed by a section discussing their application to large populations of fish, such as those treated in food fish aquaculture. Although veterinarians have not traditionally been the primary providers of health care to cultured fish species, the growing number and scale of cultured fish operations, in addition to backyards ponds and home aquaria, in the United States has resulted in the expanding involvement of veterinary practitioners.

The approval of the new antimicrobial as a VFD drug and the opportunity to utilize non-VFD medicated feeds for minor species in an extralabel fashion has resulted in an important increase in the therapeutic options for aquatic veterinarians. This increase in therapeutic options is accompanied by an increased responsibility for judicious use of antimicrobials. The new booklet will be a substantial resource for these practitioners.

For a copy of the booklet, contact Dr. David Scarfe, Assistant Director, Scientific Activities Division at the American Veterinary Medical Association, 1931 N. Meacham Rd., Suite 100, Schaumburg, IL 60173; Direct phone: 847-285-6634 or 800-248-2862 Ext 6634, email: Dscarfe@AVMA.org. Alternatively, contact the Communications Staff, FDA/Center for Veterinary Medicine, 7519 Standish Place, HFV-12, Rockville, MD 20855; 240-276-9300. **Dr. Donald A. Prater, Leader, Aquaculture Drugs Team at 301-827-7567 or dprater@cvm.fda.gov.**