U.S. Fish & Wildlife Service

The Aquatic Animal Drug Approval Partnership Program

"Working with our partners to conserve, protect and enhance the Nation's fishery resources by coordinating activities to obtain U.S. Food and Drug Administration approval for drugs, chemicals and therapeutants needed in aquaculture"

AADAP Aquatic Animal Drug Approval Partnership Program

Volume 3-1

AADAP NEWSLETTER

March 2007

WHAT'S SHAKIN'

AQUAFLOR® (florfenicol) received FDA-approval for coldwater disease for all freshwater-reared salmonids: Schering-Plough Animal Health (SPAH) recently announced (21 March 2007) that Aquaflor® now has the added approved claim for control of mortality caused by CWD in all freshwater-reared salmonids. Bravo, and thank you, to SPAH for their continued commitment to the U.S. aquaculture community. More information...

35% PEROX-AID® (hydrogen peroxide) receives FDA approval: EKA Chemicals Inc. received notice from CVM that 35% PEROX-AID® has been approved as of 11 January 2007 for three control claims: (1) fungal infections in all freshwater finfish eggs, (2) bacterial gill disease in all freshwater-reared salmonids, and (3) external columnaris in all freshwater-reared coolwater finfish and channel catfish. Congratulations are in order to Eka Chemical for "staying the course" and all the others involved, especially the USGS Upper Midwest Environmental Sciences Center. Detailed information...

13th Annual Drug Approval Coordination Workshop planned: This year's Workshop will be held 31 July through 1 August 2007 at the Holiday Inn, Bozeman, Montana. Co-hosts will be the USFWS's AADAP Program and USDA's Stuttgart National Aquaculture Research Center. We hope to persuade some of USFWS's (Washington, DC) and CVM dignitaries to attend and share their perspectives of our collective aquaculture drug approval efforts. Tentatively, Dr. Stuart Leon, Chief of the USFWS's Division of National Fish Hatchery System, and Dr. Bernadette Dunham, Deputy Director of FDA's Center for Veterinary Medicine and Director of the Office of Minor Use Minor Species will be kicking off this year's Workshop. One workshop highpoint will undoubtedly be the celebration of a couple of new FDA aquaculture drug approvals. The workshop is a great opportunity to get "up-to-speed" on recent aquaculture drug research activities and the status of initial or expanded approvals. In addition, a short session is scheduled to discuss current research and commercial status of fish vaccines. For more information, please visit our website. We hope to see you in Bozeman. More information...

2005 Public Sector Aquaculture Production Database is now a reality: The new Public Sector Aquaculture Production Database (data from calendar year 2005) is now available on the AADAP website. The Database comprises finfish production data from all 50 states, the U.S. Fish & Wildlife Service, NOAA's National Marine Fisheries Service and 19 Native American tribes. Unlike the previous version (calendar year 2000 data), the new Database is available to all visitors to our website, instead of just those that have Microsoft Access® loaded on their computer. We hope you take the time to peruse the Database, and please don't hesitate to tell us how we can improve it.

Another drug company testing the waters: Frontier Scientific, Inc. of Logan, Utah has initiated exploratory discussions with AADAP and others relative to entering the aquatic drug approval arena. A photo-sensitive product of theirs has shown very encouraging antimicrobial activity in European laboratory and field studies with rainbow trout. Several meetings have been held in the last six months, including one this past month at Aquaculture 2007 in San Antonio, Texas. The possibilities are exciting – stay tuned!!

New INAD for channel catfish pituitary established: On 6 December 2006 AADAP received authorization from CVM for the establishment of INAD 11-468 for the use of channel catfish pituitary to induce gamete maturation (ovulation and spermiation) in a variety of catfish species. Although potential application of channel catfish pituitary treatment is likely broad and varied within the catfish industry, it is of particular significance with respect to the production of hybrid catfish (e.g., channel catfish X blue catfish). For more information, click here.

Aquaculture 2007 presentation online: Many of the aquaculture drug approval-related presentations given at this year's conference (San Antonio, Texas, USA; 26 February through 2 March 2007) have been provided to AADAP and are available for your viewing on our website. As we gain permission for other presentations from the same conference, we will add those to the above noted link.

New: AADAP Research Information Bulletins (RIBs): Research is an "orderly process by which new knowledge or information is obtained in accordance with specific objectives" (Waters and Erman 1990). As such, aquaculture drug approval research can be academic science- or regulatory science-based (Uchiyama 1995), and can include both mensurative and manipulative experiments (Hurlbert 1984). Besides obtaining drug approvals, *per se*, it is perhaps an inherent desire to contribute "something new" that keeps many of us interested and focused day-in and day-out, year-in and year-out.

In 2007, AADAP developed a Research Information Bulletin (RIB) series. These in-house bulletins—although not necessarily integral to the approval of a specific drug—are brief descriptions of "bits and pieces" of new knowledge and information that we have obtained during our years of INAD, efficacy and target animal safety work.

Three RIBs have been issued to date: (1) *Buffering oxytetracycline immersion-marking solutions to maintain fish-safe pH levels*; (2) *A simple way to calculate amount of Aquaflor® premix to add to fish feed to achieve a target dosage of 10 mg florfenicol/kg fish/day*; and (3) *Modeling the safety of AQUI-S® (40 – 100 mg/L) to small rainbow trout.* All three are posted on our website. As always, we welcome your questions and comments about the information we provide.

Above cited literature:

Hurlbert, SH. 1984. Pseudoreplication and the design of ecological field experiments. *Ecological Monographs* **54(2)**:187-211.

Uchiyama M. 1995. Regulatory science—its mission and goal. *Japanese Journal of Toxicology and Environmental Health* **41(4)**:250-255 (abstract only).

Waters, WE and DC Erman. 1990. Research methods: concept and design. Pages 1–34 **In:** CB Schreck and PB Moyle (editors). *Methods for fish biology.* American Fisheries Society, Bethesda, Maryland.

New Protocols and SOPs added to JSA's Research Forum: Many thanks to those of you who have contributed research protocols and standard operating procedures (SOPs) to the JSA Research Forum section of the AADAP website. To minimize the time and frustration that we collectively face in trying to gain CVM-concurrence of research study protocols, several federal and university research entities have agreed to "share" their protocols and SOPs. To date, there are 10 protocols and over 200 SOPs available on the website. Several researchers have already used this resource while developing their own research protocols and SOPs. If interested, you can browse for items of interest, or you can use the website's search function to look for specific key words.

Hydrogen peroxide INAD requested by AADAP: AADAP, in cooperation with Eka Chemicals, Inc., has submitted a request for an INAD for 35% PEROX-AID®. The request package included an INAD study protocol and requested authorization to treat up to 10 million finfish and 10 million saltwater finfish eggs. The INAD is intended to cover investigations relevant to the control of mortalities in: (1) freshwater and marine finfish, and marine finfish eggs caused by fungi of the family Saprolegniaceae; (2) freshwater and marine finfish (other than salmonids caused) by bacterial gill disease or other bacteria typically associated with BGD; (3) freshwater cold- and warmwater finfish (except channel catfish) caused by external columnaris; (4) freshwater and marine finfish caused by diseases associated with other external bacteria; and (5) freshwater and marine finfish caused by external protozoan and metazoan parasites. As soon as INAD authorization is received, all relevant information, including sign-up forms will be available on our website.

Oxytetracycline updates:

Real progress on new therapeutic claims for salmonids: Phibro Animal Health's Terramycin® 200 for Fish, NADA #038-489 - Type A medicated feed, is very close to being amended to include claims for coldwater disease in all freshwater salmonids and systemic columnaris in steelhead (and possibly all strains/subspecies of *Oncorhynchus mykiss*). The antimicrobial resistance components of the human food safety technical section were just recently accepted by CVM, making that section complete. All components of the environmental safety technical section have been submitted to CVM and are pending review/acceptance. Hence, the only remaining components of the amended New Animal Drug Application to be submitted are administrative in nature, and will be completed by the drug sponsor. Keep your dial set right here for news!!

New claim Terramycin® 200 for Fish to be sought for skeletal marking: AADAP, working closely with Phibro Animal Health and FDA's Center for Veterinary Medicine (CVM), is moving forward to apply substantial INAD data, and a few new additional studies, toward a new claim for the use of oxytetracycline in feed for skeletal marking in salmonid finfish. A meeting is being requested with CVM to identify potential data gaps.

***O. mykiss* is *O. mykiss* is *O. mykiss*:** In February 2007, the AADAP Program, with concurrence from the National Aquaculture Drug Research Forum (NADRF), submitted a paper to the FDA's Center for Veterinary Medicine (CVM) proposing the argument that studies accepted for either freshwater-reared rainbow trout (*Oncorhynchus mykiss*) or freshwater-reared steelhead trout (also *O. mykiss*) should be acceptable to support label claims for **all** freshwater-reared *O. mykiss*. If this argument is accepted by CVM, it will expand approved label claims on either steelhead trout or rainbow trout to all freshwater-reared *O. mykiss*.

Calcein (SE-MARK®) updates:

Product Development Meeting Held: Representatives from Aquatic Life Sciences (ALS) Inc. (parent corporation of Western Chemical Inc.), members of AADAP and Roz Schnick (National Coordinator for Aquaculture New Animal Drug Applications), met on 20 December 2006 with the Center for Veterinary Medicine (CVM) to discuss detailed requirements to move ALS's skeletal marking product closer to an approval. Although SE-MARK® has the potential to be administered as an immersion bath or as a feed-based treatment, the decision has been made to gain the immersion approval first, then move on to the feed-based approval. Although the meeting was not without its "that's not exactly what I wanted to hear" moments, it was very positive and

helped tremendously to establish a clear path toward an initial approval for use in salmonids.

Aquaflor® (florfenicol) updates:

Furunculosis – all freshwater-reared salmonids: In November 2006, AADAP submitted what we hoped would be the last Final Study Report required by CVM to demonstrate the effectiveness of Aquaflor® (dosage, 10 mg florfenicol/kg fish body weight/day for 10 consecutive days) to control mortality in all freshwater-reared salmonids due to furunculosis (caused by, *Aeromonas salmonicida*). We hope to get a technical section complete letter from CVM **very** soon!

Columnaris – all freshwater-reared salmonids: Only one additional study is needed to demonstrate the effectiveness of Aquaflor® to control mortality, in all freshwater-reared salmonids, due to systemic columnaris. AADAP is working with Ken Nichols (USFWS's California/Nevada Fish Health Center) and Dr. Jed (Varney, that is) and the folks at the Bellingham Trout Hatchery (WDFW) to line up what is hoped to be the final piece of the puzzle. One successful study will result in a technical section completion for this claim.

***Streptococcus iniae* – hybrid striped bass:** AADAP initiated a Western Regional Aquaculture Center funded project with Dr. Vaughn Ostland (Kent SeaTech Corporation, Mecca, CA) to evaluate different dosage regimens to control mortality in hybrid striped bass (HSB) caused by *S. iniae*. Phase 1 of the project is to develop a disease model (injection and immersion) that meets several predetermined criteria. The in-life phase of a first experiment has been completed, and work is being conducted to refine the level of pathogens delivered to test fish. The in-life phase of a second experiment should be completed by the end of June 2007. Results from these experiments should provide us with the tools necessary to proceed with disease challenge studies in which replicated test tanks of naïve HSB will be treated with different concentrations of florfenicol-medicated feed (10, 15 or 20 mg/kg fish) for different durations (10, 15 or 20 d).

Columnaris – channel catfish in raceways: Alan Johnson (Iowa DNR, Rathbun Fish Culture and Research Facility, beautiful Moravia, Iowa) has once again established a summer veterinary student intern position for the purpose of conducting aquaculture drug effectiveness studies. The intern will, in part, focus on conducting pivotal field effectiveness studies to demonstrate the effectiveness of Aquaflor® to control mortality in raceway-reared channel catfish caused by systemic columnaris. Good luck, Alan!

Columnaris – channel catfish in ponds: Dr. Pat Gaunt (Mississippi State University, College of Veterinary Medicine, Thad Cochran National Warmwater Aquaculture Center, Stoneville, MS) has been involved in conducting studies to demonstrate the effectiveness of Aquaflor® to control mortality in earthen pond-reared channel catfish caused by systemic columnaris. Studies such as these are easy to design but very difficult to carry out. Some of the challenges Dr. Gaunt must overcome include enumerating dead or moribund fish from large earthen ponds at the end of the study, confirming cause of mortality, and staving-off secondary pathogens. Dr. Gaunt has battled these challenges in the past and has been successful on many occasions. We're all wishing her continued success.

17-α methyltestosterone updates:

Three studies were conducted to demonstrate the effectiveness of 17-α MT (60 mg/kg feed) to produce predominantly male populations of tilapia. Below is an update of each study.

Study 1: The first study was conducted at SeaPac of Idaho (thanks, Ken Ashley and crew) in Buhl, ID, and all phases (in-life, histological evaluation of gonads, data analysis and final study report) have been completed. The study went off without a hitch…well, there was one minor glitch. Analytical verification of the concentration of MT in the treated feed was 39 mg MT/kg feed. This relatively "low" concentration was due to storage of the treated feed for 9-10 weeks at ambient air temperature. Otherwise, the study was a success: (a) mean percent males in treated tanks (84%) was significantly greater than mean percent males in control tanks (38%), and (b) mean percent males in treated tanks was greater than 80%. The Final Study Report was submitted to CVM in February, 2007.

Study 2: The second study was conducted at Simaron Freshwater Fish in Waller County, TX. The in-life phase has been completed, and AADAP's Miranda Dotson is processing, embedding, and sectioning gonads from over 300 fish sampled at the end of the study. The analytically verified concentration of MT in the treated feed was 56 mg/kg feed. Stay tuned for more results.

Study 3: The third and final study is being conducted at SeaPac of Idaho, and the in-life phase will be completed in early April. The analytically verified concentration of MT in the treated feed was 55 mg/kg feed. Stay tuned for more results.

Storage of MT-treated feed: Studies conducted by Dr. Terry Barry (University of Wisconsin – Madison) have shown that storage of MT-treated feed at room temperature will result in a decrease in MT concentration over time. Dr. Barry's results showed that the MT concentration decreased at a rate of about 3% per week. Dr. Barry's results also showed that MT-treated feed stored in a refrigerator or freezer experienced no such decrease. So, the take-home message for tilapia producers who use MT-treated feed for sex reversal is to properly store your MT-treated feed.

AQUI-S® updates:

Efficacy: Good news!! AADAP has completed all studies required by CVM to demonstrate the effectiveness of 50% isoeugenol (AQUI-S®) to sedate all freshwater-reared finfish to "handleable." However, to obtain an "effectiveness technical section complete" from CVM, a study must be conducted to validate the dose verification method used in the effectiveness studies. The dose verification validation study has been completed by AQUI-S New Zealand, Ltd., and will be submitted to CVM within a few weeks.

Target Animal Safety: More good news!! In December 2006, CVM reviewed AADAP's Final Study Report on the safety of 40 mg/L AQUI-S® to small fingerling rainbow trout and found "…the data to be acceptable." Currently, AADAP is in the process of "writing up" a second pivotal AQUI-S® TAS study that was conducted on small fingerling cutthroat trout. Results from the cutthroat trout study (e.g., mortality and pathologies) were similar to results observed in the rainbow trout study. We are optimistic that the TAS data generated in the cutthroat trout study will be accepted by CVM, which will complete TAS requirements for an all freshwater-reared salmonid label claim.

Mammalian Toxicology: The National Toxicology Program has announced the 16-17 May 2007 meeting of the Board of Scientific Counselors' Technical Reports Review Subcommittee. At this meeting, results of the toxicology study conducted on isoeugenol will be discussed. Favorable review of the isoeugenol data will greatly contribute to completion of the human food safety technical section for AQUI-S® use as a zero-withdrawal anesthetic. Keep your fingers crossed!

Draft Label Claim: AADAP has been working with CVM and AQUI-S New Zealand, Ltd. to develop draft product "label claims" to sedate cold-, cool-, and warmwater freshwater finfish to "handleable." By definition, a product "label" includes information such as indications for use, product information, limitations, and cautions, and is a technical section that must be completed as part of the administrative New Animal Drug Application process. So, yet another piece of the puzzle has been put in place.

Chloramine-T updates:

Efficacy: The following research study protocol was recently submitted to CVM: "*A protocol to evaluate the effectiveness of chloramine-T (Halamid®) to control mortality in cool- and warmwater finfish caused by bacterial gill disease or external columnaris*." This protocol was developed so that AADAP can work towards conducting studies needed to complete the technical sections for coolwater (one more study required) and warmwater (two studies required) finfish.

Planned Efficacy Studies: AADAP is pleased to be working with Michael Matthews and the research crew at the Richlomb Hatchery – Florida Bass Conservation Center on much needed effectiveness studies on warmwater finfish. A plan is in place to conduct studies on two different warmwater finfish (largemouth bass and channel catfish) to demonstrate the effectiveness of chloramine-T to control mortality caused by external columnaris. A special thanks to Michael for stepping-up and agreeing to help generate these important data. Alan Johnson (Iowa DNR, Rathbun FC&RF) has also offered to step-up and help conduct a similar study on musky. Thanks again to Alan!

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

Efficacy: The following research study protocol has been submitted to CVM: *"A protocol to evaluate the effectiveness of 35% PEROX-AID® (35% active hydrogen peroxide) to control mortality in cool- and warmwater finfish caused by bacterial gill disease or external columnaris."* This protocol was developed so that AADAP can work towards conducting the necessary studies to complete these efficacy technical sections for warmwater finfish.

Planned Efficacy Studies: Have we mentioned how pleased we are to be working with Michael Matthews and the research crew at the Richlomb Hatchery – Florida Bass Conservation Center? There are also plans to work with Michael to conduct studies (the last missing piece of yet another puzzle) to demonstrate the effectiveness of 35% PEROX-AID® to control mortality in largemouth bass caused by external columnaris. Another special thanks to Michael for stepping-up and agreeing to help generate these very important data.

FEATURE ARTICLE

The following article is reprinted from Fish Farming News (Issue 4 – 2006) with their permission and with permission from Schering-Plough Animal Health. Although the article was first published prior to the newly added salmonid claim for AQUAFLOR®, the information is exceptionally relevant today.

AQUAFLOR®
(FLORFENICOL) TYPE A MEDICATED ARTICLE

Are You Ready for VFD Drugs?

Freshwater Salmonid Industry Gets Ready for Using Next Generation of In-Feed Antibiotics

SUMMIT, N.J., Sept. 11, 2006— Growers, veterinarians and feed mills in the freshwater salmonid industry need to start familiarizing themselves with regulations governing the use of what the U.S. Food and Drug Administration calls "Veterinary Feed Directive" (VFD) drugs.

"The VFD process is not a complicated matter, but it will be important for everyone in the freshwater-reared salmonid industry to know and understand the FDA's rules," says Dr. Dick Endris of Schering-Plough Animal Health Corporation.

Follow the Path to VFDs

Everyone involved in the production phase of U.S. aquaculture must understand and follow the necessary steps needed in obtaining and feeding a Veterinary Feed Directive (VFD) drug.

Here's how the process works for producers:

- Producer or hatchery manager contacts a veterinarian for diagnosis and treatment.
- Veterinarian works within the veterinarian-client-patient relationship to determine that a VFD drug is needed.
- Veterinarian issues a signed VFD form to the producer and/or feed mill.
- Producer uses the VFD form to order medicated feed from a feed supplier. The feed supplier must have a signed VFD order on file in order to deliver feed.
- Licensed feed manufacturers or distributors that ship a VFD feed to another distributor or retailer must receive and retain a copy of a written acknowledgement stating that the VFD feed will further be distributed only in accordance with FDA requirements.
- The veterinarian issuing the VFD order, the producer and the person or company supplying the VFD feed must retain copies of the signed VFD form for a minimum of two years.

The first VFD drug for aquaculture, AQUAFLOR® (florfenicol) was approved for use in catfish last year [*editor's note: 2005*]. AQUAFLOR® is expected to be approved for use in freshwater salmonids — trout, arctic char and freshwater life stages of saltwater fish like salmon — in the near future [*editor's note: approved as of 21 March 2007*].

Developed by Schering-Plough Animal Health, AQUAFLOR® is a fast-acting, broad-spectrum antibiotic developed specifically for use in veterinary medicine. Its sister product, NUFLOR® (florfenicol), has been approved by FDA for use in beef and non-lactating dairy cattle since 1996.

Why VFDs?

FDA established the VFD drug classification to more closely control new therapeutic products — primarily antimicrobials — and their use in food animals. The new classification applies only to new in-feed therapeutics approved by the FDA after 1999 and administered in feed. All products approved before 1999 have maintained their over-the-counter (OTC) status.

"The VFD allows us to continue adding new drugs to our health tool box," stresses Richard Sellers, American Feed Industry Association.

Like catfish farmers, producers of trout and other freshwater salmonids will be able to obtain VFD drugs through normal feed-distribution channels, but they must first obtain a signed Veterinary Feed Directive from a licensed veterinarian.

He adds that the VFD regulations were developed by a coalition of members in the animal health community to better control new therapeutic, antimicrobial drugs. The system aims to reduce antibiotic resistance and prolong effectiveness of new antimicrobials through judicious use.

The first VFD drug to be classified and approved by the FDA since the approval of VFD status was tilmicosin, an antimicrobial for swine respiratory disease. AQUAFLOR® became the second antibiotic in the animal health industry and the first in aquaculture to be given this exclusive status when it was licensed last fall.

How it works

The starting point for obtaining feed with a VFD drug is with the producer experiencing sick fish. Producers can get a VFD order from a diagnosing veterinarian or veterinary laboratory as long as there is what the FDA calls a "veterinarian-client-patient relationship" with the producer or hatchery manager. With the VFD form in hand, the producer can go to the feed mill to order and obtain the VFD-containing feed. (See "sidebars".)

Sellers notes that the VFD order authorizes the client to obtain the medicated feed in accordance with the directions for use approved by the FDA. There is **NO** [editor's emphasis] "extra-label" or "off label" use for any VFD drug, meaning it can be ordered only for the use specified on the product label.

Responsibility for compliance falls on the feed mills, veterinarians and producers. "A VFD drug means some additional paperwork, but it's not a big deal," acknowledges Sellers. "The VFD form needs to be completed by a vet and everything must be legal, valid and correct before the feed mill can fill that VFD order.

"Most feed mills serving the aquaculture industry have been through the federal medicated feed licensing process, so I'm confident they know what they're doing," he adds.

Feed mills already holding a Medicated Feed Mill License (MFML) — a license to manufacture medicated feed — simply need to file a notification letter with the FDA stating its intention to distribute an animal feed containing a VFD drug. All VFD orders must be retained by the feed mill for a period of two years.

What is a VCP Relationship?

What exactly is the "veterinarian-client-patient relationship" needed to obtain an order for a new VFD drug?

FDA offers the following guidelines:

- The veterinarian has assumed responsibility for making clinical judgments regarding the health of the animals and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
- The veterinarian has sufficient knowledge of the animals to initiate at least a general or preliminary diagnosis of the medical condition of the animals. This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animals by virtue of an examination of the animals or by medically appropriate and timely visits to the premises where the animals are kept.
- The veterinarian is readily available for follow-up evaluation, or has arranged for emergency coverage, in the event of adverse reactions or failure of the treatment regime.

Short learning curve

Dr. Dave Erdahl, fisheries biologist and branch chief of the Aquatic Animal Health Drug Approval Partnership (AADAP) Program of the U.S. Fish and Wildlife Service, Bozeman, Montana, doesn't think the VFD process will be a major issue for most producers raising trout and other freshwater-reared salmonids.

"The role of veterinarians in aquaculture is expanding," he says. "There are already a considerable number of operations working directly with consulting veterinarians or veterinarians on staff with state and federal agencies.

"Like anything new, it will likely be a bit problematic at first," he adds, "but I look at the VFD process as a 'growing pain' for our industry. If we want new products to maintain fish health, we have to get with the program. It's that simple."

Dr. Patricia Gaunt, associate professor, aquatic animal health, Mississippi State University College of Veterinary Medicine, says the VFD classification has not proved to be a big issue for producers or feed mills in the catfish industry

"There is always a learning curve in any new situation," Gaunt says of the VFD drug process, "but the rewards of a new drug to treat aquatic disease certainly justify the learning process.

"We're also approaching the education process through diagnostics with the farmer when they bring in diseased fish and we explain the VFD process to them," she adds.

Growers with questions on the VFD process should contact their diagnostic lab, extension service, veterinary college or veterinarian. Information about VFDs and VFD forms are also available at http://www.aquaflor-usa.com.

FINS & TAILS, BITS & BOBBERS

Need more information on VFD drugs? AADAP has compiled a series of publications and other documents that address a variety of issues pertaining to Veterinary Feed Directive drugs. Click here to access that VFD information.

List of Aquatic Animal Veterinarians: Of particular importance to aquaculturists, vis-à-vis Veterinary Feed Directive (VFD) drugs, is a website that provides a "listing" of aquatic veterinarians and aquatic animal diagnostic laboratories. The website is jointly sponsored by the American Veterinary Medical Association; GlobalVetLink, LC; Aquacultural Underwriting & Management Services, Ltd; and the National Risk Management Feasibility Program for Aquaculture (at the Department of Agricultural Economics – Mississippi State University). The website allows users to search for an aquatic veterinarian in their local area, which should help any user requiring the application of a VFD drug to treat their fish.

Is the price of a SE-MARK® (calcein) Detector keeping you from enrolling in the calcein INAD? AADAP now has an extra SE-MARK® Detector available to be loaned out to calcein INAD participants. If you would like to use it, please give Tom Bell a phone call (406-994-9911) or drop him an email.

Treatment of salmonids for CWD is no longer an available treatment option under INAD 10-697: As a result of the recent approval for the use of AQUAFLOR® (florfenicol) to control mortality caused by coldwater disease in salmonids, this treatment option is no longer available under INAD 10-697. If your salmonids have CWD and AQUAFLOR® is your drug of choice, you must use the approved AQUAFLOR® product. However, please note that INAD 10-697 may still be used for other "non-approved" uses of AQUAFLOR® in cold-, cool-, and warmwater species.

Ovaplant® is moving to the "front-burner": Aquatic Life Sciences (ALS) Inc. (parent corporation of Western Chemical Inc. and Syndel International, Inc.) and AADAP have recently engaged in serious discussion as to how best to move Ovaplant® (for use as a spawning aid) toward an initial approval for use in salmonids. Current strategy is to seek a "conditional approval" under MUMS legislation, thereby reducing overall initial data requirements. A Product Development Meeting with CVM to discuss a strategy and action plan for Ovaplant® will be requested later this month.

USGS's CORNER

AQUI-S® Human Food Safety Research: Upper Midwest Environmental Sciences Center (UMESC) submitted a letter to CVM requesting selection of isoeugenol as the marker residue for AQUI-S®. The request was based on data generated in a AQUI-S® total residue depletion study (conducted at UMESC) using radiolabelled isoeugenol where isoeugenol was the primary AQUI-S® residue in extracts from fillet tissue taken from rainbow trout sampled through a 4 hour depuration period. UMESC also completed the laboratory phase of a study validating a proposed determinative method for the probable AQUI-S® marker residue. Validation efforts were rather comprehensive and included the use of fillet tissue from nine different fish species. All data indicate that the method developed at UMESC will fulfill FDA guidelines for determinative methods. (Jeff Meinertz; La Crosse, WI, phone 608-781-6291, jmeinertz@usgs.gov)

Chloramine-T Environmental Assessment Submission: A revised version of the draft Environmental Assessment for the broad use of chloramine-T in U.S. freshwater aquaculture will be submitted by UMESC to the Center for Veterinary Medicine for review by 31 March. (Bill Gingerich; La Crosse, WI; phone 608-781-6225, bgingerich@usgs.gov)

USGS Scientists Recognized for Approval of 35% PEROX-AID®: Dave Lovetro of Eka Chemicals, Inc., Marietta, Georgia, recognized nine research staff of the USGS, Upper Midwest Environmental Sciences Center, La Crosse, Wisconsin on Tuesday, 13 March for their efforts to secure the approval of 35% PEROX-AID®. Information about the drug label and the research produced by UMESC to support the approval can be accessed at http://www.umesc.er.usgs.gov/ (Bill Gingerich; La Crosse, WI; phone 608-781-6225, bgingerich@usgs.gov)

A welcome back to Mark Gaikowski: First sergeant Mark P. Gaikowski returned from a year's tour of duty in Afghanistan with the Wisconsin National Guard in January 2007 and has rejoined the staff at the Upper Midwest Environmental Sciences Center, La Crosse. Welcome back Mark! (Bill Gingerich; La Crosse, WI; phone 608-781-6225, bgingerich@usgs.gov)

MEETINGS, ETC.

Recently held meetings

Aquaculture 2007; 26 February – 2 March 2007; San Antonio, Texas, USA: As always, the triennial joint-conference of the World Aquaculture Society, the National Shellfisheries Association and the American Fisheries Society's Fish Culture Section was a grand event. And, as is usually the case, it appeared to be even bigger than previous triennial events. This year's conference comprised 15 concurrent sessions being held every day for 4 days. Sessions topics were too numerous to count, and included such diverse topics as: "Aquaculture Marketing: The Big Picture," "Biotech Aquaculture: Environmental Sustainability," "Physiological Insights toward Improving Fish Culture," "Therapeutic Drug Research," and "Aquaculture & Disasters: Dealing with the Mayhem." Many of the aquaculture drug approval-related presentations given at this year's conference have been provided to AADAP and are available for your viewing on our website. As we gain permission for other presentations from the same conference, we will add those to the above noted link.

Upcoming meetings

Fish Immunology Workshop; 15-19 April 2007; Wageningen University, The Netherlands: The annual Fish Immunology workshop comprises presentations (30 minutes to one-hour) by experienced lecturers, taking time to thoroughly introduce each subject, and two practical afternoons. *Objective*: To provide participants with advanced knowledge, both theoretical and practical, on t he fish immune system. Emphasis will be placed on innate and acquired immunity, on immune modulation and on immunity to infection. During the workshop the latest insights into the evolution of the immune system, and related issues such as (experimental) animal welfare and the influence of stress on the immune response, will be discussed. *Level*: The workshop is targeting academic and company researchers as well as management staff in the aquaculture industry. PhD students are welcome and a lower registration fee is available to them. The official language of the workshop is English. The number of participants is limited to 30 persons, admitted on a 'first-come' basis. Registration fee is 250 € (Ph.D.), 450 € (academic staff) or 550 € (company staff). For all-in registration (including accommodation and all meals) add 450 € for the whole workshop period. Click here for additional information on the Workshop, including accommodations, program agenda, registration, etc.

Flavobacterium 2007 Workshop; 2-4 May 2007; Shepherdstown, West Virginia, USA: The U.S. Department of Agriculture's Agriculture Research Service, in cooperation with Clear Springs Foods, Washington State University and Pennsylvania State University – Erie are sponsoring a three-day workshop to be held at the U.S. Fish & Wildlife Service's National Conservation Training Center. The scheduled sessions include: genomics and proteomics, pathogenesis, vaccines and immunity, taxonomy, diagnostics, broodstock evaluation for disease resistance and environmental flavobacteria. For more information contact Dr. Greg Wiens (greg.wiens@ars.usda.gov) .

48th Western Fish Disease Workshop and American Fisheries Society Fish Health Section Annual Meeting; 4-6 June 2007; Moran, Wyoming, USA: This combined meeting will be held at the Jackson Lake Lodge in Grand Teton National Park. Agenda and other information can be obtained at the meeting webpage. To learn more about the Jackson Lake Lodge, go to http://www.gtlc.com/lodgeJac.aspx.

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 Bøgwald, 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.abdn.ac.uk/noffi/.

32nd Annual Eastern Fish Health Workshop; 18-22 June 2007; Gettysburg, Pennsylvania, USA: The annual EFHW will be held this year at the Eisenhower Inn and Conference Center in historic Gettysburg. For further information, contact Dr. Rocco Cipriano at phone: 304-724-4432 or

email: rcipriano@usgs.gov. Early registration is due 1 May 2007 (registration form). Abstracts are due 15 April 2007 (abstract and presentation information).

Salmonid Disease Workshop; 18-29 June 2007; Corvallis, Oregon, USA: This 10-day workshop is designed for professionals working in the fish health field and will emphasize recent advances and developments in our understanding of salmonid diseases. The workshop includes lectures and laboratory exercises with plenty of opportunity for discussion. There is a limit of 20 participants on a first come, first served basis. Graduate students may take the course for 5 credits. Details can be found at the workshop webpage.

13th Annual Drug Approval Coordination Workshop; 31 July-1 August 2007; Bozeman, Montana, USA: This year's Workshop will be held 31 July through 1 August 2007 at the Holiday Inn, Bozeman, Montana, USA. Co-hosts will be the USFWS's AADAP Program and USDA's Stuttgart National Aquaculture Research Center. One workshop highpoint will undoubtedly be a celebration of a couple of new FDA aquaculture drug approvals. The workshop is a great opportunity to get "up-to-speed" on recent aquaculture drug research activities and the status of initial or expanded approvals. In addition, a short session is scheduled to discuss current research and commercial status of fish vaccines. For more information, please visit our website. We hope to see you then in Bozeman. More information...

Asian-Pacific Aquaculture 2007; 5-8 August 2007; Hanoi, Vietnam: This is the first major aquaculture conference to take place in Vietnam, and the theme of this year's conference is "Prospering from Dynamic Growth." Conference organizers have plans for more than 20 sessions, including an aquatic animal disease session. The deadline for submission of abstracts has already passed (15 March). Early registration fees are available if you register before 25 May or 12 July. See conference brochure for more details.

137th Annual Meeting of the American Fisheries Society; 2-6 September 2007; San Francisco, California, USA: This year's meeting is being held at the Marriott Hotel (downtown San Francisco). "Thinking Downstream and Downcurrent: Addressing Uncertainty and Unintended Consequences in Fish and Fisheries" is the theme for the conference. Detailed information can be obtained at the conference website.

Mollusc Health and Disease Management Course; 13-19 September 2007; Atlantic Veterinary College University Of Prince Edward Island, Canada: This advanced five-day training targets diagnosticians, scientists, students and professionals of mollusc health management. The session will address major issues and challenges surrounding the most important mollusc species in wild and farmed situations. Topics will include significant infectious diseases, disease causation, techniques for sampling for the presence/prevalence of disease, diagnostic techniques and test interpretation, and outbreak investigation. Laboratory sessions will involve the whole range of technical procedures for diagnosis and demonstrations of significant diseases and conditions, including field exercise. This is a 5-day course, the formal classes of which run on September 13, 14, 17, 18 &19 (participants can attend the International Shellfish Festival on 15-16 September). More information on registration, accommodations, etc. is available on their website at http://www.upei.ca/cai/molluschealth.htm.

13th International EAFP Conference on Diseases of Fish and Shellfish; 17-21 September 2007; Grado, Italy: This year the European Association of Fish Pathologists (EAFP) will hold their 13th annual conference at the Conference Centre in Grado, Italy. Scientific and technical sessions consisting of poster presentations, invited talks, keynotes, oral presentations, workshops and an EAFP general assembly will take place during the conference. Planned social events include a welcome cocktail party, a civic reception and the traditional conference banquet. The conference is being organized by the council of the EAFP and the local organizing committee. Additional information can be found on the conference webpage.

7th International Symposium on Fish Parasites and the 3rd Myxozoan Workshop; 24-28 September 2007; Viterbo, Italy: This year's symposium is being held at the Palazzo dei Papi on the 24th and Domus la Quercia on the 25th through the 28th. There are 20 planned sessions on a diversity of topics, including "Helminth systematics: from faunistics to DNA barcoding," "Parasites as biological tags of fish stocks and biology," and "Fish parasites control." The deadline for Abstract submissions is 15 May 2007. Additional information can be found at their website: http://www.7isfp.com. For additional information on the Myxozoan Workshop, click here.

Health Management of Laboratory Fish course; 17-22 September 2007; Salisbury Cove, Maine, USA: This one week course is being offered by the Mount Desert Island Biological Laboratory of Salisbury Cove. Topics to be discussed include general system design and water quality management, anatomy and histology of fish, general fish diseases and disease management strategies. Faculty from Oregon State and Cornell Universities are scheduled to conduct the classes. Registration deadline is 1 June 2007. For more information refer to the course website.

Aquaculture Canada[OM] 2007; 23-26 September 2007; Edmonton, Alberta, Canada: The 24th annual meeting of the Aquaculture Association of Canada will be held at the Shaw Conference Centre and the Westin Edmonton. This is Canada's national forum on business, science and technology of aquaculture. For more information contact Christopher M. Pearce at PearceC@pac.dfo-mpo.gc.ca or refer to the conference website.

Aquaculture Europe 07; 24-27 October 2007; Istanbul, Turkey: This year's annual meeting of the European Aquaculture Society will be held at the World of Wonders City Hotel (conference portion) and the Istanbul Expo Centre (exhibits portion) both in Yesilkoy, Istanbul and opposite Istanbul's Ataturk Airport. The conference theme "Competing Claims" addresses the various levels of competition that aquaculture faces at present, but upon which its future development will depend. For more information, refer to their website. The conference comprises 5 thematic sessions, as well as 12 subject-specific sessions, including a "Health Management and Welfare" session. The deadline for submission of abstracts has passed (1 April). Early registration fees are available if you register before 15 May or 10 September. See conference webpage for more details, including conference brochure, on-line registration, accommodations, etc.

Caribbean and Latin American Aquaculture 2007; 6-9 November 2007; San Juan, Puerto Rico: The Latin American and Caribbean Chapter of the World Aquaculture Society are organizing this year's conference and have more than 20 sessions planned with one for "fish and shrimp health management" and one on "aquatic animal-derived therapeutic drugs for humans." The conference is being held at the Condado Plaza Hotel in San Juan. Submission of abstracts must be made online by 15 April 2007. Please refer to the conference website for more details.

Aquaculture America 2008; 9-12 February 2008; Lake Buena Vista, Florida, USA: The 2008 conference will be held at Walt Disney World's Coronado Springs Resort. This year's conference is being held in conjunction with Marine Ornamentals '08. The deadline for submission of abstracts is 3 August 2008. For more information refer to the conference website.

ROZ's CORNER

This was a good quarter for aquaculture drug approvals!

Eka Chemicals, Inc. obtained an approval for 35% PEROX-AID® (hydrogen peroxide) for control of mortality in (1) freshwater-reared finfish eggs due to saprolegniasis, (2) freshwater-reared salmonids due to bacterial gill disease, and (3) freshwater-reared coolwater finfish and channel catfish due to external columnaris disease on 11 January 2007. Eka Chemicals, Inc. recognized the contributors to the approval at Aquaculture 2007 during my producer session entitled "Aquaculture Drug Approval Successes". Because no representative from the Upper Midwest Environmental Sciences Center (UMESC) was able to attend the recognition ceremony, Eka Chemicals, Inc. came to La Crosse, Wisconsin on 13 March 2007 to present the awards directly to the scientists who provided the environmental assessment, target animal safety, and effectiveness data for the approval.

Schering-Plough Animal Health (SPAH) obtained an approval for Aquaflor® (florfenicol) for control of mortality associated with coldwater disease in freshwater-reared salmonids on 19 March 2007. The approval of Aquaflor® is the result of cooperation between SPAH and federal and state researchers: Aquatic Animal Drug Approval Partnership Program (AADAP, Bozeman, Montana), UMESC, and the Montana Department of Fish, Wildlife, and Parks. SPAH previously recognized AADAP and UMESC for contributions to the approval of Aquaflor® for the control of mortality due to enteric septicemia in catfish at Aquaculture America 2006 during my producer session.

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