



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 1 - 1

AADAP NEWSLETTER

October 2004

WHAT’S SHAKIN’

AADAP is here: In August 2003 the U.S. Fish & Wildlife Service formally established the Aquatic Animal Drug Approval Partnership as a new branch of the Division of the National Fish Hatchery System (Washington Office). The AADAP program, located in Bozeman, Montana, is an enhanced version of the Service’s successful National INAD Office (NIO). The AADAP program is not yet fully implemented as originally planned, but is staffed with two more members than the original NIO. Tom Bell and Miranda Dotson have joined the staff, and will allow the AADAP to enhance the Service’s leadership and coordination roles in gaining new drug approvals for aquatic species. For more information see our website at: <http://fisheries.fws.gov/aadap>.

Quarterly AADAP Newsletter: This is the inaugural issue of AADAP’s quarterly newsletter. We intend it to be a “short and sweet” summary of what’s happening in the aquatic animal drug approval arena. We promise to try to limit its length to no more than three sheets of paper. We hope that the Newsletter and our Website will be complementary and invaluable sources of information for you.

AADAP Website: Our new website debuted August 3, 2004. It can be found at <http://fisheries.fws.gov/aadap>. Its present configuration is what we call Phase 1. However, we will be constantly striving to improve the site to meet your needs. Quite simply, our goal is for the site to be a “one-stop-shopping” source for information that is as current as you can get, and can be found as intuitively as possible. From the very simplest status of how close are we to a specific new approval, to pivotal and supplemental study raw data, to making it easier for you participate in our INAD program, we plan to eventually make it all available. The site will reflect comments received from an earlier questionnaire, and we welcome and will attempt to honor any suggestions you might make. Please take a look at our new website and send us your comments, suggestions or information to share.

New Drug Approvals: Pharmaq AS (previously known as Alpharma Animal Health, Aquatic Products; Brainerd, Minnesota) received FDA approval for two new drugs for fish this past December (2003). The drugs are not “new,” they are either new formulations or new approved uses of currently approved drugs. **OxyMarine**[®] is a soluble oxytetracycline product approved for finfish skeletal marking. **Romet-TC**[®] is a type-B medicated feed article and basically an improved version of the old Romet-B. Pharmaq AS reports it to be more palatable than Romet-B. A second major advantage of Romet-TC[®] is that it can be top-coated on the feed at the farm. Both products are currently available. For more information contact: PHARMAQ AS; Harbitzalleen 5; P.O. Box 267 Skøyen; N-0213 Oslo, Norway.

MUMS Act is signed by the President and is now Federal Law:

On August 2, 2004, President Bush signed into law "The Minor Use and Minor Species Animal Health Act of 2004." The Act provides new means by which aquaculturists and others involved in the rearing of minor species (i.e., any animal other than horses, cows, pigs, dogs, cats, chickens and turkeys) can legally gain access to new drugs. The Act contains provisions for: (a) the creation of the Office of Minor Uses and Minor Species, (b) funding incentives to pharmaceutical companies, (c) a special designation for drugs for minor uses and minor species (similar to an orphan drug designation for human drugs), (d) a "drug index" list for drugs that have been assessed by a non-FDA expert panel relative to efficacy and safety, allowing for their legal marketing even though not approved and (e) a "conditional approval" whereby a drug can be legally marketed for a set period without all efficacy data being collected. For more detailed information refer to the following link: <http://www.fda.gov/cvm/index/updates/mums804.htm>

EPA’s New Aquaculture Effluent Guidelines (Final Rule) published in the Federal Register:

On August 23, 2004 the Environmental Protection Agency’s new “Effluent Limitations Guidelines and New Source Performance Standards for the Concentrated Aquatic Animal Production Point Source Category” were published in the Federal Register (Volume 69, Number 162). The published guidelines include the following summary excerpt:

“Today’s final rule establishes Clean Water Act effluent limitations guidelines and new source performance standards for concentrated aquatic animal production facilities. ... The regulation establishes technology-based narrative limitations and standards for wastewater discharges from new and existing concentrated aquatic animal production facilities that discharge directly to U.S. waters. EPA estimates that compliance with this regulation will affect 242 facilities. The rule is projected to reduce the discharge of total suspended solids by about 0.5 million pounds per year and reduce the discharge of biochemical oxygen demand (BOD) and nutrients by about 0.3 million pounds per year. The estimated annual cost for commercial facilities is \$0.3 million. The estimated annual cost to Federal and State hatcheries is \$1.1 million. EPA estimates that the annual monetized environmental benefits of the rule will be in the range of \$66,000 to \$99,000.”

An EPA-produced Fact Sheet on the aquaculture guidelines can be found at: <http://epa.gov/guide/aquaculture/fs-final.htm>. The guidelines, *per se*, are also on EPA’s website, located at: <http://www.epa.gov/fedrgstr/EPA-WATER/2004/August/Day-23/w15530.htm>, as well as on the AADAP website under the menu button labeled “Drug-use Guidance.”

FEATURE ARTICLE

The U.S. Food and Drug Administration's Animal Drug Approval Process: The FDA's Center for Veterinary Medicine (CVM) is the responsible agency for approving all new animal drugs. This includes drugs for any animal reared or kept by Americans for any reason; e.g., horses, cows, chickens, dogs, cats, goldfish, rainbow trout, pheasants, crickets, chimpanzees, elephants and earthworms.

Although the entire process to gain an approval for a new animal drug is long, expensive and complicated, it can be boiled down into two relatively easy to understand components. However, as many of us have come to learn, although the components seem to be simple enough on paper to comprehend, their actual completion can oftentimes appear unachievable, or at least extremely difficult.

The two major components of the drug approval process, in which we all participate to some degree, are New Animal Drug Applications (NADAs) and Investigational New Animal Drug (INAD) exemptions. An NADA is the formal application made by a drug company sponsor to CVM petitioning CVM to approve the new drug based on evidence generated and gathered by the sponsoring drug company. An INAD exemption allows the drug company or other INAD sponsors to legally transport the unapproved drug across state boundaries and to use the drug to generate the necessary evidence for their NADA.

Before we discuss the INADs and NADAs in more detail, a little background is appropriate. For a new animal drug to be approved, CVM must be provided with sufficient and appropriately formatted evidence (i.e., data) demonstrating that the candidate drug is: (a) safe to the animals being treated, (b) safe to people administering the drug, (c) safe to people who may consume previously treated animals (in the case of food animals), (d) safe to the environment, (e) effective in doing what it is claimed to do and (f) manufactured (from batch to batch) to have a consistent composition resulting in safe and effective treatments when used per the label. The precise language that spells out these requirements, and other particulars as to how the FDA and CVM operate, can be found in the Federal Food, Drug and Cosmetic Act (FFDCA) and the "New Animal Drug" regulations found in 21 CFR or Title 21 of the Federal Code of Regulations (searchable at <http://www.gpoaccess.gov/cfr/index.html>).

One perplexing part of the FFDCA is that it is illegal to use any animal drug unless it is a CVM-approved drug. Strictly speaking, this would preclude the experimental use of an unapproved drug to gather the necessary data to demonstrate its safety and effectiveness. Fortunately, Federal law also created INADs, that permit holders (or sponsors) of INADs to legally use the drug under limited and experimental conditions. Some INADs (including many aquaculture INADs) also include permission to slaughter the experimentally treated animals for human consumption, but like the drug's experimental use, such a slaughter authorization is very strictly controlled.

Typically, INAD sponsors are pharmaceutical companies that are gathering the required data to gain approval for their new terrestrial animal drug. Their investigational work is normally conducted in house (or subcontracted) and includes a very limited number of animals. Most often the investigational drug is intended to be a new (and/or improved) addition to the medicine chest for a specific animal-disease combination.

However, in most cases, the investigational drug is often not the only approved drug that can lead, via disease control and prevention, to successful rearing of that animal population. Hence, unlike the aquaculture industry, terrestrial animal operations have minimal need for investigational drugs to treat the major disease conditions experienced under intensive rearing conditions. Further, major pharmaceutical companies perceive the economic value of developing drugs for aquaculture to be low. Many pharmaceutical companies cannot justify investment in research and development of aquaculture drugs.

Due to the relatively few drugs approved for use in aquaculture, there is frequently a need to utilize investigational drugs to prevent excessive morbidity and mortality. Access to investigational drugs, under an INAD exemption, allows access to these important medications, but also comes with the responsibility to use them under strict protocols for the collection of data that will ultimately support their approval.

This leads us to the INAD process in which the AADAP Program and many independent state, federal, tribal and private entities participate. In lieu of active drug company involvement, we sponsor INADs, the primary purpose of which is to allow access to investigational drugs, while collecting effectiveness and safety data for ultimate inclusion in an NADA submission. The AADAP's National INAD Program (NIP) permits us to administer several large collaborative INADs, with many co-investigators, to generate the extensive range of safety and effectiveness data required to support broad approvals for aquaculture drugs that may cover hundreds of different species.

An NADA can only be submitted to CVM by the manufacturer or licensed distributor of the new drug. Additionally, the submitting company must be either a U.S. company or have a U.S.-based representative. As noted earlier, the NADA basically contains evidence supporting the company's claim that the drug is consistently safe and effective when used as described on the drug label. In spite of the fact that very significant portions of the evidence submitted in an NADA may have been generated under an INAD(s) not held by the drug company, the drug company must assemble the NADA package and provide the evidence to show that they can ensure the drug's purity and consistency over time.

Over the past decade, we in the aquaculture industry have been generating data sets required by CVM. These data sets are referred to by CVM as "Technical Sections." An example of an Efficacy Technical Section might be – "all effectiveness data to support the label claim that Chloramine-T (at a given dose and duration) works to control bacterial gill disease in all freshwater salmonids." For the most part, the aquaculture community (not counting the drug companies) has the potential to complete the studies for all technical sections except manufacturing. We have, however, been severely constrained by lack of funds and staff to complete these technical sections in a timely manner.

In no way should the previous paragraph be misconstrued as indicating a lack of performance. Considering that pharmaceutical companies have estimated that it takes anywhere from \$10 million (for a non-food animal) to over \$50 million (for cattle) and ten years to bring a new animal drug from its research and development stage to a CVM-approval the aquaculture industry has done exceptionally well. Within the past 20 years, we have brought nearly a dozen new drugs more than 75% of the way

towards their approvals with a “mere” fraction of such monies. Obviously, our collaborative challenge now is to ensure that these efforts are brought to completion and result in new animal drug approvals.

INAD INFORMATION & STATUS

This section of the AADAP Newsletter will be devoted to current information and status of the INADs that the U.S. Fish & Wildlife Service administers. Our plan is to include practical and detailed information on the use of INAD drugs, gained through our experience and that of our co-investigators. Such information will help you increase your chances of conducting an effective treatment and improve the quality of the data collected. Additional information tidbits of a less technical nature can be found in the “Fins & Tails, Bits & Bobbers” Section of the Newsletter.

To achieve our goal for this section of the Newsletter, we strongly encourage those enrolled in our National INAD Program to provide us feedback (positive and/or negative) regarding your experiences with using any of the INAD drugs (contact: Ms. Bonnie Johnson; phone: 406-587-9265 x 136; fax: 406-582-0242; email: bonnie_johnson@fws.gov).

Annually we will provide a complete listing of all the INAD drugs that we have administered, currently administer or may possibly administer in the near future. This list is only meant to update you on what drugs are being managed by AADAP. For detailed information about any or all of these drugs, refer to our website: <http://fisheries.fws.gov/aadap>.

This is the inaugural issues of our Newsletter, and as such, it may be the first opportunity for some people to learn about the FWS’s National INAD Program (NIP). The following paragraphs briefly describe the NIP. For more detailed information about the NIP and other AADAP activities, refer to our website under the menu button entitled “About Us.”

Prior to 1998, all INAD exemptions held by the U.S. Fish and Wildlife Service (Service) were restricted to use by Service facilities only. In 1998, the Service’s National INAD Office in Bozeman, MT established the fledgling National INAD Program (NIP) which, for the first time, allowed participation by non-Service entities on Service-held INADs. Not only was the NIP the “right thing” for the Service to initiate, it was also supported by an FDA Workload Plan that strongly encouraged the aquaculture community to use large, consolidated INADs.

When the NIP was established in 1998, participation was restricted to state, tribal, and private aquaculture agencies and facilities that had been part of the recently terminated Western Regional INAD Project (i.e., folks in the states of Alaska, California, Idaho, Montana, Oregon, and Washington). In 1999, the NIP was expanded to allow participation by similar entities in all 50 states. Over time, participation in the NIP has fluctuated with the ever-changing needs of fisheries management. However, cumulative participation in the program has steadily grown. To date, more than 330 non-FWS aquaculture facilities located in 34 states have participated in the NIP. From a Service perspective, the NIP has been a resounding success, and has provided needed access to drugs and therapeutants to fisheries management programs throughout the United States. Participant response with respect to the NIP, including frequent comment from the FDA, has been similarly positive.

The NIP is operated on a cost-reimbursable basis with an annual cost of \$400.00 per INAD per facility per year. All money collected is directed towards funding the operational needs of the NIP. Participation also requires that all participating agencies/organizations sign a Cooperative Agreement with the Service. Additional information regarding the NIP can be accessed via the AADAP website (<http://fisheries.fws.gov/aadap>). If you have questions about the NIP, or should wish to sign-up for participation in the NIP, please contact Ms. Bonnie Johnson (phone: 406-587-9265 x 136; fax: 406-582-0242; email: bonnie_johnson@fws.gov).

AADAP INAD DRUGS	
INADs currently administered by AADAP	
Chloramine-T (gill microbicide)	CCP (spawning aid)
Oxytetracycline (feed additive therapeutant)	KMnO ₄ (all purpose microbicide)
Oxytetracycline (immersion therapeutant)	CuSO ₄ (all purpose microbicide)
Oxytetracycline (immersion marking)	Florfenicol (feed additive therapeutant)
Oxytetracycline (injection therapeutant)	Calcein (immersion marking)
Oxytetracycline (feed additive marking)	AQUI-S [®] (anesthetic)
Formalin (fungicide)	Diquat (gill microbicide)
LHRHa (spawning aid)	17α-methyltestosterone (gender manipulation)
INADs previously administered by AADAP	
Formalin (parasiticide)	HCG (spawning aid)
Prospective AADAP INADs	
Erythromycin (feed additive therapeutant)	sGnRH (spawning aid)
Slice [®] (parasiticide; emamectin benzoate)	

FEATURED INAD DRUG

Florfenicol (Aquaflor[®]): The following is a brief status report on initial approval activities for the use of florfenicol to control mortality in catfish caused by enteric septicemia and to control mortality in freshwater-reared salmonids caused by coldwater disease and furunculosis.

Schering-Plough Animal Health Corp. (SPAH; Union, NJ) is the sponsor and has been working diligently to gain U.S. approval for the use of Aquaflor[®] (50% active florfenicol) to control mortality in a variety of fish caused by pathogens susceptible to florfenicol. At present, florfenicol is approved in:

- 🐟 Canada (as Aquaflor[®]) to control mortality in Atlantic salmon caused by furunculosis,
- 🐟 the UK (as Florocol[®]), Norway, Israel, Spain, Japan, and Chile (as Aquaflor[®]) to control mortality in a variety of fish species caused by a variety of fish pathogens, and
- 🐟 most major markets worldwide, including the U.S. (as Nuflor[®], an injectable form of florfenicol) for the treatment of bovine respiratory disease and foot rot.

However, U.S. aquaculturists know that aquaculture approvals in other countries and non-aquaculture approvals in the U.S. do not equate to an approval for use in U.S. aquaculture. Fortunately, SPAH has aggressively pursued U.S. approval for two initial label claims: enteric septicemia in

catfish and coldwater disease and furunculosis in freshwater-reared salmonids. Approval of these two initial label claims is nearing completion; FDA has accepted the following broad technical sections:

- mammalian safety including toxicology, antimicrobial resistance, and analytical methods development and transfer;
- environmental safety for catfish (i.e., environmental assessment for static ponds); and
- product chemistry.

In addition, nearly all research work has been accepted by FDA (excluding a recently submitted final study report to evaluate the efficacy of florfenicol to control mortality of chinook salmon, *Oncorhynchus kisutch* caused by furunculosis) resulting in completion of the following technical sections:

- residue depletion (part of the mammalian safety technical section) for channel catfish (*Ictalurus punctatus*) and rainbow trout (*Oncorhynchus mykiss*), the latter representative for all salmonids;
- microbial safety and antimicrobial resistance in freshwater-reared salmonids;
- target animal safety - channel catfish and rainbow trout (as a representative for all salmonids);
- efficacy - control mortality in channel catfish caused by enteric septicemia (causative agent *Edwardsiella ictaluri*)
- efficacy - control mortality in all freshwater-reared salmonids caused by coldwater disease (causative agent *Flavobacterium psychrophilum*), and
- efficacy - control mortality of all freshwater-reared salmonids caused by furunculosis (causative agent *Aeromonas salmonicida*).

In addition, FDA has agreed to shorten the withdrawal period for freshwater-reared salmonids from 21 to 15 d. SPAH is hopeful that all the pieces will be in place to apply for a New Animal Drug Application approval for the above-described label claims in the next 6 - 12 months. This is great news !! For more information, visit the AADAP website.

FINS & TAILS, BITS & BOBBERS

- For best results when mixing up a batch of AQUI-S[®], weigh desired amount into a plastic bottle with a leak-proof lid. Add at least 10 times as much water as AQUI-S[®] and shake vigorously. Pour this milky-white solution into the “knock-out” tub containing the appropriate amount of water. Rinse the bottle a few times with water from the tub, return the rinse water to the tub, and then stir to completely disperse the AQUI-S[®].
- To calculate the weight of AQUI-S[®] to add to your “knock-out” tank to obtain a specific target concentration, refer to our website homepage under the “Drug-use Guidance” menu button. There, you will find a worksheet and several tables to guide you in the calculation.
- If you plan to topcoat feed with florfenicol (Aquaflor[®] or Florocol[®] premix) at your facility, you must first blend the premix into the feed, then spray the feed with fish oil or vegetable oil and mix thoroughly. The oil will discourage any leaching of the florfenicol premix.

- To determine the amount of florfenicol premix needed to treat fish in your test tanks, refer to our website homepage under the “Drug-use Guidance” menu button. There, you will find a worksheet and table to guide you in the determination.

PARTNERS' CORNER

Montana Fish, Wildlife and Parks (MFWP): In Montana, the decision to participate in the U.S. Fish & Wildlife Service's [National] INAD program was easy. Like all resource agencies with the responsibility of rearing fish for public waters, we need to be able to treat a variety of fish ailments. The National INAD program, now [part of the] AADAP program, gave us the mechanism we needed to legally access fish drugs. It allows us to use drugs without having to go through the lengthy and slow process of developing our own INADs, but it doesn't relieve us of the paperwork and reporting requirements for their use.

INAD forms and reporting have been enough to discourage some states from participating. What is needed is a way to join the program and keep the paperwork to a minimum. In Montana, the answer was to contract the INAD monitor's job to a private contractor. Enter Bob Piper (now retired), former Director of the Bozeman Fish Technology Center. Montana Fish, Wildlife and Parks contracted Bob to coordinate all FDA- and AADAP-required paperwork, and to ensure that the proper forms are completed and filed each time we use a drug under the INAD program.

The contract with Bob has been a time saver. Bob enjoys the relatively small amount of time he spends on INAD work, and it frees up MFWP staff to do other things. Bob's oversight of the program has ensured the job is per FDA and AADAP requirements and is completed on time.

Whether a state is now participating in AADAP's INAD program or considering enrolling, contracting the paperwork is an option worth considering. Not every state has a Bob Piper, but every state has a retired hatchery manager or fish culturist who would be qualified to do this work and who would probably love to take on a small contract. *Jim Peterson, MFWP Fish Health Lab.*

MEETINGS, ETC.

Annual INAD Workshop was bigger and better (and has a new name): The 10th Annual “Drug Approval Coordination Workshop” was held August 3 - 4, 2004, in Bozeman, MT. More than 60 people attended, and there were representatives and presenters from several federal and state agencies, university programs, private pharmaceutical companies, and a professional animal-health organization. The meeting was organized by the AADAP program and co-hosted by Roz Schnick, National Coordinator for Aquaculture New Animal Drug Applications. For the first time, the meeting was coordinated with the Fish Health Section of the American Fisheries Society. Many local businesses donated door prizes (awarded after meeting breaks), and an evening barbeque “social” was held at a picturesque, high-elevation, mountain reservoir.

The theme of this year's Workshop was “*Gathering Strays and Lining-out the Herd for the Trail Ahead,*” and the meeting was organized around overview, status, and technical sessions. For example, there were overviews of potential aquaculture drug approvals that will be affected by work done or decisions made by a number of organization including: the Joint Subcommittee on Aquaculture's Quality Assurance in



Aquaculture Production Working Group (QAAPWG), the International Association of Fish and Wildlife Agencies' Drug Approval Working Group, the U.S. Fish & Wildlife Service, the NADA Coordinator, the U.S. Department of Agriculture, the U.S. Geological Survey, the U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM), the U.S. Environmental Protection Agency, the American Veterinary Medical Association, USDA's NRSP-7 program, and the Animal Drug User Fee Act and the Minor Use and Minor Species legislation.

In addition, updates on the status of proposed initial or expanded label claims were presented or discussed for chloramine-T, florfenicol, hydrogen peroxide, erythromycin medicated-feed and injectable therapies, oxytetracycline medicated-feed and immersion therapy, calcein (marking agent), AQUI-S[®] (anesthetic), formalin, copper sulfate, potassium permanganate, and other drugs on the horizon (e.g., Slice[®], Pyceze[®], Diquat, Mincare[®], LHRHa). Finally, there were overview or technical presentations related to CVM's veterinary feed directives, CVM's criteria for commercial feed mills, federal criteria for Good Manufacturing Practices, criteria related to CVM's environmental safety technical sections, and the QAAPWG's Strategic Plan and new National Research Forum.


The 11th annual Drug Approval Coordination Workshop will be held August 2-4, 2005, in Bozeman, MT. Please contact Ms. Molly Bowman (email: molly_bowman@fws.gov; phone: 406-587-9265 ext 139) if you would like to be added to the mailing list for the meeting announcement and program schedule.


Zero-withdrawal Fish Anesthetic Roundtable Discussion; American Fisheries Society Meeting; Madison, Wisconsin; August 22, 2004: Rosalie Schnick, National Aquaculture NADA Coordinator, convened a roundtable discussion on August 22, 2004, at the American Fisheries Society Conference in Madison, WI. The discussion subject was the need for a zero-withdrawal anesthetic in public aquaculture. To lead the discussion, presentations by Ms. Schnick and Jim Bowker (U.S. Fish & Wildlife Service, AADAP) summarized information about: (1) FDA-approved anesthetics and potential zero-withdrawal anesthetics, (2) the general agreement that AQUI-S[®] is the fish anesthetic standing the best chance of gaining FDA approval as a zero-withdrawal anesthetic, and (3) progress towards completion of the technical sections required for an initial approval of AQUI-S[®] to anesthetize salmonids to a "handleable" stage.




After the presentations, discussions focused on how to:





-  secure research support and additional funding to pursue a broad approval of AQUI-S[®], and
-  alert fisheries communities of the need for broad approval, support, and additional funds for AQUI-S[®].

Discussions led to the following proposed courses of action:

-  fish culturists and managers must be informed that the most effective method to generate substantial effectiveness and safety data on AQUI-S[®] (to gain approval for a broad variety of species) is during routine fish culture or management procedures. However, it is important for managers to note that not all fish within a lot/population need to be tested with AQUI-S[®];

-  fisheries chiefs and supervisors must play a role in communicating several facts to their fish culturists and managers:

-  it is illegal to use clove oil,
-  it is illegal to use MS-222 on fish to be slaughtered or released before the 21-day withdrawal period, and
-  the importance of their participation in the AQUI-S[®] INAD program;

-  additional funding will be pursued to expand the initial AQUI-S[®] approval to include coolwater and warmwater fish, and/or for its use to sedate fish for long-haul transport (note: only research for current label claims are funded);
-  find the best methods to survey fish culturists and managers about the need for a transport sedation approval;
-  identify and pursue potential sources for new funding; and
-  determine ways to more effectively use meetings, newsletters (AFS and WAS), journals, websites and fact sheets to alert the fisheries community to the need for a broad approval of a zero-withdrawal anesthetic.

NRSP-7 International Minor Species Workshop: The workshop covered all minor species, spotlighting drug availability and approval requirements. Discussions focused on commonalities and the potential for international harmonization, or at least data sharing, in the future. Significant differences were often noted to be a function of whether a particular animal group was a major or minor food source, e.g., sheep are a minor species in the U.S., while they are a major species in New Zealand and Australia. Many presentations and discussions centered on aquaculture species. The Workshop was held **October 7th & 8th** at the Doubletree Hotel in Rockville, Maryland. The FDA's Center for Veterinary Medicine plans to make all presentations available in the near future on their website. Presentations can be found at the following address under the topic "Final Agenda":
<http://www.fda.gov/cvm/index/mums/MUMSIntMtg.htm>.

Aquaculture America 2005; Marriott New Orleans; January 17-20, 2005; New Orleans, Louisiana: Information on the annual conference and exposition of the National Aquaculture Association, the U.S. Aquaculture Society and the U. S. Aquaculture Suppliers Association can be found at: <http://www.was.org/meetings/ConferenceInfo.asp?MeetingCode=AA2005>. This annual conference and trade show is being hosted by the Louisiana Aquaculture Association and co-sponsored by a host of trade and professional organizations. Several sessions relating to aquatic animal health and drug approval activities are on the agenda and can be found at: <http://www.was.org/meetings/pdf/AA2005SessionsbyDay.pdf>.

ROZ's CORNER

The Federal-State Aquaculture Drug Approval Partnership Project (known as the IAFWA Project) is formally completed but work still continues to complete the goal of broad approvals for the nine drugs selected by the states for approvals. We have had successes in gaining two label claim extensions for formalin as a parasiticide and fungicide for all fish and all fish eggs, and an initial label claim for oxytetracycline as an immersion marking aid for all fish.

Recently, 17 new label claims have moved closer to completion as a result of new data package submissions from sponsors/researchers and/or their acceptance by CVM. Between September 2003 and August 2004, the AADAP Program had 13 submissions and eight acceptances of efficacy studies, company sponsors 11 submissions and six acceptances for several technical sections, and the Upper Midwest Environmental Sciences Center (UMESC) three submissions and seven acceptances for several technical sections, for a total of 27 submissions and 21 acceptances. All the research data except for a few data packages have been submitted for chloramine-T, copper sulfate, florfenicol, formalin (control of saprolegniasis), hydrogen peroxide, oral oxytetracycline, and immersion oxytetracycline.

In May 2004, the company sponsors for oral oxytetracycline and AQUI-S[®] met with CVM to determine the remaining data requirements and the R&D plan for a broad approval as a zero withdrawal anesthetic. Many agencies, organizations and the sponsor of AQUI-S[®] are mounting an aggressive program, including securing new funds, to develop all the data needed for this most important drug. An example of this combined effort is the joint funding from the North Central Regional Aquaculture Center and the company sponsor for radio-labeled material that will be used by the UMESC to perform essential residue chemistry studies. *Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, La Crosse, Wisconsin*

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CVM's NOTES

The U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM) would like to remind sponsors and clinical investigators developing protocols to support the effectiveness section of a New Animal Drug Application (NADA) of a CVM guidance document. The document is entitled: "Guidance for Industry (#85): Good Clinical Practices: VICH GL9, Final Guidance." The objective of this document is to provide guidance on the design and conduct of all veterinary product clinical studies in the target species. It is directed at all individuals and organizations involved in the design, conduct, monitoring, recording, auditing, analysis and reporting of clinical studies in target species and is intended to ensure that such studies are conducted and documented in accordance with the principles of Good Clinical Practice (GCP). Good Clinical Practice is intended to be an international scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing and reporting clinical studies evaluating veterinary products. Compliance with this standard provides public assurance about the integrity of the clinical study data, and that due regard has been given to animal welfare and protection of the personnel involved in the study, the environment and the human and animal food chains. The document can be found on CVM's website at: <http://www.fda.gov/cvm/guidance/guide85.PDF>. *Dr. Donald A. Prater, Leader, Aquaculture Drugs Team; U.S. Food and Drug Administration, Center for Veterinary Medicine.*

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Save a tree; request an
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contacting:
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