



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 2-4

AADAP NEWSLETTER

December 2006

WHAT’S SHAKIN’



Best Wishes for the Holiday Season



All of us here at AADAP in warm and sunny Bozeman, Montana would like to extend to you and yours our sincere wishes for a happy holiday season & wonderful New Year



2007 INAD Sign-up Forms are now available: Once again it is that time of year for renewal of your facility’s INADs for calendar year 2007. Please send in the completed sign-up sheets to the Bozeman INAD/AADAP Office by 31 Dec 2006. Invoices will then be mailed out by the end of January. Also, if you have not already done so, 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 facilities for INAD Year 2006. All 2007 sign-up forms are available for downloading on our website at <http://www.fws.gov/fisheries/aadap/signup.htm>.

Drug Approval Coordination Workshop: The 12th Annual Aquaculture Drug Approval Coordination Workshop was held in La Crosse, Wisconsin on 1-2 August 2006 at the Radisson Hotel. The workshop was attended by 87 participants. Of the participants, 18 represented pharmaceutical companies interested in aquaculture drugs. Many people agreed that the lead-off speakers were exceptional; Gary Whelan and Meg Oeller, thanks for coming! The first session included presentations by representatives from the U.S. Food and Drug Administration’s Center for Veterinary Medicine (CVM). The presentations were well prepared and informative, and some are [currently available on the web](#). The balance of the workshop included presentations

concerning the development and status of aquaculture drugs under investigation. Included in those sessions were insightful presentations by researchers and a number of drug company representatives. During the workshop, the break refreshments complemented an atmosphere fostering informal discussions among researchers and representatives from CVM, hatcheries, and drug companies. Workshop participants were impressed and appreciated the [Upper Midwest Environmental Sciences Center \(UMESC\)](#) tour where they were introduced to the comprehensive capabilities of the Center. The Tuesday evening paddlewheel boat ride was well received. The boat ride not only provided a scenic view of the Mississippi River, but also a cool breeze, great food, and cold beverages to offset a hot summer day. A warm thanks to Roz Schnick for hosting the picnic at her home located on Lake Onalaska. The picnic was attended by about 70 people who again enjoyed pleasant conversation, great food, and cold beverages. Thanks to the [University of Wisconsin-La Crosse, Office of Continuing Education and Extension](#), for all the help coordinating the workshop. Finally, a hearty mid-western thanks to the drug companies who sponsored the workshop amenities and evening activities. Click here to view a [few Workshop photos](#).

CVM Issues Proposed Regulations on MUMS Indexing – Public Comment Period to close 20 December 2006:

The second of a series of features of the Minor Use and Minor Species Animal Health Act of 2004, drug indexing, is one step closer to being implemented. CVM published proposed regulations to implement Section 572 of the Food, Drug and Cosmetic Act entitled “Index of Legally Marketed Unapproved New Animal Drugs for Minor Species” (“the Index”). These regulations propose administrative procedures and criteria for index listing a new animal drug for use in a minor species. Such indexing provides a basis for legally marketing an unapproved new animal drug intended for use in a minor species. **However, the “Index” is limited to nonfood-producing minor species with a limited exception for some early life stages of food animals, such as fish eggs.** The Index is intended to be a means by which companies can legally market veterinary drugs for minor species that pose no human food safety concerns without having to go through the long and expensive process of a new animal drug approval. Inclusion in the Index will largely be based on the evaluation of the target animal safety and effectiveness of each specific product by a panel of qualified experts who

will report their findings to the FDA. The Public Comment period has been extended from 20 November to 20 December 2006. For more details refer to the [22 August "CVM Update"](#) and/or the actual [Federal Register Notice of 22 August 2006](#) and the [Federal Register Notice of 2 October 2006](#), which extends the comment period.

CVM names new Director of the Office of Minor Use and Minor Species (OMUMS): In preparation for Dr. Andy Beaulieu's January 2007 retirement as the Director of OMUMS, Dr. Burnadette Dunham has been named to assume Dr. Beaulieu's position. Dr. Beaulieu has been the Director of OMUMS since its inception shortly following the signing of the Minor Use and Minor Species Animal Health Act of 2004 in August of 2004. Dr. Beaulieu led CVM's formulation of recommendations to Congress that formed the basis for the MUMS legislation. Dr. Beaulieu has been an exceptionally ardent supporter of aquaculture and will be sorely missed. For more information on Dr. Dunham and the transition, refer to the [23 August "CVM Update."](#)

Aquatic Life Sciences and Eka Chemicals announce distribution agreement for 35% PEROX-AID® (aquatic grade hydrogen peroxide) in North America: [Eka Chemicals Inc.](#) and [Aquatic Life Sciences \(ALS\) Inc.](#), announced that an agreement has been finalized which appoints the Aquatic Life Sciences companies ([Western Chemical Inc.](#) & [Syndel Laboratories Ltd.](#)) as the exclusive distributors for 35% PEROX-AID® throughout the United States and Canada. To read more about this agreement refer to the ALS [press release](#).

Low Regulatory Priority Status for hydrogen peroxide to be rescinded: FDA's Center for Veterinary Medicine has indicated that the Low Regulatory Priority (LRP) Drug status for this drug will be rescinded once an initial approval for hydrogen peroxide (35%PEROX-AID®) is granted. For more information, please refer to the official Association of Fish and Wildlife Agencies "[Drug Alert Statement](#)."

AADAP to establish an INAD for hydrogen peroxide: In light of the anticipated approval of hydrogen peroxide (Eka Nobel's 35%PEROX-AID®) for saprolegniasis on freshwater (FW) finfish eggs, bacterial gill disease in FW salmonids and external columnaris in FW coolwater finfish and channel catfish coupled with the simultaneous removal of LRP status for hydrogen peroxide, there will soon be a clear need for an INAD for use-patterns not covered by the new approved NADA. As a means to counter this "down-side" of the hydrogen peroxide approval, AADAP is in the process of assembling an INAD request package for use on all remaining FW and marine fish as a broad-spectrum external microbicide. As soon as the INAD is accepted by CVM, all relevant information, including sign-up forms will be available on our website.

New Protocols and SOPs added to JSA's Research Forum information: The example set of study protocols and Standard Operating Procedures (SOPs) assembled by the [JSA - Working Group on Aquaculture Drugs](#),

[Biologics, and Pesticides'](#) National Aquaculture Drug Research Forum (NADRF) has been recently updated and is now available to you as reference material. You can access these protocols and SOPs on AADAP's website at: http://www.fws.gov/fisheries/aadap/Res_Forum_protocols.htm.

USFWS and USGS's Leetown National Fish Health Research Lab to collaborate on new disease diagnostic method: The [Lamar Fish Health Lab](#) and AADAP will assist Dr. Rocco Cipriano ([USGS, Leetown Science Center](#)) on a project entitled: "*Modeling Microbial Diversity of Infection to Affect FDA Revision of Licensed Antibiotics from "Control of Mortality" to "Control of Pathogen."*" The project will also include collaboration with CVM's Office of Research. The project team was recently informed that the two-year project will be funded by USGS Science Support Project funds. The purpose of the project is to develop and pilot test a new disease management and control tool that should accurately establish the need, and timing, for administration of antimicrobial therapeutants to fish populations to effectively reduce and/or preclude mortalities. If the procedures prove successful, the hope is to be able to convince CVM that the label for any new antibiotics might include the claim for "control of pathogens" as opposed to the historically used "control of mortalities" claim.

2005 Public Sector Aquaculture Production Database is coming soon: As we go to press (so to speak), more than 80% of the States' and several other Federal and Tribal agencies have contributed their most current (which includes at least a portion of calendar year 2005) fish production data to AADAP for compilation into a revised public sector "Aquaculture Production Database." We anticipate that the newly revised database will be on our website by the 1 January 2007. Look for it !!

Oxytetracycline update:

New formulation approved for Phibro's OTC product: [Phibro Animal Health's](#) NADA (#038-489) has now been amended to change the formulation from oxytetracycline hydrochloride to a dihydrate salt of oxytetracycline. In addition to the supplement providing for the approval of the dihydrate salt, it also provided for a change of oxytetracycline concentration in the Type A medicated article, and the addition of an indication for control of gaffkemia in lobsters. For more information, view the [Federal Register Notice published on 8 August 2006](#). Phibro Animal Health is to be commended for their efforts in this regard and for supporting the aquaculture industry.

Calcein (SE-MARK®) update:

Product Development Meeting Planned: Western Chemical, a division of [Aquatic Life Sciences \(ALS\) Inc.](#) continues to aggressively engage in activities pursuant to assembling NADAs for their calcein marking agent (SE-MARK®). Western recently (early



October) met again with staff from AADAP, [Bozeman Fish Technology Center](#) and [Lamar Fish Technology Center \(PA\)](#) to formulate plans to meet with FDA's Center for Veterinary Medicine for a product development session. The meeting is scheduled to take place 20 December 2006.

Aquaflor® (florfenicol) update:

Bellingham Technical College Studies: Just as we started putting our drug efficacy field study gear into winter storage, we got another call from Earl Steele, head of the [Bellingham Technical College's](#) aquaculture program. It appeared as though some young rainbow trout that Earl and his students had been diligently trying to get to break with a good case of columnaris for the past several months had finally succumbed.....in October! With field efficacy trials in general, and columnaris studies in particular, when things happen, they happen fast. So we started rolling some resources Earl's way, including Aquaflor® and Dr. Jed Varney ([Washington Department of Fish and Wildlife](#)) to perform the initial fish health evaluations. Earl and his crew quickly mobilized resources and the study is underway. We thank Earl for continually giving it the "old college try" and hope this study works out. We'll keep you posted.

Publications: The soon to be published issue (2006) of [Waterlines](#) contains an article written by Jim Bowker and Dr. Vaughn Ostland. The article is entitled: "Evaluating the effectiveness of various dosages of Aquaflor®."

17- α methyltestosterone update:

There is considerable activity to report relative to progress on completion of the efficacy technical section for 17- α methyltestosterone (MT; 60 mg MT/kg fish/d for 28 d) to produce predominately male populations of tilapia.

Study #1: On 12 July 2006 AADAP initiated a MT efficacy study at SeaPac of Idaho's Canyon Springs (Buhl, ID) facility. With the assistance of Ken Ashley (SeaPac) we worked out study logistics, and with the help of Dave Brock and Doug Ramsey ([Rangen Inc.](#)) we were able to cover MT medicated feed and fish health support needs. We took our bag of tricks down to the nursery, and working with the Canyon Springs staff (Ray Gill and Patty Sheen) successfully got the study up-and-running. If you've ever tried hand-counting 400 1-cm (0.003 g) fish into each of eight test tanks, then you'll appreciate how much patience was needed to get this study going! Three short months later (18 October), test fish had reached the magic size (~5 in) and the in-life phase of the study was terminated. At that time 40 fish from each of the four treated and four untreated tanks were randomly collected and evaluated to determine: (1) fish size, (2) gross necropsy results (i.e., fish health) and (3) gross visual determination of gender. Whole gonads from each fish were also fixed in Davidson's solution

for histological confirmation of fish gender at a later date. Preliminary results indicate that the study hypotheses (i.e., MT medicated feed treatment will result in at least 80% males) will be met.....which is great news!! Even though the use of MT medicated feed to produce populations of predominately male fish is a "tried and true" methodology in the tilapia industry, the generation of hard data (i.e., conducting a successful pivotal study) for submission to FDA to support an NADA claim is always cause for celebration. Many thanks to Ken Ashley and his crew at SeaPac for their invaluable assistance in completing this study.

Study #2: On 7 September 2006 AADAP initiated a second MT efficacy study at Simaron Fresh Water Fish (Hempstead, TX). Exhibiting exemplary management skill, General Manager Rob Schmid promptly turned the hard work over to co-workers Terry Washburn and Aron Collins, and together, we all worked hard to get the study up-and-running. With starting numbers of 10,000 fish per treatment group, this study is being conducted on a bit more grandiose scale than the study conducted at SeaPac, and consequently we spent a full day hand-counting the little devils into treatment tanks. At press time we are through the 28-d treatment period, test fish are doing well, and our fingers remain crossed. Due to cooler water temperatures at Simaron, this study is not scheduled to end until sometime in February 2007. In the interim, Terry and Aron are keeping a close eye on things, collecting all the required daily data, and keeping us up-to-speed regarding study progress. Many thanks to Rob and his crew for doing the bulk of the leg work on this study....and stay tuned!!

Study #3: On 29 November 2006 AADAP returned to SeaPac of Idaho and initiated a third MT efficacy study. Although initially we had hoped that two pivotal studies would be sufficient to complete effectiveness technical section data requirements, unanticipated "issues" with respect to MT dosage mandated a third study. As a result of the warmer water temperatures at SeaPac, this study will also end in February 2007. With any luck a' tall, this will be the final MT efficacy study required. Once again, many thanks to Ken and his crew for doing the lion's share of the work!!

AQUI-S® update:

Target animal safety study on cutthroat trout: AADAP recently completed the in-life phase of a study to demonstrate the safety of 40 mg/L AQUI-S® (the highest proposed efficacious dose for freshwater salmonids) to small fingerling cutthroat trout. Preliminary results indicate that there is an adequate margin of safety associated with overexposing (i.e., 2x duration) test fish at 40 mg/L AQUI-S® and for overdosing (i.e., 2x dose) test fish at 80 mg/L AQUI-S®. We are currently in the process of an "all-hands-on-deck" effort to process fish tissues for histological evaluation. Results from this study, in



combination with results from a previously completed (and submitted) target animal safety study conducted on rainbow trout, will hopefully satisfy the safety data requirements for all freshwater salmonids. Once again, stay tuned.

Preliminary TAS studies on blue catfish and largemouth bass: During August 2006 AADAP completed preliminary safety studies to determine whether smaller blue catfish and largemouth bass were more or less sensitive to overdosing and overexposing with AQUI-S[®] than larger fish. As anticipated, it was found that smaller test fish were indeed more sensitive than larger fish. Based on the results of this preliminary study, it would appear that there is more than an adequate margin of safety associated with overexposing small blue catfish and largemouth bass with 60 mg/L AQUI-S[®]. Based on these results, AADAP will overexpose representative cool- and warmwater test fish in full-blown, pivotal TAS studies with 60 mg/L (the highest proposed dose for cool- and warmwater fish) and 120 mg/L AQUI-S[®] (the overdose concentration). We plan to start the first of these studies in spring 2007.

Publications: The AADAP program, working hand-in-hand with staff at the FWS's Washington Office of Public Affairs Branch of Printing and Publishing, has established a Biological Publication Series to more expeditiously disseminate drug approval research reports and information bulletins. The first such report was written by Jim Bowker, Dan Carty, and Molly Bowman. The report is entitled: "*The Efficacy of AQUI-S[®] as an Anesthetic for Use on Juvenile and Adult Largemouth Bass Micropterus salmoides.*" Many thanks to Mark Newcastle for helping us through this process and providing critical review.

Chloramine-T update:

Supportive Field Study: As part of a joint effort, the AADAP staff worked closely with researchers from [Iowa Department of Natural Resources Rathbun Fish Culture Research Facility](#) this past summer to conduct a field study to substantiate the effectiveness of 20 mg/L chloramine-T to control mortality caused by external columnaris in walleye *Sander vitreus*. The study only needs to be considered supportive by CVM's Aquaculture Team (based on previous discussion with CVM's Aquaculture Team Leader) to substantiate results from a study conducted by Jeff Rach ([USGS/UMESC](#)) that demonstrated the effectiveness of chloramine-T for this claim. The Final Study Report is going through the internal review process and should be submitted to CVM with a request for a formal review soon. Many thanks to Alan Johnson, Jay Rudacille, and Brad Bond for carrying the water on this study.

FEATURE ARTICLE

AADAP's Website: Goals and Objectives, Form and Function, & Navigation

Tom Bell & Dan Carty; U.S. Fish & Wildlife Service;
Aquatic Animal Drug Approval Partnership Program;
4050 Bridger Canyon Road;
Bozeman, Montana 59715



Introduction

The Aquatic Animal Drug Approval Partnership (AADAP) Program of the US Fish & Wildlife Service (FWS) exists to perform several public service functions. The basis for these functions is spelled out in our mission statement:

"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 and fisheries management programs."

A key component of any successful partnership is the open exchange and timely dissemination of information. To that end, AADAP has established two vehicles for exchanging and disseminating information: (1) a website (<http://www.fws.gov/fisheries/aadap>) and (2) a quarterly newsletter. The form and function of our website - with tips on navigation - are the subjects of this article.

Goals and Objectives

The goals and objectives of our website are to:

1. Facilitate the approval of new drugs for aquaculture by allowing others to learn from AADAP's and others' experience.
2. Provide those participating in the FWS Investigational New Animal Drug (INAD) program as much information as we can to make their involvement as easy and meaningful as possible.
3. Provide "one stop shopping" for information on aquatic animal drug approval activities, drug-use guidance, and drug approval status.
4. Serve as an information- and experience-exchange forum for all those working in the aquatic animal drug approval arena.
5. Be as dynamic, up-to-date, and user-friendly as possible.

Form and Function

General Issues

General topics: To fulfill our third website objective (“one-stop shopping” for aquaculture drug approval information), we face a dilemma not uncommon on many websites. That dilemma is how to maximize the amount of information available, while at the same time minimizing the difficulty for users to find and retrieve that information. There appears to be no easy solution to this, and hence, some may not find navigation and finding specific information on the AADAP website to be intuitive. We apologize for this, but can only promise to continue to try our darnedest to make it as user-friendly as possible. Any advice or suggestions from our users is welcome and would be greatly appreciated.

Web-browsers: The AADAP website was designed with the assumption that most users would access the site with some version of Microsoft’s Internet Explorer (IE). Currently, AADAP test drives the site *per se*, and all changes to the site, on IE (Version 7). Mozilla’s Firefox browser and Netscape’s browser are also used to test-drive most new changes to the site.

We have noticed the least number of operational idiosyncrasies when viewing the AADAP site while using Firefox or Netscape. Microsoft’s support of Macromedia flash movies (e.g. the introductory fish-in-the-stream movie, and the buttons on the home page) often requires an extra step to activate the button or bypass a movie. In the case of the series of buttons horizontally placed near the top of the page, you need only to scroll over these for their respective submenus to appear when using Firefox or Netscape, whereas with IE, you are prompted to “click to activate and use this control.” When using IE, the selection of any of the buttons in the left hand panel requires a double-click, while Firefox and Netscape only require a single-click.

If you are using an older version of Microsoft Internet Explorer (i.e., older than Version 7), scrolling down a page with the far right scroll bar will not be smooth, but instead will appear rather jerky. Neither Firefox nor Netscape produce the same jerky scrolling.

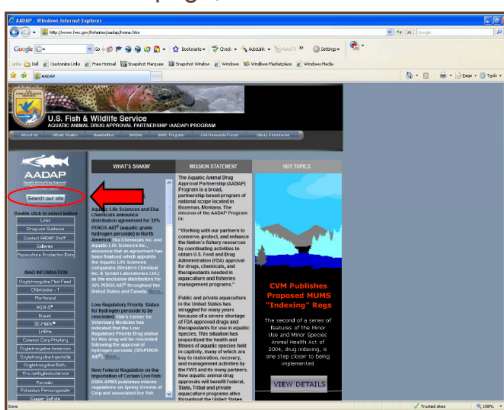
Access speed: The AADAP site was designed with the assumption that high-speed internet access is the norm. Technically, all pages should be available to you if you are operating with a dial-up connection. However, it may be impractical to access some of the larger documents based on the time to download. If you do have a problem related to your access speed and your inability to retrieve a specific document, please don’t hesitate to contact us via email or phone, and we will make other arrangements to ensure that document is made available to you.

Macromedia’s Flash Player: Currently the AADAP site contains several features that require a recent version of Macromedia’s Flash Player (Version 8 or newer) be installed on your computer. The Flash Player, like Adobe’s Acrobat Reader, is readily available as a [free](#)

[download](#) on Macromedia’s website. A link to the Flash download is also available at the bottom of the [opening page](#) of AADAP’s website. Some of the website’s features (e.g. navigation buttons) were designed using Flash to reduce the amount of work required for routine updating and minor site revisions. Other components (e.g. opening page fish-art, photo galleries and special announcements) were designed as Flash “movies” more for aesthetics rather than improved functionality. Presently, we do not anticipate eliminating all Flash components from the AADAP site. Some users have experienced problems downloading the Flash Player. Typically this is a problem based on either their computer’s internal firewall or, in the case of users that access the web through a local area network (LAN), their network’s installed firewall. In both cases, temporary “permission” can usually be granted to allow the Flash Player to be downloaded.

Adobe Reader: Like many organization today, the AADAP Program maintains a lot of our archival documents as Adobe PDF files, in particular those documents that are intended to be shared with our partners. Hence, nearly all documents accessible on our website are PDF files. Not only does the use of PDF files significantly reduce the amount of space required for their storage on our server, but their small size (compared to the same document in a word processing format) dramatically reduces the amount of time for the file to be downloaded by a user. Adobe PDF files have proven to be near universally readable, the only limitation being that the person wanting to read the file must have a current copy of Adobe Reader on their computer. Similar to the Flash Player mentioned in the previous paragraph, Adobe Reader is available as a [free download](#) on Adobe’s website.

AADAP’s Search Engine: The AADAP website contains a link to a Google™ search engine. The “Search our site” button is located near the top of the left hand panel of the home page. Selecting the button will take the user to a “disclaimer” page, where he/she is informed that to use



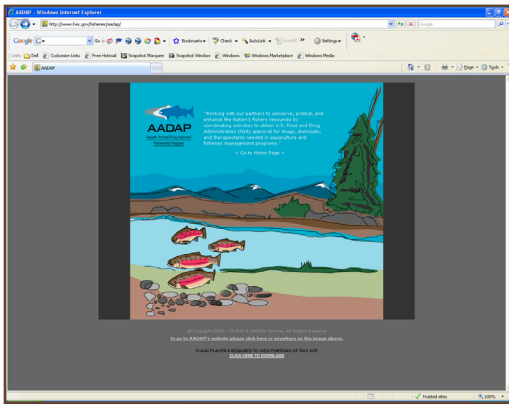
the search function, one has to temporarily leave the AADAP site. On this disclaimer page, the user has the option of searching ONLY the AADAP site

or all US Fish & Wildlife Service sites. Regardless of which search is picked, a new window will open in which the user can enter search criteria in the same manner as one would specify these criteria in Google™ or any other search engine (e.g. [Yahoo!®](#) or [DogPile®](#)). Either closing

the Google™ window or selecting a found item will return you to AADAP's site.

Screen resolution: As in the case of nearly any website, the resolution to which you have set your monitor will affect the amount of scrolling required to see an entire page. Unfortunately for some, the AADAP site was designed with the assumption that the majority of users have a high resolution monitor set by the user to display at a moderate to high resolution (e.g. 1280 by 960 pixels or higher). We have tried to help in this regard by installing an internal scroller (not the scrolling function of the browser, which is located on the extreme right hand side of the page), which operates independent of screen resolution. If you are able to do so, we would suggest that you consider changing your display (screen) settings to maximize the screen resolution.

Fish-art opening page: Although it is purely personal preference, we thought some users might enjoy opening our site with something different than the standard set of buttons and lists. Hence, our opening page is a kind of artsy Flash movie depicting a trout filled stream in the mountain west. Unless you have visited the site before and you have not cleaned up your temporary file cache



recently, this movie takes about 20 seconds to load. We can understand that after awhile this may get rather old and you may want to skip the artsy stuff. If that is the

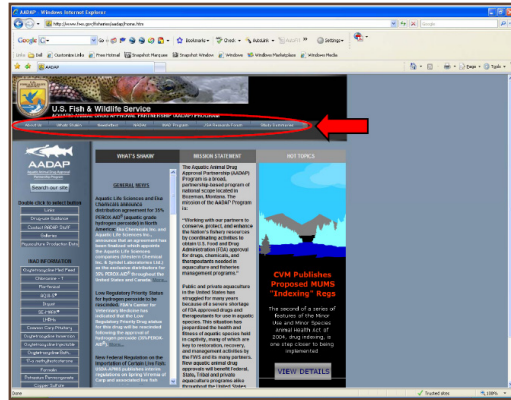
case, it is fairly simple to bypass the movie in one of three ways: (1) select the “Double Click to Skip Intro” phrase in the bottom right corner of the movie *per se*, (2) select the underlined phrase “To go to AADAP’s website...” near the bottom of the screen, or best of all (3) once you are at the actual AADAP home page (not the intro movie page), place this page in your “Favorites” list.

Navigation

General topics: Our website has many topic categories (buttons) and much built-in redundancy (i.e., several ways to “get at” a specific INAD form or other piece of information). These “traits” make it easier for some people to find forms or other information but can make it more difficult for other people - simply because all of us “navigate” in slightly different ways. For example, some people are primarily text-oriented, others are primarily graphics-oriented, and still others are primarily search engine-oriented. We trust that the following tips will prove useful to all three types of navigators.

Navigation buttons:

The first set of buttons (About Us, What’s Shakin’, etc.) is displayed horizontally across the top of the home page. Hold your mouse pointer over one of these buttons (no clicking required unless you are using

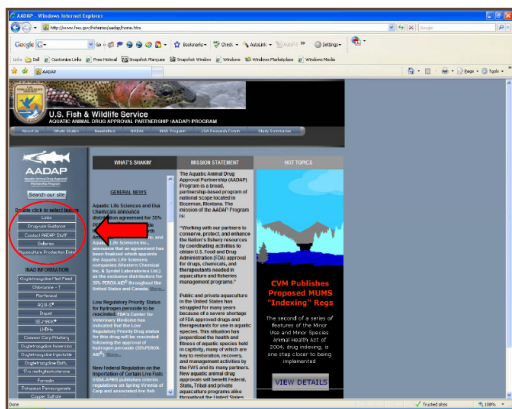


Microsoft’s IE browser) and a list of subtopics will be “displayed” in a second horizontal row. To select a subtopic, slide your cursor straight to the horizontal row of subtopics and then over to your choice, then click. In the following descriptions of these buttons, an active link is provided to each of the subtopics, which permits you to quickly take a first-hand look at what is being described.

- “About Us”: (a) a brief overview [summary of the AADAP program](#); (b) a discussion of our [National INAD Program](#); (c) history and information about [AADAP’s Research Program](#); (d) an introduction to, and contact information for, [AADAP’s staff](#) and (e) a spiffy [Fact Sheet](#) on the AADAP Program.
- “What’s Shakin’”: (a) [miscellaneous new information](#) about drug approval activities, (b) information on [New Drug Approvals](#), (c) [Fin & Tails, Bits & Bobbers](#) – helpful tidbits in particular for those participating in INAD studies, (d) information on [AADAP’s annual INAD Workshops](#) both past and upcoming, (e) recent [formal presentations by AADAP staff](#), (f) [upcoming meetings](#) of interest to those working in the drug approval arena and (g) info on [recently held meetings](#).
- “Newsletter”: (a) the [current AADAP Newsletter](#), (b) archived copies of the [previous AADAP Newsletters](#), (c) a page allowing you to [subscribe to the AADAP Newsletter](#), (d) a page allowing you to [unsubscribe to the AADAP Newsletter](#) and (e) a list, with active links, to [other newsletters](#) of possible interest to our users.
- “NADAs”: (a) the National Coordinator for Aquaculture New Animal Drug Applications’ (NADAs) [Drug Approval Status Reports](#), (b) AADAP’s [abridged version of the Drug Approval Status Reports](#) and (c) a link to the [FDA – Center for Veterinary Medicine’s website](#) and their latest information on aquaculture drug approvals.
- “INAD Program”: (a) [INAD Signup Information and necessary forms](#) to be completed, (b) other [forms regarding drug use on threatened and endangered species](#) and (c) [generic examples of all completed forms](#).

- “JSA Research Forum”: Information pertaining to the US Joint Subcommittee on Aquaculture’s National Aquaculture Drug Research Forum (NADRF), which includes subtopics on the following: (a) [background information and recent news](#) about the NADRF; (b) a [directory of subject-experts](#) involved in aquaculture drug research; (c) an extensive list (more than 200) of, and active links to, pivotal research and INAD [protocols and associated Standard Operating Procedures](#) (SOPs) used by AADAP, USGS’s La Crosse Lab, USDA’s Stuttgart Lab and the University of Florida’s Tropical Aquaculture Lab; and (d) [notes for all previous NADRF meetings](#).
- “Study Summaries”: (a) the list, and links to, [AADAP’s Annual INAD Reports](#) submitted to CVM for each drug for which the FWS administers an INAD, and (b) other reports, including the [Final Study Reports on pivotal and supportive studies](#) that have been submitted by AADAP to CVM in support of a drug’s effectiveness and/or target animal safety.

The second set of buttons (Links, Drug-Use Guidance, etc.) occupies the top section of the left-hand panel of the home page.



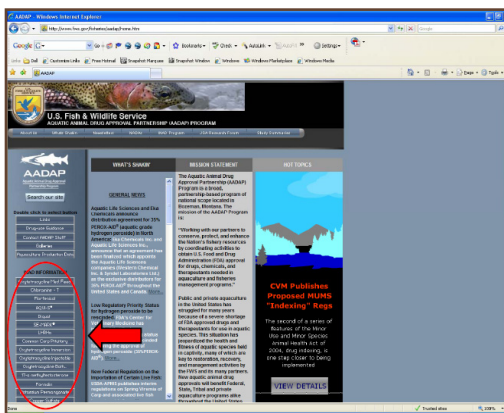
These buttons require a double-click to activate (if you are using Microsoft’s IE as your browser) and immediately take the user to a new page on

which there are many links to information related to the name of the button. The following is a brief description of each of these buttons:

- “[Links](#)”: Selecting this button takes the user to an extensive list of (and links to) entities involved in aquaculture drug approvals (e.g., government agencies, universities, consortia, non-governmental organizations, trade organizations, and others).
- “[Drug-use Guidance](#)”: This button leads the user to a new page with a broad list of topics and information links pertaining to just about every aspect of the use of aquaculture drugs, under a variety of use-patterns. These include, but are not limited to: approved drugs; low regulatory priority drugs (LRP drugs); GRAS or Generally Recognized as Safe drugs; drugs forbidden for use by FDA; CVM’s complete list of “Guidance Documents for the Industry” that are applicable to aquaculture drugs; EPA’s Aquaculture Effluent Guidance (which includes guidance on drug use); and JSA’s recently revised “Guide to Drug, Vaccine and Pesticide Use in Aquaculture.”

- “[Contact AADAP Staff](#)”: This button takes the user to a page with a link to a contact page for each AADAP staff member.
- “[Galleries](#)”: Selecting the Galleries button opens a series of photo galleries with pictures from AADAP’s and some of our partners’ aquaculture drug approval activities.
- “[Aquaculture Production Data](#)”: This button guides the user to a report-driven Microsoft Access database. Currently the data comprise that collected for calendar year 2001 from nearly all public-sector aquaculture organizations; i.e. federal, state and tribal hatcheries. Early in 2007, or possibly late December 2006, the database will be updated with the most recent data (i.e., data from at least a portion of calendar year 2005) from the same organizations.

A third set of buttons occupies the lower portion of the



left-hand panel. These buttons comprise one of the primary building blocks of our program, i.e., all information pertaining to the INAD exemptions

that we administer for the FWS hatcheries and our 250+ participating co-investigators. Currently, AADAP administers 15 INADs, including those for oxytetracycline (medicated feed); oxytetracycline (therapeutic immersion); oxytetracycline (therapeutic injectable); chloramine-T, Aquaflor® (florfenicol); AQUI-S®; diquat; SE-MARK® (calcein); LHRHa; Common Carp Pituitary; 17-α methyltestosterone; formalin (as a fungicide); potassium permanganate; copper sulfate; and Ovaplant® (sGnRHa).

Selecting a specific “drug button” leads the user to a master page for that drug. Each master drug page includes a standard, concise compilation of information about the drug, such as (but not limited to) contact information, indications for use, and treatment regimen (i.e., concentration/dose, frequency, and duration). Using [chloramine-T](#) as an example, each drug page also has a series of relevant topics (and associated links) located on the left-hand side of the page. The topics include: (a) a [summary and history](#) of the drug, (b) the [drug forms to be completed](#) once you are participating in the INAD for this drug, (c) [generic examples](#) of completed drug forms, (d) the [protocol](#) for co-investigators to follow for use of the drug under the INAD, (e) the [Material Safety Data Sheet](#) (MSDS) for the drug, (f) the [study summaries](#) or Annual Reports submitted to CVM for each year of drug use under the INAD, (g) the form to complete to sign-up for

participation in this drug INAD for both [federal](#) and [non-federal](#) facilities, (h) the [current status of work](#) leading to the drug's approval, (i) information on EPA's [National Pollutant Discharge Elimination System](#) (NPDES) permits and (j) a link to permit the printing of a slick pdf version of [this drug's "Fact Sheet"](#) or the ["Fact Sheets" for all of the drugs](#) for which AADAP has an INAD exemption.

Possibly the most important button on the entire AADAP website is the "Search our site" button and it is located at the very top of the left hand panel. To reiterate [information previously stated in this article](#), selecting this button ultimately takes the user to a Google™ search engine, which is preprogrammed to search only AADAP's website or only all US Fish & Wildlife Service websites.

The Future of AADAP's Website

The last, but certainly not the least, important objective for our website is for it to be as dynamic and up-to-date as possible, while hopefully maintaining its user-friendly aspects. The following are a few items that are being worked on now or are being planned for the future. As with any other topic, we welcome your thoughts on ways to improve the site, so please don't hesitate to [contact us](#) if you have an idea(s) about something to add or modify on the AADAP website.

- **New Look to the AADAP Website:** In July of this year (2006), we began the process of completely changing the look of our website. The "old version," albeit one that is possibly easier for some to use, was becoming extremely difficult to manage from the perspective of routine maintenance and frequent updating. We made a conscious effort to try to retain as much of the old version as possible, and hence, most of the changes were made to the opening page, the home page, and the top and left panels on all secondary pages. In spite of our best intentions, there have been some complaints, and consequently we are in the process of new changes to address these complaints. Standby, and as we have stated in our goals/objective, we intended the site to be dynamic.
- **FAQs:** Although we have not received a deluge of questions and comments about AADAP's website, we will be compiling a list of frequently asked questions and answers pertaining to the website content and its use.
- **INAD Drug-use Tips:** Recently we have begun to provide tidbits of information in our Newsletter about the actual administration of FWS-administered INAD drugs. Up to now, these have had a tendency to "become lost" after the publication of the Newsletter. In the future, we will include on each drug page a special link to those tips specific to that INAD drug.
- **Topic Index:** In the near future we will add a simple-to-use "Topic Index." Together with our search function, it should provide users with a reasonably

simple and comprehensive method of finding information on the site.

- **INAD Forms:** All participants in the FWS INADs are required to complete a form to enroll in an INAD and, once enrolled and conducting studies, a series of forms for submission to AADAP. Historically blank forms were mailed to participants to complete. Now INAD participants are informed each year when new forms become available for downloading from our website. We plan to take this one step further by eventually making all the forms "fillable PDF forms." Once instituted, an INAD participant will not have to download the file, print it out and then fill it in by hand or on a typewriter. The fillable form can be filled-in on your computer and then printed.
- **2005 National Aquaculture Production Database:** As you read this, the last of the aquatic species production data received from Federal, State, and Tribal resource agencies are being entered into our National Aquaculture Production Database. The website currently houses similar data from 2001. The 2005 Database should be on the website by the New Year. Like the 2001 Database, the 2005 version will be in the form of a Microsoft Access file, and unfortunately you will not be able to view its information and reports unless your computer has a version of Access installed. But don't throw up your hands just yet; by spring of 2007 we plan to have converted the database into one that can be downloaded and run without having Microsoft Access installed on your computer. It will appear as a fully functional Access file, but in a read-only mode.

As we stated when our website first went on-line, it belongs to you every bit as much as it belongs to us. ***Please do not hesitate to [contact us](#) with complaints, comments or information you would like to share with our aquaculture drug approval community.***

FINS & TAILS, BITS & BOBBERS

STOP THE PRESSES!!! National INAD Participants - Did you know that you are only required to keep your INAD-related paperwork archived for 2 years after the completion of a specific field trial or study?? Well, we didn't either until just recently! Upshot....please feel free to go ahead and recycle those study packets that are over 2 years old and reclaim some of your office space!!

LHRHa INAD Participants: Last year we received several reports of LHRHa drug shipments being held up by U.S. Customs when shipped across the border from [Syndel Laboratories Ltd.](#) In some cases, shipments were delayed by almost 3 weeks. Although we are not really sure of the exact cause for this delay, it may have been related to the carrier used to deliver the LHRHa?? Upshot....please consider ordering LHRHa well in advance if you are planning to purchase any for use this spawning season!

AADAP to establish an INAD for hydrogen peroxide: as [noted earlier in the "What's Shakin' section](#), AADAP is in the preparation stage of a request to establish an INAD for use-patterns not covered by the anticipated new approved NADA for hydrogen peroxide. Watch our website for an announcement when the INAD is received.

PARTNERS' CORNER

Schering-Plough, USFWS team up for SLICE™ approval: [Schering-Plough Animal Health Corporation](#) is seeking approval from the U.S. Food and Drug Administration to use the parasiticide SLICE™ (emamectin benzoate) in freshwater-reared salmonids and ornamental fish.

According to Schering-Plough Animal Health, SLICE™ is the only in-feed treatment and number one product worldwide for use in control of sea lice on salmon. In Canada, Chile and Europe, where the product is already approved, SLICE™ has provided effective control of all parasitic stages of sea lice (e.g., chalimus, pre-adults, and adults including gravid females). This in turn has allowed farmers to maintain optimum fish health throughout the entire salmon production cycle.

The U.S. Fish and Wildlife Service in Bozeman applied for an INAD, which will allow for the use of SLICE™ to treat freshwater copepods such as *Argulus* spp. and *Salmincola* spp. At least seven operations are now planning to be involved with the SLICE™ trials, but more are welcome to participate. For information, contact Dr. Dave Erdahl at USFWS (Phone: 406-587-9904).

Participants will be asked to complete a survey of effluent patterns for each test facility. As part of the protocol mandated by FDA, commercial facilities wishing to use SLICE™ under this INAD must submit information to support an assessment of environmental exposure following treatment. All information gathered will be used by Schering-Plough Animal Health to complete the environmental assessment as required by FDA for site enrollment. However, information about individual farms will be kept confidential.

SLICE™ is not the first project that has brought Schering-Plough Animal Health and USFWS together. USFWS was instrumental in conducting efficacy trials to support the use of AQUAFLO® (florfenicol) in freshwater-reared salmonids.

AQUAFLO® — the first in-feed antibiotic approved for U.S. aquaculture in more than 20 years — just completed its first full season in the catfish market, where it is used for control of catfish mortality due to enteric septicemia (ESC) associated with *Edwardsiella ictaluri*. A conditional approval allowing the use of AQUAFLO® in catfish infected with columnaris disease associated with *Flavobacterium columnare* is expected next year. **Joseph Feeks; PR Works; PO Box 9000, PMB 239; Edgartown, MA 02539.**

MEETINGS, ETC.

Upcoming meetings

The 67th Midwest Fish and Wildlife Conference; 3-6 December 2006; Omaha, Nebraska, USA: The Omaha



Doubletree Hotel and Executive Meeting Center is the site for the 67th Midwest Conference. This year's theme is "The Economic and

Social Values of our Natural Resources." The conference already has over 300 presentations represented in over 20 sessions. Detailed information can be found at <http://www.ngpc.state.ne.us/midwest2006/>. Presentation topics include such diverse subjects as: aquatic nuisance species, fish biology, percids and wetlands.

57th Annual Northwest Fish Culture Conference; 4-6 December 2006; Portland, Oregon, USA: This U.S. Fish & Wildlife Service-sponsored annual event is being held



this year at the Doubletree Hotel Lloyd Center in Portland. This year's theme is "Northwest Fish Culture for a Sustainable Future." For more information go to their website (www.fws.gov/nwfcc2006/) or contact

Margaret Anderson (phone: 208-378-5299 or email: margaret_anderson@fws.gov).

Northeast Aquaculture Conference & Exposition; 6-8 December 2006; Mystic, Connecticut, USA: This year's

Northeast Conference is being held at the Mystic Marriott Hotel & Spa in Mystic, Connecticut, and its theme is "Aquaculture is Agriculture: Farming the Waters." Of particular note: the National Oceanographic and Atmospheric Administration is holding a special session focusing on their Milford Laboratory's annual aquaculture seminar and the keynote speaker will be Dr. John

Connelly, the president of the National Fisheries Institute (USA). For more information see

www.northeastaquaculture.org or contact Tessa Getchis at phone: 860-405-9104 or email: tessa.getchis@uconn.edu.

2007 Coolwater Fish Culture Workshop; 7-9 January 2007; Allamuchy, New Jersey, USA: This 3-day

conference is being held for the first time in New Jersey and will take place at [The Inn at Panther Valley](#). The organizers, New Jersey Division of Fish and Wildlife and New Jersey Muskies Inc. Chapter 22, are planning on presentations on the following topics: cool water research and production methods, cool water diet studies (live vs. dry or both?), brood stock acquisition and spawning techniques, fish disease and treatments, fish stocking and transport methods, cases of hatchery reared fish creating fisheries/rearing methods, new construction and innovations in coolwater hatcheries and recirculation water systems for cool water culture. More information can be obtained at:

http://www.fisheries.org/fhs/meeting_files/2007_coolwater_culture.pdf.

2007 American Heartland Aquaculture Conference; 19-20 January 2007, Whittington, Illinois, USA: This year's American Heartland Aquaculture Conference is



being held at the Rend Lake Resort & Conference Center. Presentations range from fish diseases, to aquatic nuisance

species, to aeration, taxidermy. The last day for pre-registration is 29 December 2006. Additional information can be found at their website:

http://www.ksuquaculture.org/american_heartland%202007.htm.

Aquaculture 2007; 26 February – 2 March 2007; San Antonio, Texas, USA: The

international triennial meeting of the World Aquaculture Society, the National Shellfisheries Association and the American Fisheries Society-Fish Culture Section will be held in February 2007 at the San Antonio Convention Center. At least a dozen other national and international associations are co-sponsoring the event, which is being billed as "the largest aquaculture meeting in the world!" Session topics number more than 30 and include such topics as: Aquaculture Biosecurity, Best Management Practices, Drugs & Therapeutants, Water Quality and Effluents, and Yellow Perch & Walleye. A conference brochure and registration package can be found at



<http://www.was.org/meetings/pdf/AQ2007RegBro.pdf>.

Further information can be acquired from the Conference Manager by phone at 760-751-5005.

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 from David Money at DMoney@uwyo.edu or Andy Goodwin at agoodwin@uaex.edu. To learn more about the Jackson Lake Lodge, go to <http://www.gtlic.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 Børgwald, Norwegian College of Fishery Science, University of Tromsø, N-9037 Tromsø, Norway. E-mail: jarlb@nfh.uit.no. For further details contact Janina Costa or Kim Thompson, Institute of Aquaculture, University of Stirling, Stirling, Scotland FK9 4LA Fax: 0044 1786 472133 Tel: 0044 1786 467912 Email: noffi@stir.ac.uk. Conference updates may be viewed at NOFFI's website: <http://www.noffi.org>.

32nd Annual Eastern Fish Health Workshop; 18-22 June 2007; Gettysburg, Pennsylvania, USA: The

annual EFHW will be held next 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](#)).



13th International EAFP Conference on Diseases of Fish and Shellfish; 17-21 September 2007; Grado, Italy:



Next 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. In order to ensure that appropriate topics are covered, including emerging areas, the EAFP would be interested in hearing from individuals with suggestions for topics for a session or a workshop at the conference. EAFP members and nonmembers are encouraged to submit ideas. A form can be downloaded from the EAFP website (www.eafp.org) and mailed, emailed or faxed. Alternatively, any views, thoughts or proposals can be emailed to the EAFP meetings secretary, stephen.feist@cefias.co.uk.

ROZ's CORNER

[Eka Chemicals, Inc.](#) received acceptance from the Center for Veterinary Medicine (CVM) for the final technical sections (Environmental Safety, All Other Information, and

Labeling) in June, September, and November 2006, respectively, for the approval of three label claims for 35% PEROX-AID[®] (hydrogen peroxide). The label claims include the control of mortality due to (1) saprolegniasis on all freshwater-reared fish eggs, (2) bacterial gill disease on all freshwater reared salmonids, and (3) external columnaris disease on all coolwater fish and channel catfish. Eka Chemicals, Inc., and their new distributor, Western Chemical Inc. met in October 2006 with the National Aquaculture NADA Coordinator and UMESC to discuss the final arrangements for an Administrative NADA on PEROX-AID[®].

[AQUI-S New Zealand Ltd.](#) met with the National Toxicology Program (NTP) in June 2006 to provide background information on AQUI-S[®], the candidate for a zero withdrawal sedative in the United States and Europe and to determine the schedule for the release of the two-year carcinogenicity studies in rats and mice using isoeugenol, the active ingredient in AQUI-S[®]. NTP officials indicated that the isoeugenol Pathology Working Group report would be released in 2006 and the peer review of the final reports in May 2007. At that time, the final reports can be made available to the regulatory agencies in the United States and Europe.

We are making progress in addressing a difficult requirement for approval of antibacterials - microbial food safety. CVM recently accepted submissions for erythromycin, hydrogen peroxide, and oxytetracycline. Two additional submissions for oxytetracycline and one for erythromycin were submitted for acceptance and two documents are about to be submitted for chloramine-T.

On 30 June 2006, CVM accepted the product chemistry package from [Phibro Animal Health](#) to change their oxytetracycline product (Terramycin[®] 200 for Fish) from the quaternary salt formulation to the dihydrate salt formulation. **Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, La Crosse, Wisconsin.**

Aquatic Animal Drug Approval Partnership Program
U.S. Fish and Wildlife Service
4050 Bridger Canyon Rd.
Bozeman, MT 59715

