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 9-3

AADAP NEWSLETTER

December 2013

Crazy Mountains near Wilsall, Montana

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WHAT'S SHAKIN'

HALAMID® AQUA (Chloramine-T): Anticipated Approval in 2014 !!

Axcentive SARL is proud to announce that it is in the final stages of completing all of the requirements for an original New Animal Drug Application (NADA) for the anticipated approval of HALAMID® AQUA (chloramine-T) for three label claims. These label claims will be for the control of mortality in (1) freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp., (2) walleye due to external columnaris disease associated with *Flavobacterium columnare*, and (3) freshwater-reared warmwater finfish due to external columnaris disease associated with *Flavobacterium columnare*. Axcentive SARL anticipates that the HALAMID® AQUA NADA will be granted approval by the U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) sometime in early 2014.

Many agencies, organizations, and the sponsor have played major roles in achieving this incredibly difficult, original NADA approval, which has been 30 years in the making. Under the umbrella of the Federal-State Aquaculture Drug Approval Partnership Project (AFWA Project), data and documents were developed that are leading to this anticipated approval of HALAMID® AQUA, mainly through its public partners—the Aquatic Animal Drug Approval Partnership Program (AADAP, U.S. Fish and Wildlife Service, Bozeman, Montana) and the Upper Midwest Environmental Sciences Center (UMESC, U.S. Geological Survey, La Crosse, Wisconsin); the National Coordinator for Aquaculture New Animal Drug Applications from 1995 to 2010 (National NADA Coordinator); and the sponsor, Axcentive SARL (and its predecessor, Akzo Nobel, Inc.). The AFWA Project (officially from 1994 to 2002) took up the effort to gain approval of chloramine-T (active ingredient in HALAMID® AQUA) that had started with UMESC and the National Research Support Project 7 Program (NRSP-7) in the early 1980s and then continued by AADAP, UMESC, the National NADA Coordinator (now Roz Schnick Consulting, LLC), and Axcentive SARL until the present.

Here are the major contributions from each entity for the approval of HALAMID® AQUA:

1. AADAP developed the data on chloramine-T for the following: (1) effectiveness for all three label claims and (2) target animal safety for all freshwater-reared salmonids. AADAP developed all of the documents associated with these studies to include Technical Section Complete letters. They coordinated major efforts at obtaining the effectiveness data through its public partners in the U.S. Fish and Wildlife Service and several states, and private aquaculture facilities. AADAP also helped coordinate the overall efforts for approval through its annual workshops.
2. UMESC developed the data and methods on chloramine-T for the following: (1) effectiveness for the walleye label claim, (2) target animal safety for all freshwater-reared warmwater and coolwater finfish (including walleye), and (3) human food safety to include (a) residue depletion studies for all finfish species, (b) analytical methodology (determinative and confirmatory) for detection of chloramine-T in water and all finfish tissue, and (c) safety of chloramine-T marker residues in human intestinal flora. UMESC developed all of the documents associated with these studies to include Technical Section Complete letters. They helped coordinate all the research efforts on chloramine-T. UMESC also wrote the environmental assessment that completed the environmental safety requirements.
3. National NADA Coordinator (currently Roz Schnick Consulting, LLC) helped coordinate the efforts toward approval of HALAMID® AQUA and wrote the documents for the following: (1) Guidance for Industry (GFI) #159: safety of chloramine-T residues in human food, (2) GFI #152: safety of chloramine-T related to its microbiological effects on bacteria of human health concern, (3) Minor Use and Minor Species (MUMS) designations for HALAMID® AQUA, (4) AFWA Project and National NADA Coordinator annual progress reports, and (5) Technical Section Complete letters for HALAMID® AQUA for environmental safety, human food safety, labeling, and all other information on safety and effectiveness. Roz Schnick is in the process of completing the original Administrative NADA for HALAMID® AQUA as the final submission to FDA CVM for approval.
4. The sponsor, Axcentive SARL, developed the data and/or completed the requirements for HALAMID® AQUA for (1) toxicology, (2) environmental safety, (3) microbial food safety, and (4) chemistry, manufacturing and controls. The company worked with UMESC on the environmental assessment and with the National NADA Coordinator (currently Roz Schnick Consulting, LLC) to complete all the requirements for each major and minor technical section that will lead to the submission of the Administrative NADA for HALAMID® AQUA.

This anticipated approval of HALAMID® AQUA is important because it will be:

- THE SECOND new waterborne drug approved for disease claims for finfish species in almost 30 years,
- THE THIRD new aquaculture drug with an original approval covering multiple label claims for use in a variety of finfish species, and
- THE FOURTH aquaculture drug to gain NADA approval through MUMS designations under the Minor Use and Minor Species Animal Health Act that entitles Axcentive SARL to 7 years of exclusivity for marketing rights for the approved label claims.

All of the participants involved in this anticipated approval of HALAMID® AQUA are to be thanked and congratulated for their major contributions to this significant effort. A special thank you also goes to all the staff at FDA CVM, who helped us understand the approval requirements and worked with us to meet them.

Text provided by Roz Schnick, Principal; Roz Schnick Consulting, LLC; La Crosse, Wisconsin USA (*rozschnick@centurytel.net*)

- ***Editor's Note**: The Federal-State Aquaculture Drug Approval Partnership Program (AFWA Project) was established as a cooperative initiative between the Association of Fish and Wildlife Agencies (representing all 50 states), USFWS, USGS, USDA/ ARS and the National NADA Coordinator to fund, conduct, and coordinate research directed towards gaining U.S. Food and Drug Administration (FDA) approval of 8 high priority drugs (including chloramine-T) for use in aquaculture. Although the AFWA Project's membership has evolved somewhat over time, it continues today to lead partnership-based aquatic species drug approval activities. AFWA Project efforts are coordinated by AFWA's Drug Approval Working Group (DAWG), which is a working group of AFWA's Fisheries and Water Resources Policy Committee.*

Aquaflor®: New and Pending Approvals!!

Merck Animal Health (Merck) has been notified by the FDA that (1) Aquaflor® (50% florfenicol) has been approved for use in freshwater recirculating aquaculture systems and that (2) approval is pending for a dose increase in freshwater-reared salmonids from 10 mg flofenicol/kg fish/day to 10-15 mg florfenicol/kg fish/day. The pending approval for the dose increase in

salmonids is expected to become final in February 2014, after which Merck can release an updated Aquaflor® label and make these new indications available to customers. For more information about Aquaflor® and its current FDA-approved uses, please visit http://www.aquaflor-usa.com/.

Fish Drug Questions Answered by the FDA

The much anticipated article, *Fish Drug Questions Answered by the FDA*, has been published in the American Fisheries Society (AFS) monthly publication, *Fisheries* (Volume 38, Number 12, pages 549-552), and on the U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) website. The article touches on many important issues related to the U.S. aquaculture drug-approval process, including:

- Meet FDA's Center for Veterinary Medicine
- What's a drug?
- What's an approved new animal drug?
- What does FDA's approval provide?
- What's a conditionally approved new animal drug?
- Is the approval/conditional approval process the only legal pathway to the marketplace for a new animal drug?
- How can I find out if an animal drug is legally marketed?
- What's the difference between a finished drug product and an active ingredient?
- What's the difference between an approved new animal drug and a drug that has an INAD exemption?
- What should I do if I experience a problem with a fish drug?
- What are FDA's concerns about unapproved animal drugs? Why should I care?
- What about products I hear referred to as "low regulatory priority"?
- Resources for you.

The article as published on the FDA CVM website includes only the text written by FDA CVM. The article as published in *Fisheries* includes an introduction by Jim Bowker (AADAP) and Dr. Jesse Trushenski (Southern Illinois University, Carbondale, Illinois), as well as the text written by FDA CVM. As Jim and Jesse wrote in their introduction, "We commend the many individuals within CVM who prepared this article, having worked hard to address fisheries professionals' concerns in an accessible way while maintaining legal accuracy. Working together, we are committed to reaching out to the fisheries and fish culture communities, and we hope this article provides fisheries professionals and others with valuable information regarding fish drugs."

Second Edition of *Quick Desk Reference Guide to Approved Drugs for Use in Aquaculture* to be released in 2014

The second edition of the *Quick Desk Reference Guide to Approved Drugs for Use in Aquaculture* (*Desk Reference*) will be released by June 2014. The second edition of the *Desk Reference*—like the *first*—will include up-to-date information about all FDA-approved aquaculture drugs, including trade names, active ingredients, approved uses, allowable treatment regimens, supplier contact information, and example treatment scenarios and calculations.

The *Desk Reference* was originally developed and sponsored by the U.S. Fish and Wildlife Service Aquatic Animal Drug Approval Partnership Program, the American Fisheries Society Fish Culture and Fish Health sections, and the Association of Fish & Wildlife Agencies—Fisheries and Water Resources Policy Committee's Drug Approval Working Group. In addition to these entities, the second edition of the *Desk Reference* will have one additional sponsor—Merck Animal Health (Merck), Summit, New Jersey. Merck has graciously agreed to contribute to the cost of printing the second edition, and thus their logo will appear on the second edition's back cover.

AADAP Website to be Revamped in 2014

If all goes well, the *AADAP website* will be revamped and updated by June 2014. Plans call for "rebuilding" the website with software that will make it easier for AADAP staff to maintain and keep current. Until then, please email or call if the AADAP website does not provide you with the information you need. Our contact information is located at http://www.fws.gov/fisheries/aadap/contactstaff.htm.

AADAP DRUG UPDATES

The fun never stops, and as we complete one major project, we launch into another. Here is what we've been up to:

AQUI-S®20E (10% eugenol)

Label—Based on comments provided to us by FDA, we have revised the draft product label (which will be affixed to the final approved product) and have sent it to the sponsor. Labeling is one of the minor technical sections, and it is the responsibility of the sponsor to provide FDA with product labeling that is accurate, clear, and concise to minimize the chances of the product being misused by end-users. This is one more piece of the puzzle that is nearing completion.

Target Animal Safety—Good news!! On December 12, we received a letter from the FDA stating that they

concurred with our conclusion that there is an adequate margin of safety associated with sedating small fingerling rainbow trout to handleable. In our study, test fish were safely exposed to the highest proposed efficacious dose (40 mg/L eugenol) and to a dose 1.5 times higher (60 mg/L eugenol) for several minutes longer than the time required to sedate these fish to handleable. Based on these results, FDA also informed us that they considered the target animal safety technical section to be complete for freshwater salmonid finfish. Good news indeed!!

We're optimistic that the Final Study Reports we recently submitted to FDA summarizing results from similar studies that were conducted to evaluate the safety of AQUI-S®20E to fingerling yellow perch and channel catfish will also be accepted. To ensure that we check all the boxes, we have submitted a letter requesting that the target animal safety technical section be considered complete for the use of AQUI-S®20E to sedate all freshwater finfish to handleable. As per FDA requirements, included in the request letter is information about (a) draft label language, (b) dose characterization, and (c) all other safety-related information. Stay tuned.

Pennox 343 (75.6% oxytetracycline hydrochloride; OTC-HCl)

Effectiveness—With invaluable help from Mike Matthews (Florida Bass Conservation Center, Richloam Fish Hatchery, Webster, Florida), we launched a study to evaluate the effectiveness of Pennox 343 static-bath immersion treatment to control mortality in bluegill due to columnaris disease associated with *Flavobacterium columnare*. The study started on December 2, 2013, and consisted of administering Pennox 343 as a static bath at a dosage of 20 mg OTC HCl/L for 60 min/d on three consecutive days. Water samples were collected on each treatment day from one treated tank and one control tank, and the samples were sent to the U.S. Geological Survey Upper Midwest Environmental Sciences Center (La Crosse, Wisconsin) for dose-verification analysis. Fish mortality and behavior were monitored for 14 d posttreatment. Preliminary results indicated that although mean cumulative mortality in treated tanks was lower than that in control tanks, the differences were not statistically significant. Based on dose-verification results, we were "spot-on" administering the OTC-HCl to the treated tanks. Mike has been our warmwater go-to guy for several years and has conducted more field effectiveness trials on our behalf that anyone else. That said, Mike is prepared to repeat the bluegill field trial right after New Year's. Thanks Mike!

Recent DRIBs

AADAP's *Drug Research Information Bulletins* (DRIBs) are in-house publications that briefly (1-4 pages) summarize work we and our partners have done to evaluate the efficacy and target animal safety of aquaculture drugs being considered for approval by the FDA. The most recently published DRIBs are:

- DRIB No. 36—Safety of AQUI-S®20E (10% eugenol) as a sedative for rainbow trout (Niccole Wandelear, Jim Bowker, Molly Bowman, and Dan Carty).
- DRIB No. 37—Safety of AQUI-S®20E (10% eugenol) as a sedative for yellow perch (Jim Bowker, Niccole Wandelear, Dan Carty, and Molly Bowman).
- DRIB No. 38—Safety of AQUI-S®20E (10% eugenol) as a sedative for channel catfish (Niccole Wandelear, Jim Bowker, and Molly Bowman).
- DRIB No. 39—Efficacy of 17α-methyltestosterone administered in feed to produce predominantly male populations of tilapia (Dan Carty, Jim Bowker, Molly Bowman, and Niccole Wandelear)

Recent Peer-Reviewed Publications

Since the previous newsletter, we've worked with several collaborators to publish the following peer-reviewed articles:

- Bowker, J. D., D. Carty, and M. P. Bowman. 2013. The safety of Aquaflor (50% florfenicol) administered in feed to fingerling yellow perch. *North American Journal of Aquaculture* **75:517-523**.
- Bowker, J. D., and J. Trushenski. 2013. Fish drug questions answered by the FDA. *Fisheries* **38:549-552**.

Text provided by Jim Bowker, Research Program Manager; USFWS AADAP; Bozeman, Montana USA. (*jim_bowker@fws.gov*)

FINS & TAILS, BITS & BOBBERS

2013 INAD Wrap-Up

All 2013 Investigational New Animal Drug (INAD) study data need to be entered in the INAD Program Management System (IPMS) on-line database by 12/31/13. However, please note that:

1. If your facility will be conducting treatments in December, you will have time in January to complete data entry;
2. All 2013 study requests must have been completed before 12/15/13 for any previous studies that have been conducted, but not reported;
3. **No study numbers will be issued for 2013 studies once January 1, 2014, has arrived**; and
4. If your facility fails to report any 2013 INAD studies…sorry, but you will be on your own should FDA conduct an audit of your facility.

Also, now is a good time for all Investigators to take a minute or two to "double-check" their drug inventory information to make sure it is correct. If no studies

occurred and no study worksheets were initiated in 2013, there is no need for your facility to do anything else to wrap up year 2013.

INAD Enrollment Open for 2014

It is time for renewal of your facility's INADs for Calendar Year (CY) 2014. Investigators will need to log into their INAD IPMS accounts; click on the *Account Info* tab; click on the *add Drug/INAD* button; and select INADs, fish species, and enter fish number (anticipated use) for CY 2014. **Please note**: INAD participation is not renewed automatically in the IPMS from the previous year, so you will need to have this done before 1/31/2014.

INADs currently available are:

- Chloramine-T
- Oxytetracycline Medicated Feed
- Calcein
- Florfenicol
- Oxytetracycline Immersion
- LHRHa
- Carp Pituitary
- sGnRHa (OvaRH®; injectable)
- sGnRHa (Ovaplant®)
- Catfish Pituitary
- Diquat
- Hydrogen Peroxide
- Benzoak
- AQUI-S 20E
- SLICE
- 17-alpha methyltestosterone medicated feed.

Note: Currently, we do not know how what the cost (i.e., INAD fee) will be to participate in the National INAD Program in 2014. However, it is very likely that there will be a "fee increase" for all INADs. Although we apologize for both the need for a potential fee increase and our inability to provide clear guidance at this relatively late date, rest assured that we will let y'all know as soon as we know. If your program has enrolled in 2014 but you decide not to participate, please contact Bonnie Johnson, who will remove you from the program.

Text provided by Bonnie Johnson, National INAD Program Administer; USFWS AADAP; Bozeman, Montana USA (*bonnie_johnson@fws.gov*)

USGS's UMESC CORNER

AQUI-S®20E (10% eugenol)

The U.S. Geological Survey's (USGS) Upper Midwest Environmental Sciences Center (UMESC) in La Crosse, Wisconsin, completed a definitive study to characterize the depletion, distribution, and identification of eugenol residues in the fillet tissue from exposed fish (a total residue depletion study). Rainbow trout were exposed to 100 mg ^{14}C labeled AQUI-S®20E/L for 1 h. Data indicated that (1) maximum eugenol and ^{14}C-eugenol equivalent residue concentrations in the fillet tissue were measured immediately after the exposure; (2) eugenol was the primary ^{14}C-residue in extracts from fillet tissue taken from fish sampled immediately after the exposure; and (3) the depletion of ^{14}C-eugenol residues from the fillet tissue was rapid after transferring the exposed fish to fresh flowing water. The final report was submitted to the FDA Center for Veterinary Medicine (CVM) on April 19, 2013. On September 19, 2013, we received the following statement from CVM:

"Based on the information you submitted on April 19, 2013, we conclude that the total residues for eugenol are satisfactorily characterized for all freshwater fish. We concur that the marker residue is eugenol for all freshwater fish. The data support zero withdrawal for eugenol used in fishery management because the total residues are substantially below the safe concentration calculated from the ARfD."

Selection of a marker residue for AQUI-S®20E completes another crucial step in the pursuit of AQUI-S®20E approval. Contact Jeff Meinertz, *jmeinertz@usgs.gov*, for more information.

UMESC completed work to assess a method as the determinative method for eugenol in the edible fish fillet tissue, where eugenol is the marker residue for AQUI-S®20E. The following method characteristics were assessed: selectivity, sensitivity, accuracy and precision with eugenol fortified tissue, precision with tissue containing biologically incurred eugenol, stability, and method ruggedness. With regard to selectivity, there were no compounds in fillet tissue extracts from seven fish species that would interfere with eugenol analyses. In addition, select aquaculture drugs incorporated into fish fillet tissue did not interfere with eugenol analyses. Method sensitivity (~0.01 µg/g) was more than adequate relative to the working tolerance of 11 µg/g established by CVM. Method accuracy and precision with eugenol fortified fillet tissue were within CVM acceptance criteria, i.e., a recovery of 80-110% for accuracy and a precision of <10% CV (coefficient of variation). Method precision with biologically incurred eugenol was within CVM acceptance criteria, i.e., <10% CV in virtually all cases. Eugenol was stable for at least 14 d in solutions of acetonitrile and water, in tissue extracts for 4 d, in frozen fillet tissue for more than 12 weeks, and in tissue undergoing freeze-thaw cycles. In most cases, the

method was rugged, i.e., small changes in the method procedures did not impact method performance. Compilation of the final report (2,091 pages) was completed in October 2013. The text of the final report passed a Good Laboratory Practice compliance review. The data audit for the comprehensive final report (version with all 72 appendices) is ongoing.

UMESC conducted a series of studies to assess the utility of using AQUI-S®20E as a sedative to reduce the activity of yellow perch and tilapia during live transport. A portion of the research assessed exposure parameters (concentration and duration) that would safely sedate fish while maximizing fish loading density during transport. Both species were exposed to 0, 100, 200, and 300 mg AQUI-S®20E/L at three loading densities: yellow perch at 120, 240, and 360 g/L; and tilapia at 240, 360, and 480 g/L. After exposure durations of up to 10 h at all concentrations and densities, there was >95% survival with yellow perch and >90% survival with tilapia. Preparation of data to submit to CVM is ongoing. Contact Aaron Cupp, acupp@usgs.gov, for more information.

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

UMESC is conducting research to expand the label for 35% PEROX-AID® (35% hydrogen peroxide) to include the reduction of *Gyrodactylus* sp. infestation density on cool- and warmwater fish species. Two trials have been completed, one with fathead minnows with a natural infestation of *G. hoffmani* and a second trial with yellow perch with a natural infestation of *G. freemani*. The study objective was to assess the efficacy of 35% PEROX-AID® to reduce *Gyrodactylus* sp. infestation density and included the evaluation of parasite density on fish following assignment to one of three treatment regimens: (1) a nontreated control group; (2) a group treated at 50 mg/L for 60 min; and (3) a group treated at 75 mg/L for 60 min. The 35% PEROX-AID® treatments were applied once daily on alternate days for a total of three treatments. Following treatment, both fathead minnows and yellow perch experienced a reduction of >97% in parasite density on fish in the treated groups. The comprehensive final reports are being compiled. Contact Sue Schleis, sschleis@usgs.gov, for more information.

SLICE® (0.2% emamectin benzoate)

SLICE® is currently approved for use to control sea lice on marine-reared fish in the United Kingdom, Europe, Norway, Chile, and Canada. SLICE® has been shown to be effective for reducing infestations of freshwater copepods on freshwater-reared fish. Therefore, there is interest in pursuing approval of SLICE® for freshwater uses. UMESC is gearing up to conduct drug depletion studies with SLICE® in which fish in a freshwater recirculating aquaculture system (water temperature, 15°C) and in freshwater flow-through aquaculture systems (water temperatures, 6 and 15°C) will be treated with SLICE®-medicated feed and the depletion of the SLICE® marker residue, emamectin benzoate, from the fillet tissue characterized after treatment. UMESC has received protocol concurrence from CVM to conduct these studies. Retrofitting UMESC environmental chambers and setup of the aquaculture systems in those environmental chambers are ongoing. Training to conduct the procedures described in the analytical method for determining emamection concentrations in fish fillet tissue is also ongoing. Contact Jeff Meinertz, jmeinertz@usgs.gov, for more information.

Text provided by Jeff Meinertz, Research Physiologist; USGS UMESC; La Crosse, Wisconsin USA (jmeinertz@usgs.gov)

FDA's CVM Notes

FDA Takes Significant Steps to Address Antimicrobial Resistance: Agency Implementing Plan to Ensure Judicious Use of Antibiotics in Food Animals

The U.S. Food and Drug Administration announced on December 11, 2013, that it is implementing a plan to help phase out the use of medically important antimicrobials in food animals for food production purposes, such as to enhance growth or improve feed efficiency. The plan would also phase in veterinary oversight of the remaining appropriate therapeutic uses of such drugs.

Certain antimicrobials have historically been used in the feed or drinking water of cattle, poultry, hogs, and other food animals for production purposes such as using less food to gain weight. Some of these antimicrobials are important drugs used to treat human infection, prompting concerns about the contribution of this practice to increasing the ability of bacteria and other microbes to resist the effects of a drug. Once antimicrobial resistance occurs, a drug may no longer be as effective in treating various illnesses or infections.

Because antimicrobial drug use in both humans and animals can contribute to the development of antimicrobial resistance, it is important to use these drugs only when medically necessary. The plan announced today focuses on those antimicrobial drugs that are considered medically important (i.e., are important for treating human infection) and which are approved for use in feed and water of food animals.

In a final guidance issued (*Guidance for Industry #213*), the FDA lays out a road map for animal pharmaceutical companies to voluntarily revise the FDA-approved use conditions on the labels of these products to remove production indications. The plan also calls for changing the current over-the-counter (OTC) status to bring the remaining appropriate therapeutic uses under veterinary

oversight. Once a manufacturer voluntarily makes these changes, its medically important antimicrobial drugs can no longer be used for production purposes, and their use to treat, control, or prevent disease in animals will require veterinary oversight.

The FDA is asking animal pharmaceutical companies to notify the agency of their intent to sign on to the strategy within the next 3 months. These companies would then have a 3-year transition process.

In order to help phase in veterinary oversight of those drugs covered by the guidance that are intended for medically appropriate uses in feed, the FDA also has issued a proposed rule to update the existing regulations relating to Veterinary Feed Directive (VFD) drugs. The use of VFD drugs requires specific authorization by a licensed veterinarian using a process outlined in the agency's VFD regulations. The VFD proposed rule is intended to update the existing VFD process and facilitate expanded veterinary oversight by clarifying and increasing the flexibility of the administrative requirements for the distribution and use of VFD drugs. Such updates to the VFD process will assist in the transition of OTC products to their new VFD status.

The guidance for animal pharmaceutical companies is now in final form, and *the proposed VFD rule* is open for public comment for 90 days starting on December 12, 2013. To electronically submit comments on the proposed VFD rule, go to *http://www.regulations.gov* and insert docket FDA-2010-N-0155. Send written comments to the Division of Dockets Management, Food and Drug Administration, Room 1061, 5630 Fishers Lane, Rockville, MD 20852.

Fish Drug Questions Answered by the FDA

The FDA's Center for Veterinary Medicine (CVM) wrote an article for the American Fisheries Society monthly publication, *Fisheries* (Volume 38, Number 12, pages 549-552), which answers frequently asked questions that we receive regarding fish drugs. Also, the article can be viewed on the CVM website by clicking *here*. It's full of lots of great information and clears up some common myths. Please take a look!

- ***Editor's note**: Please see the What's Shakin' section of this newsletter for more details about this article.*

New Phone Numbers for ONADE Staff

The Office of New Animal Drug Evaluation (ONADE) has switched to a new phone system, and thus we have new phone numbers. You can download a list of phone numbers (MS Excel *.xls spreadsheet) for CVM personnel by clicking on this *link*. Alternatively, you can do a general internet search or search from the FDA website for "CVM directory" and it should direct you to the spreadsheet. We are experiencing some problems with the new phone system, so over the next few weeks please contact with us via email and we will reply to your email or give you a call as soon as possible.

Text provided by Dr. Jennifer Matysczak, Leader; Aquaculture Drugs Team; Office of New Animal Drug Evaluation; Center for Veterinary Medicine; Food and Drug Administration; Rockville, Maryland USA (*Jennifer.Matysczak@fda.hhs.gov*)

RELEVANT LITERATURE

Listed below are journal citations with particular relevance to the broad topic of drugs and aquaculture species. With some exceptions, this list includes citations not previously included in our newsletter. Our most recent Relevant Literature Master list, which dates back to 2009, can be viewed or downloaded at: *http://www.fws.gov/fisheries/aadap/PDF/Relv%20Lit_Master%20List_12-20-12.pdf*.

Inclusion of a citation in our newsletter does not imply (1) acceptance by the U.S. Food and Drug Administration's Center for Veterinary Medicine of a drug's safety or effectiveness, (2) endorsement of a drug or product by the U.S. Fish and Wildlife Service, (3) recommendation of the technique to any particular situation, or (4) concurrence with a treatment procedure/drug. **Note**: Please send citations of interest to Dan Carty (*dan_carty@fws.gov*).

Antibiotic and Bacterial

Balasundaram, A, et al. 2013. A study on genetic variability of pathogenic *Aeromonas hydrophila* strains and the varied responses of the strains towards phyto-extracts. *Pakistan Journal of Biological Sciences* **16(21):1303-1310**.

Bowker, JD, et al. 2013. The safety of Aquaflor (50% florfenicol) administered in feed to fingerling yellow perch. *North American Journal of Aquaculture* **75(4):517-523**.

Damir, K, et al. 2013. Occurrence, characterization and antimicrobial susceptibility of *Vibrio alginolyticus* in the Eastern Adriatic Sea. *Marine Pollution Bulletin* **75(1-2):46-52**.

Dobšíková, R, et al. 2013. The effect of oyster mushroom β-1.3/1.6-D-glucan and oxytetracycline antibiotic on biometrical, haematological, biochemical, and immunological indices, and histopathological changes in common carp (*Cyprinus carpio* L.). *Fish & Shellfish Immunology* **35(6):1813-1823**.

Fodey, TL, et al. 2013. Approaches for the simultaneous detection of thiamphenicol, florfenicol and florfenicol amine using immunochemical techniques. *Journal of Immunological Methods* **393(1-2):30-37**.

Gaikowski, M, et al. 2013. Safety of florfenicol administered in feed to tilapia (*Oreochromis* sp.). *Toxicologic Pathology* **41(4):639-652**.

Gaunt, PS, et al. 2013. Multidose pharmacokinetics of orally administered florfenicol in the channel catfish (*Ictalurus punctatus*). *Journal of Veterinary Pharmacology and Therapeutics* **36(5):502-506**.

Huang, W-M, et al. 2013. Identification and drug sensitivity of bacteria *Aeromonas veronii* and *A. media* isolated from Chinese sucker *Myxocyprinus asiaticus*. *Fisheries Science* **32(4):210-214**.

Jester, ELE, et al. 2014. Performance evaluation of commercial ELISA kits for screening of furazolidone and furaltadone residues in fish. *Food Chemistry* **145:593-598**.

Jun, JW, et al. 2013. Protective effects of the *Aeromonas* phages pAh1-C and pAh6-C against mass mortality of the cyprinid loach (*Misgurnus anguillicaudatus*) caused by *Aeromonas hydrophila*. *Aquaculture* **416-417:289-295**.

Kołodziejska, M, et al. 2013. Aquatic toxicity of four veterinary drugs commonly applied in fish farming and animal husbandry. *Chemosphere* **92(9):1253-1259**.

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UPCOMING MEETINGS

2014 Cool Water Fish Culture Conference (January 13-15, Syracuse, New York)

The New York Department of Environmental Conservation will host the 2014 Cool Water Fish Culture Workshop on January 13-15 at the Embassy Suites Syracuse in Syracuse, New York USA. The purpose of the workshop is to provide a forum for the exchange of information among those actively involved in or interested in the propagation of cool water fishes. Contact Martha Wolgamood (wolgamoodm@michigan.gov) for registration information, Jan VanAmberg (vanambergj@michigan.gov) for presentation information, and http://embassysuites.hilton.com/en/es/groups/personalized/SSYRDWES-CWF-20140113/index.jhtml?WT.mc_id=POG to book a room.

2014 Catfish Farmers of Arkansas Annual Convention (January 16-17, Hot Springs, Arkansas USA)

The 2014 Annual Catfish Farmers of Arkansas Convention will be held January 16-17 at the Embassy Suites in Hot Springs< Arkansas USA. Please contact Mr. Bo Collins (870-672-1716) for registration information.

Texas Aquaculture 44th Annual Conference and Trade Show (January 29-31, Fredericksburg, Texas)

The Texas Aquaculture Association will hold its 44th Annual Conference and Trade Show on January 29-31, 2014, in Fredericksburg, Texas USA http://www.texasaquaculture.org/.

Midcontinent Warmwater Fish Culture Workshop (February 3-5, Council Bluffs, Iowa USA)

The 36th Annual Midcontinent Warmwater Fish Culture Workshop will be held February 3-5, 2014, in Council Bluffs, Iowa USA. The workshop will begin with a Welcome Social on the evening of February 3, and technical sessions will be held February 4-5. Participants will share and learn what many public fish culture facilities, researchers, universities, and aquaculture-related businesses have been working on during the past year. For more information, please visit http://www.wisconsinaquaculture.com/Events_Details.cfm?RID=72.

Aquaculture America 2014 (February 9-12, Seattle, Washington USA)

Aquaculture America 2014 will be held February 9-12, 2014, at the Washington State Convention Center in Seattle, Washington USA. In 2014, the U.S. Aquaculture Society (formerly the U.S. Chapter of the World Aquaculture Society) will be joined by the National Aquaculture Association and the U.S. Aquaculture Suppliers Association to produce this conference. In addition, the annual meetings of the (1) Aquacultural Engineering Society, (2) American Tilapia Association, (3) Striped Bass Growers Association, (4) U.S. Trout Farmers Association, (5) U.S. Shrimp Farming Association, and many more associations will be held, which will make Aquaculture America 2014 the one meeting in the U.S. that you don't want to miss!

Update: A 1-day aquaculture statistics workshop will be held February 9. This workshop is intended to serve as an introduction to the broad array of Multivariate Statistical Methodologies and Data Visualization techniques. Discussion of Multivariate Data Structure will be central to each methodology, and differences between the analytic roles of variable types (numeric and categorical) will be addressed. Additional issues discussed with each methodological approach will include sample size requirements, statistical assumptions, and interpretation.

For complete Aquaculture America 2014 meeting details, please visit: https://www.was.org/meetings/default.aspx?Code=AA2014.

2014 Catfish Farmers of America Annual Convention (February 13-15, New Orleans, Louisiana USA)

The Catfish Farmers of America will hold their 2014 Annual Convention February 13-15 at The Hotel Monteleone in the heart of the French Quarter of New Orleans, Louisiana USA. Registration details and a preliminary agenda can be found at http://www.catfishfarmersofamerica.com/events.html.

2014 North Central Regional Aquaculture Conference (February 22-23, Toledo, Ohio USA)

The North Central Regional Aquaculture Center (NCRAC) and the Aquaculture Associations of Indiana, Michigan, and Ohio are pleased to announce the 2014 North Central Aquaculture Conference scheduled for February 22-23, 2014, in Toledo, Ohio USA at The Hotel at the University of Toledo Medical Center. The program will feature an aquaculture trade show and industry, academic, and agency experts from across the Midwest, who will lead discussions on fish/shrimp culture, nutrition, health, aquaponics, technology, laws, and emerging issues and opportunities. Visit http://ohioaquaculture.org for full details.

39th Annual Eastern Fish Health Workshop (April 28-May 2, 2014, Shepperdstown, West Virgina USA)

The 39th Annual Eastern Fish Health Workshop will be held April 28-May2 at the Clarion Hotel and Conference Center, Shepperdstown, West Virginia USA. The meeting will consist of scientific presentations and a 1-day Continuing Education workshop. For additional information, go to *https://www.facebook.com/pages/Eastern-Fish-Health-Workshop/164449723610923*.

World Aquaculture 2014 (June 7-11, Adelaide, South Australia)

World Aquaculture 2014 will be held June 7-11, 2014, in Adelaide, South Australia. Australia is proud to be hosting World Aquaculture for the first time since 1999. This annual event will incorporate the biennial Australasian Aquaculture conference and trade show and will see several thousand attendees from around the world converge on the city of Adelaide and tour the central hub of Australian aquaculture in Port Lincoln. Contributions to the progress of developing new and existing ideas to stimulate this vital industry are welcome. With almost half of the world's consumption of seafood coming from farms, aquaculture is playing an increasingly important role in meeting the challenge of global food security. World Aquaculture 2014 will be an opportunity for the international aquaculture community—academics, industry researchers, market and industry analysts, government officials, policy makers and industry representatives to present their work and exchange ideas and develop a vision for the future of the aquaculture industry as we focus on the theme of *Create, Nurture, Grow*. An event not to be missed, World Aquaculture 2014 will offer a chance to gauge the sector's progress, whilst we discuss and debate the issues, ideas, mechanisms and hands-on practical approaches towards building a better industry. In addition, there will be ample opportunity to network during both structured and free-flowing events. We look forward to seeing you in Adelaide. For complete details, visit: *https://www.was.org/meetings/default.aspx?code=WA2014*.

20th Annual USFWS Aquaculture Drug Coordination Workshop (tentatively July 29-31, 2014, Bozeman, Montana USA)

The 20th Annual U.S. Fish and Wildlife Service Aquaculture Drug Coordination Workshop is tentatively scheduled to be held July 29-31 in Bozeman, Montana USA. As always, The Workshop will update attendees on the status of recently completed and ongoing aquaculture drug approval work in the USA. Also, there will be a session on the status and use of vaccines in USA aquaculture. Details will be available from *AADAP* in spring 2014.

144th Annual Meeting of the American Fisheries Society (August 17-21, 2014, Quebec City, Canada)

The 144th Annual Meeting of the American Fisheries Society (AFS) will be held August 17-21, 2014, in Quebec City, Canada. The meeting will be hosted by Fisheries and Oceans Canada, the Northeastern Division, the Atlantic International Chapter, and the Canadian Aquatic Resources Section of the American Fisheries Society. Preliminary meeting details can be found at *http://afs2014.org/*.

International Symposium on Aquatic Animal Health (August 31-September 4, 2014, Portland, Oregon USA)

The next International Symposium on Aquatic Animal Health (ISAAH) will be held in Portland, Oregon August 31-September 4, 2014. This is an international American Fisheries Society-Fish Health Section meeting that happens only once every 4 years. This will be a well-attended meeting with a lot of participation from outside of the USA. It will be a great place to learn, to meet new people, and to establish new collaborations. Portland is a fun place to visit for both a unique urban experience and easy proximity to the natural wonders of the Pacific Northwest. Details can be found at *http://www.afs-fhs.org/*.

Note: Information about many other aquaculture-related meetings being held in the USA and around the world during 2014 can be found via the following links:

https://www.was.org/EventCalendar.aspx

http://aquaculturedirectory.co.uk/events/

http://www.thefishsite.com/events/

Cover Photo:

The Crazy Mountain range (Crazies) in southwest Montana are 40-50 miles long and nearly 15 miles wide at their widest point. The highest peak in the range—Crazy Peak—reaches an elevation of 11,214 ft. The Crazies contain many alpine streams and lakes, some of which hold popular sportfish such as rainbow trout, golden trout, cutthroat trout, and brook trout. The range also supports healthy populations of many of Montana's big game animals, including elk, mule deer, and whitetail deer. If you find yourself fishing, hunting, camping, hiking, horseback riding, or cross-country skiing in the Crazies, you just might be lucky enough to catch a glimpse of the occasional and elusive wolverine (*Gulo gulo*). A 7-min video of early summer hiking in the Crazies can be accessed at: *http://www.youtube.com/watch?v=mdAoeiQcbn8*.