

**NATIONAL COORDINATOR FOR AQUACULTURE NEW  
ANIMAL DRUG APPLICATIONS**

**TWELVETH ANNUAL REPORT OF ACTIVITIES**

**May 15, 2006 to May 14, 2007**

**Submitted by**

**Rosalie A. Schnick  
National Aquaculture NADA Coordinator  
Michigan State University  
3039 Edgewater Lane  
La Crosse, Wisconsin 54603-1088  
Phone: (608) 781-2205  
Fax: (608) 783-3507  
E-mail: [RozSchnick@centurytel.net](mailto:RozSchnick@centurytel.net)  
Web site: <http://aquanic.org/jsa/aquadrugs/index.htm>**

**June 14, 2007**

## ACRONYMS AND ABBREVIATIONS USED

|          |  |
|----------|--|
| AADAP    | Aquatic Animal Drug Approval Partnership Program   |
| AFS      | American Fisheries Society   |
| AFWA     | Association of Fish and Wildlife Agencies (formerly was IAFWA; the AFWA Project refers to the Federal-State Aquaculture Drug Approval Partnership Project) |
| °C       | degrees Celsius  |
| CCP      | crude carp pituitary   |
| CVM      | Center for Veterinary Medicine   |
| DAWG     | Drug Approval Work Group   |
| EA       | environmental assessment   |
| EPA      | U.S. Environmental Protection Agency   |
| ESC      | enteric septicemia of catfish  |
| FOI      | Freedom of Information   |
| FMCS     | Fishery Management Chemicals Subcommittee  |
| FWS      | U.S. Fish and Wildlife Service   |
| g        | gram   |
| GFI      | Guidance for Industry document   |
| GRAS     | Generally Recognized as Safe   |
| INAD     | Investigational New Animal Drug  |
| lb       | pound(s)   |
| MT       | 17 $\alpha$ -methyltestosterone  |
| MUMS     | Minor Use and Minor Species  |
| NADA     | New Animal Drug Application  |
| NCRAC    | North Central Regional Aquaculture Center  |
| NHP      | necrotizing hepatopancreatitis   |
| NRSP-7   | National Research Support Project Number Seven (7)   |
| NTP      | National Toxicology Program  |
| OTC      | oxytetracycline  |
| ppm, ppb | parts per million, parts per billion   |
| p-TSA    | para-toluenesulfonamide  |
| ®        | Registered name  |
| SNARC    | Harry K. Dupree Stuttgart National Aquaculture Research Center   |
| SPAH     | Schering-Plough Animal Health  |
| ™        | trademark  |
| UMESC    | Upper Midwest Environmental Sciences Center  |
| UW-M     | University of Wisconsin-Madison  |

**TWELFTH ANNUAL SUMMARY OF ACTIVITY HIGHLIGHTS FOR THE NATIONAL COORDINATOR  
FOR AQUACULTURE NEW ANIMAL DRUG APPLICATIONS (NATIONAL AQUACULTURE NADA  
COORDINATOR)**

(May 15, 2006 to May 14, 2007)

**2007 APPROVALS!!**

- **35% PEROX-AID® ORIGINAL NADA APPROVAL FOR THE CONTROL OF MORTALITY DUE TO (1) SAPROLEGNIASIS ON ALL FINFISH EGGS, (2) BACTERIAL GILL DISEASE ON ALL FRESHWATER-REARED SALMONIDS, AND (3) EXTERNAL COLUMNARIS DISEASE ON ALL COOLWATER FISH AND CHANNEL CATFISH (JANUARY 11, 2007)**
- **AQUAFLO® SUPPLEMENTAL NADA APPROVAL FOR THE CONTROL OF MORTALITY DUE TO COLDWATER DISEASE IN ALL FRESHWATER-REARED SALMONIDS (MARCH 19, 2007)**
- **AQUAFLO® CONDITIONAL APPROVAL FOR THE CONTROL OF MORTALITY DUE TO EXTERNAL COLUMNARIS DISEASE IN CATFISH (APRIL 18, 2007)**
- **TETROXY AQUATIC® ABBREVIATED ORIGINAL(GENERIC) NADA APPROVAL FOR USE AS A SKELETAL MARKING AID IN FINFISH FRY AND FINGERLINGS (MAY 9, 2007)**

**CHLORAMINE-T=HALAMID®—EXTERNAL ANTIBACTERIAL (Two initial label claims close to completion: (1) control of mortality due to (1) bacterial gill disease on all freshwater-reared salmonids and (2) external columnaris disease on walleye)**

- On May 22, 2006, the sponsor, Axcentive SARL, submitted a product chemistry package for their chloramine-T product (HALAMID®).
- On June 13, 2006, the Center for Veterinary Medicine (CVM) granted Minor Use and Minor Species (MUMS) designation to Axcentive SARL, the sponsor of Halamid®, for the following label claims for the control of mortality in: (1) freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium psychrophilum*, (2) walleye due to external columnaris disease associated with *Flavobacterium columnare*, and (3) all freshwater-reared finfish (except walleye) due to external columnaris disease associated with *Flavobacterium columnare*. On September 15, 2006, CVM granted MUMS designation for the control of mortality in freshwater-reared finfish (except freshwater-reared salmonids) due to bacterial gill disease associated with *Flavobacterium psychrophilum*.
- In November 2006, Axcentive submitted the following to CVM: (1) Guidance for Industry Document (GFI) #152 on microbial food safety, (2) GFI #159 on residues effects in the human gut flora, and (3) labeling.
- On April 13, 2007, the Upper Midwest Environmental Sciences Center (UMESC) submitted the final environmental assessment (EA) on chloramine-T to CVM.
- In May 2007, CVM accepted the microbial food safety for all finfish (GFI #152) from Axcentive SARL.

**CLOVE OIL (MAINLY EUGENOL)—ANESTHETIC (not currently under development for approval)**

- On April 24, 2007, CVM revised Guidance for Industry #150 dealing with concerns related to the use of clove oil (eugenol) as an anesthetic for fish by correcting information on its ingredients and safety.

**COPPER SULFATE=TRIANGLE BRAND COPPER SULFATE®—EXTERNAL MICROBICIDE (One initial label claim close to completion: (1) control of mortality due to ichthyophthiriasis on channel catfish)**

- On June 30, 2006, the Harry K. Dupree Stuttgart National Aquaculture Research Center (SNARC) submitted to CVM the label claim and other requested information to complete the target animal safety technical section for channel catfish.
- On October 30, 2006, CVM granted MUMS designation to Phelps Dodge Sales Company, the sponsor of Triangle Brand Copper Sulfate®, for the treatment of *Ichthyophthirius multifiliis* on channel catfish cultured in earthen ponds.
- In December 2006, SNARC submitted the final EA for earthen pond systems to CVM.

**ERYTHROMYCIN=AQUAMYCIN 100®—ORAL ANTIBACTERIAL (One initial label claim close to completion: (1) control of mortality due to bacterial kidney disease in salmonids)**

- On November 22, 2005, CVM accepted the risk assessment for microbial food safety for salmonids (GFI #152) from the University of Idaho.
- On October 2, 2006, the University of Idaho submitted to CVM the on the safety of residues in human food for all freshwater-reared salmonids (GFI #159).
- In January 2007, CVM accepted as complete the safety of residues in human food for all freshwater-reared salmonids (GFI #159).
- On January 4, 2007, CVM granted MUMS designation to Bimeda, the sponsor of AQUAMYCIN 100®, for the control of mortality in freshwater-reared salmonids due to bacterial kidney disease associated with *Renibacterium salmoninarum*.
- In May 2007, the University of Idaho submitted the final EA to CVM.

**FLORFENICOL=AQUAFLO®—ORAL ANTIBACTERIAL (ONE LABEL CLAIM APPROVED ON MARCH 19, 2007 FOR THE CONTROL OF MORTALITY IN FRESHWATER-REARED SALMONIDS DUE TO COLDWATER DISEASE; ONE CONDITIONAL APPROVAL OBTAINED ON APRIL 18, 2007 FOR THE CONTROL OF MORTALITY IN CATFISH DUE TO COLUMNARIS DISEASE; other label claims under consideration)**

- **ON MARCH 19, 2007, CVM APPROVED THE AQUAFLO® SUPPLEMENTAL NADA FOR THE CONTROL OF MORTALITY DUE TO COLDWATER DISEASE IN ALL FRESHWATER-REARED SALMONIDS!**
- **ON APRIL 18, 2007, CVM GRANTED CONDITIONAL APPROVAL FOR AQUAFLO® FOR THE CONTROL OF MORTALITY DUE TO EXTERNAL COLUMNARIS DISEASE IN CATFISH!**
- On April 20, 2007, the final rule for the March 19, 2007 NADA approval for Aquaflor® appeared in The Federal Register (Vol. 72, No. 76, Pages 19797-19798).

**HYDROGEN PEROXIDE=35% PEROX-AID®—EXTERNAL MICROBICIDE (THREE INITIAL AND ORIGINAL LABEL CLAIMS APPROVED ON JANUARY 11, 2007: CONTROL OF MORTALITY DUE TO (1) SAPROLEGNIASIS ON ALL FINFISH EGGS, (2) BACTERIAL GILL DISEASE ON ALL FRESHWATER-REARED SALMONIDS, AND (3) EXTERNAL COLUMNARIS DISEASE ON ALL COOLWATER FISH AND CHANNEL CATFISH; one label claim in progress: (1) control of mortality on all warmwater fish due to saprolegniasis)**

- On June 22, 2006, CVM accepted the EA for hydrogen peroxide from UMESC and determined that the drug has a Finding of No Significant Impact on the environment.
- On September 6, 2006, CVM accepted the All Other Information Technical Section for the first three broad label claims listed above from Eka Chemicals, Inc. in collaboration with the National Aquaculture NADA Coordinator.
- On October 3-4, 2006, Eka Chemicals, Inc. and Western Chemical Inc. (distributor for 35% PEROX-AID®) met with the National Aquaculture NADA Coordinator and UMESC to discuss the research and its relationship to the safe and effective use of the product when it is approved.
- On November 9, 2006, CVM accepted the 35% PEROX-AID® labeling for the first three broad label claims listed above from Eka Chemicals, Inc.
- On November 22, 2006, CVM accepted the Freedom of Information Summary for 35% PEROX-AID® for the first three broad label claims listed above.
- On November 30, 2006, Eka Chemicals, Inc. submitted the original NADA package for the first three broad label claims listed above to CVM for approval.
- **ON JANUARY 11, 2007, CVM APPROVED THE 35% PEROX-AID® ORIGINAL NADA FOR THE CONTROL OF MORTALITY DUE TO (1) SAPROLEGNIASIS ON ALL FINFISH EGGS, (2) BACTERIAL GILL DISEASE ON ALL FRESHWATER-REARED SALMONIDS, AND (3) EXTERNAL COLUMNARIS DISEASE ON ALL COOLWATER FISH AND CHANNEL CATFISH!**
- On February 6, 2007, the final rule for the NADA approval for 35% PEROX-AID® appeared in The Federal Register (Vol. 72, No. 24, Pages 5329-5330).
- On May 2, 2007, CVM removed hydrogen peroxide from the list of Low Regulatory Priority aquaculture drugs because the drug is now the subject of an approved NADA for 35% PEROX-AID®. This means that 35% PEROX-AID® is the only hydrogen peroxide product that is legal to use.

**ISOEUGENOL=AQUI-S®—ANESTHETIC (One initial label claim in progress: (1) zero withdrawal anesthetic for sedation to handleable condition of all freshwater fish)**

- CVM accepted from the Aquatic Animal Drug Approval Partnership Program (AADAP) efficacy studies on fingerling walleye (June 12, 2006), June suckers (July 7, 2006), and fingerling and juvenile kokanee salmon (July 7, 2006).
- On June 15, 2006, AQUI-S New Zealand Ltd. and the National Aquaculture NADA Coordinator met with National Toxicology Program (NTP) officials to discuss progress on the isoeugenol mammalian safety studies being conducted under NTP.
- On September 21, 2006, UMESC submitted a final report to Association of Fish and Wildlife Agencies (AFWA) on the development and validation of a determinative method to detect isoeugenol in fish tissues.
- On November 28, 2006, CVM accepted as complete from AADAP the effectiveness studies for all freshwater-reared finfish for sedation to handleable stage. Validation of the dose verification method is required before a technical section complete letter can be granted.

- On December 8, 2006, CVM accepted the target animal safety study on rainbow trout from AADAP.
- On January 31, 2007, UMESC submitted a response to CVM comments on the total residue depletion studies and a letter requesting the selection of the marker residue.
- On April 27, 2007, AADAP and UMESC announced they were suspending all research until the completion of the NTP review scheduled for February 2008 on studies conducted on mice and rats. The review had originally been scheduled for May 2007 but due to other priorities was delayed.

**17 $\alpha$ -METHYLTESTOSTERONE (MT) =MASCULINIZING FEED FOR TILAPIA®—GENDER MANIPULATION AID (One initial label claim in progress: (1) masculinization of female early life-stage tilapia)**

- In 2006, CVM Office of Research published a regulatory analytical method that will quantify and confirm the presence of MT in the muscles of tilapia, rainbow trout, and salmon.
- The lack of an internal standard for analyzing the MT-medicated feed for the target animal safety and efficacy studies delayed those studies until a standard was made. On June 5, 2006, AADAP received word that the internal standard was completed at Steraloids and it was being made available to the testing facility, CanTest, to begin the transfer validation.
- Studies were initiated for effectiveness and target animal safety in late 2006 and early 2007.

**METOMIDATE=AQUACALM®--SEDATIVE (one label claim for use as a sedative during transport of ornamental finfish)**

- On November 13, 2006, CVM granted MUMS designation to Syndel Laboratories, LTD, the sponsor of AQUACALM®, for use as a sedative during transport of ornamental (non-food) finfish.

**OVAPRIM® (SGNRHA AND DOMPERIDONE)—SPAWNING AID (one label claim under investigation: For the induction of spawning in ornamental fish)**

- On July 27, 2006, CVM granted MUMS designation to Syndel Laboratories, LTD, the sponsor of Ovaprim®, for the induction of spawning in ornamental fish.

**OXYTETRACYCLINE=TERRAMYCIN 200® FOR FISH—ORAL ANTIBACTERIAL (Two supplemental label claims close to completion: control of mortality due to (1) systemic columnaris disease in rainbow trout and (2) systemic coldwater disease in all freshwater-reared salmonids; one label claim in progress: (1) control of mortality in penaeid shrimp due to necrotizing hepatopancreatitis [NHP])**

- On June 6, 2006, the University of Arizona submitted documents on the safety of oxytetracycline (OTC) residues in penaeid shrimp in human food to CVM (GFI #159).
- On June 30, 2006, CVM accepted from the sponsor (Phibro Animal Health) the product chemistry package to change their oxytetracycline product (TERRAMYCIN® 200 for Fish) from the quaternary salt formulation to the dihydrate salt formulation.
- On July 18, 2006, AADAP submitted to CVM the OTC microbial food safety for freshwater-reared salmonids (GFI #152).

- On July 19, 2006 and August 25, 2006, Phibro Animal Health with the assistance of the National Aquaculture NADA Coordinator and UMESC submitted to CVM documents on the OTC safety of residues in all freshwater-reared finfish in human food to CVM (GFI #159).
- On August 15, 2006, CVM accepted the safety of OTC residues in penaeid shrimp in human food from the University of Arizona (GFI #159).
- On September 20, 2006, CVM accepted the OTC safety of residues in all freshwater-reared finfish in human food from Phibro Animal Health (GFI #159).
- On October 13, 2006, CVM requested a revision of the EA from UMESC.
- On November 28-30, 2006, the National Aquaculture NADA Coordinator met with Phibro animal Health to discuss the final requirements for approval and to go over the draft NADA package.
- On March 15, 2007, CVM accepted GFI #152 for all freshwater-reared salmonids from AADAP.

**OXYTETRACYCLINE, IMMERSION=SEVERAL COMMERCIAL PRODUCTS—MARKING AID AND EXTERNAL ANTIBACTERIAL (one label claim in progress: control of mortality in coolwater and warmwater finfish due to external columnaris disease)**

- **ON MAY 9, 2007, THE FINAL RULE FOR THE ABBREVIATED ORIGINAL (GENERIC) NADA APPROVAL FOR TETROXY AQUATIC® SPONSORED BY CROSS VETPHARM GROUP LTD FOR USE AS A SKELETAL MARKING AID IN FINFISH FRY AND FINGERLINGS WAS ANNOUNCED IN THE FEDERAL REGISTER (VOL. 72, NO. 89, PAGE 26289).**
- In May 2007, UMESC submitted to CVM efficacy studies on the control of mortality in coolwater and warmwater finfish due to external columnaris disease.

**POTASSIUM PERMANGANATE=CAIROX®—EXTERNAL MICROBICIDE (one label claim in progress: control of mortality in channel catfish due to external columnaris disease)**

- On September 12, 2006, CVM granted MUMS designations to Carus Chemical Company, the sponsor of Cairox®, for the following label claims: For the control of mortality in (1) freshwater-reared finfish due to external columnaris disease associated with *Flavobacterium columnare*, (2) freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, and (3) freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum*.

**GENERAL**

- The National Aquaculture NADA Coordinator developed a survey the public aquaculture sector to determine the unmet label claim needs for the AFWA Project drugs. It was sent on September 21, 2005 under the authorization of Doug Hansen to state stakeholders who had funded the AFWA Project to determine if the AFWA Project is meeting their label claim needs. There was 100% response. She tabulated and analyzed the results and provided a final report to the Drug Approval Working Group members on March 25, 2006. It was distributed to state stakeholders in July 2006.
- The designation provision of the new Minor Use and Minor Species Animal Health Act of 2004 (MUMS) gives sponsors seven years of marketing exclusivity. There have been NADA approvals for two MUMS designations for Schering-Plough Animal Health's Aquaflor® and three MUMS designations for Eka Chemicals, Inc.'s 35% PEROX-AID®. So far, the MUMS Office has granted

44 designations, 40 of those were for aquaculture uses to aquaculture drug sponsors who received extensive help from the National Aquaculture NADA Coordinator.

- On May 4, 2007, CVM clarified the extra-label use of medicated feeds in minor species under the Compliance Policy Guide (#615.115) to include (1) veterinarian involvement, (2) treatment use only, (3) no production use, and (4) no feed reformulation or relabeling.

### **PUBLICATIONS, PRESENTATIONS, AND SPECIAL REPORTS**

- The National Coordinator for Aquaculture New Animal Drug Applications had three publications, presented 23 papers, and wrote 27 special reports during this time period.

### **PROJECT OBJECTIVES**

The overall goal of this project is for the National Coordinator for Aquaculture New Animal Drug Applications (National Aquaculture NADA Coordinator) to coordinate activities for investigational new animal drug exemptions (INADs) and new animal drug applications (NADAs) to expedite approval for the use of various drugs in aquaculture. Specific objectives related to that goal are to:

- Serve as an information conduit between INAD/NADA applicants and the U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM);
- Identify and encourage prospective INAD participants to become involved in specific investigational studies and NADA approval-related research;
- Seek the support and participation of pharmaceutical sponsors for INAD studies and NADAs and coordinate with INAD/NADA sponsors to achieve CVM approval more quickly;
- Guide prospective and current INAD holders on the format for INAD exemption requests and related submissions to CVM;
- Identify existing data and remaining data requirements for NADA approvals;
- Review, record, and provide information on the status of INADs and NADAs;
- Provide liaison and coordination among all the federal agencies involved in the INAD/NADA process; and
- Provide public education related to training and guidance in obtaining INAD exemptions and pursuing NADA approval.

### **PROGRESS AND PRINCIPAL ACCOMPLISHMENTS**

The National Aquaculture NADA Coordinator provided many information transfers from May 15, 2006 to May 14, 2007 and worked to obtain INADs, NADAs, and approvals for a number of drugs that are considered to be of high priority for approval by the public and private aquaculture communities.

### **THERAPEUTANTS**

**Amoxicillin trihydrate USP powder** (oral antibacterial) —Status: Early development stage; antimicrobial resistance issue needs to be addressed. Kent Sea Tech Corporation, the U.S. representative for the sponsor, GB Research, submitted a Research and Development Plan to CVM files.

Progress on amoxicillin (May 15, 2006 to November 9, 2006): No progress to report.

**Chloramine-T=HALAMID®** (external antibacterial) —Status: Was a Federal-State Aquaculture Drug Approval Partnership (i.e. AFWA) Project drug and now under development by the sponsor (Axcentive SARL, formerly Axcentive bv and Akzo Nobel Chemicals, Inc.), UMESC, and AADAP; two label claims close to completion: control of mortality due to (1) bacterial gill disease on all freshwater-reared salmonids and (2) external columnaris disease on walleye.

Progress on chloramine-T (May 15, 2006 to May 14, 2007):

- On May 22, 2006, the sponsor, Axcentive SARL, submitted a product chemistry package for their chloramine-T product (HALAMID®).
- On June 13, 2006, the Center for Veterinary Medicine (CVM) granted Minor Use and Minor Species (MUMS) designation to Axcentive SARL, the sponsor of Halamid®, for the following label claims for the control of mortality in: (1) freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium psychrophilum*, (2) walleye due to external columnaris disease associated with *Flavobacterium columnare*, and (3) all freshwater-reared finfish (except walleye) due to external columnaris disease associated with *Flavobacterium columnare*.
- On August 14, 2006, the NADA Coordinator submitted to Axcentive SARL a draft of the HALAMID® labeling for submission to CVM.
- On August 22, 2006, the NADA Coordinator submitted to Axcentive SARL a draft document on microbial food safety for HALAMID (Guidance for Industry Document #152) for submission to CVM.
- On August 21, 2006, the NADA Coordinator submitted to Axcentive SARL a draft document on safety of residues in human food for HALAMID® (Guidance for Industry Document #159) for submission to CVM.
- On August 28, 2006, CVM indicated that the draft EA was generally acceptable; it still requires revisions with respect to risk mitigation and product labeling.
- On September 15, 2006, CVM granted MUMS designation to Axcentive SARL, the sponsor of Halamid®, for the control of mortality in freshwater-reared finfish (except freshwater-reared salmonids) due to bacterial gill disease associated with *Flavobacterium psychrophilum*.
- In November 2006, Axcentive submitted the following to CVM: (1) Guidance for Industry Document (GFI) #152 on microbial food safety, (2) GFI #159 on residues effects in the human gut flora, and (3) labeling.
- On April 13, 2007, the Upper Midwest Environmental Sciences Center (UMESC) submitted the final environmental assessment (EA) on chloramine-T to CVM.
- In May 2007, CVM accepted the microbial food safety for all finfish (GFI #152) from Axcentive SARL.

Current status of technical sections on chloramine-T:

- *Product Chemistry*—The sponsor, Axcentive SARL (a 100% daughter company of PNP Holding bv, Bouc Bel Air, France) submitted the product chemistry technical section for HALAMID PHARMA GRADE® to CVM on May 22, 2006.

- *Environmental Safety*—CVM accepted from UMESC a dilution model to detect effluents from waterborne drugs at the outlet pipe (May 7, 2003). UMESC submitted an environmental summary to CVM into Public Master File Number 5637 (October 31, 2002); these data are available to any chloramine-T sponsors. UMESC also developed a proprietary EA that was submitted by Axcentive SARL on July 16, 2003 to CVM under INAD #8086 for HALAMID PHARMA GRADE®. CVM sent a review to the sponsor on September 17, 2004; UMESC revised the EA and submitted it to CVM on February 9, 2006. UMESC revised the EA based on CVM comments of August 28, 2006 and submitted it to CVM on April 13, 2007.
- *Human Food Safety-Toxicology*—Axcentive SARL addressed this technical section. CVM declared that para-toluenesulfonamide (p-TSA) is not genotoxic based on proprietary data submitted by Axcentive SARL (July 19, 2002). CVM accepted additional proprietary mammalian safety data from Axcentive SARL; based on those data, CVM declared that the safe concentration of p-TSA in edible tissue of fish is 1 ppm (April 9, 2003).
- *Human Food Safety-Residue Chemistry*—CVM accepted as complete from UMESC (1) total residue depletion and metabolism of chloramine-T in rainbow trout; p-TSA was established as the major metabolite in fish and declared as a marker residue for chloramine-T in juvenile rainbow trout (July 20, 1995), (2) liquid chromatographic determination of p-TSA in edible tissue from three fish species (May 18, 1999), (3) marker residue depletion in rainbow trout, yellow perch, and hybrid striped bass (April 23, 2002), (4) regulatory method for p-TSA in edible tissue of rainbow trout, channel catfish, and walleye (April 24, 2003), (5) validation of the p-TSA determinative method in several species and species from several regions of the U.S. (April 24, 2003), and (6) confirmatory method for p-TSA in fish tissue to satisfy an all fish label claim (March 4, 2005). UMESC submitted a Freedom of Information (FOI) summary on human food safety to CVM (April 23, 2002). CVM declared that the safe concentration of p-TSA in edible tissue of fish is 1 ppm (April 9, 2003).
- *Human Food Safety-Microbial Food Safety*—Axcentive SARL submitted GFI #152 and #159 in November 2006 to CVM; Accepted from Axcentive SARL GFI #152 (May 2007).
- *Target Animal Safety*—CVM accepted as complete from (1) AADAP the target animal safety technical section on freshwater-reared salmonids (September 13, 2002) and (2) UMESC the target animal safety technical section on all coolwater and warmwater fish (March 11, 2004 and March 11, 2005).
- *Efficacy*—CVM accepted from UMESC a simple colorimetric procedure for use in efficacy studies for monitoring chloramine-T concentrations in treatment waters (July 27, 1997 and January 15, 2003). CVM accepted as supportive from UMESC data call-in on efficacy studies for control of mortality due to bacterial gill disease on (1) tiger musky (November 29, 1999) and (2) salmonids (July 12, 2000). CVM accepted as complete from (1) AADAP the efficacy technical section for control of mortality due to bacterial gill disease on all freshwater-reared salmonids (June 10, 2002) and (2) UMESC the efficacy technical section for controlling external columnaris disease on walleye (January 30, 2004).

**Copper Sulfate=Triangle Brand Copper Sulfate®** (external microbicide) —Status: Was an AFWA Project drug and now under development by the sponsor (Phelps Dodge Sales Company) and SNARC; one label claim close to completion: control of mortality due to ichthyophthiriasis on channel catfish.

Progress on copper sulfate (May 15, 2006 to May 14, 2007):

- On June 30, 2006, the Harry K. Dupree Stuttgart National Aquaculture Research Center (SNARC) submitted to CVM the label claim and other requested information to complete the target animal safety technical section for channel catfish.
- On October 30, 2006, CVM granted MUMS designation to Phelps Dodge Sales Company, the sponsor of Triangle Brand Copper Sulfate®, for the treatment of *Ichthyophthirius multifiliis* on channel catfish cultured in earthen ponds.
- In December 2006, SNARC submitted the final EA for earthen pond systems to CVM.

Current status of technical sections on copper sulfate:

- *Product Chemistry*—CVM accepted as complete from the sponsor, Phelps Dodge Refining Corporation.
- *Environmental Safety*—The revised environmental safety technical section for use in earthen ponds with no outflows was reviewed by CVM in 2000 and CVM is requiring an additional study. A study at SNARC addressing the use of copper sulfate in ponds was completed and was incorporated into a revised EA submitted to CVM in December 2006.
- *Human Food Safety-Toxicology*—CVM accepted as complete from the sponsor, Phelps Dodge Refining Corporation; FOI summary written by CVM on March 3, 2000.
- *Human Food Safety-Residue Chemistry*—CVM accepted as complete from SNARC the human food safety technical section; FOI written by CVM on March 3, 2000—no tolerances, regulatory methods, or withdrawal times are needed for finfish treated with copper sulfate.
- *Target Animal Safety*—SNARC submitted literature on target animal safety studies and a target animal safety study on channel catfish with a histopathology component as requested by CVM. The channel catfish study was accepted by CVM May 25, 2005. SNARC submitted to CVM the label claim and other information on June 30, 2006 to complete this technical section.
- *Efficacy*—CVM accepted as complete from SNARC the efficacy technical section for control of ichthyophthiriasis on all fish. SNARC is also conducting pivotal efficacy studies to control fungi on catfish eggs.

**Diquat Dibromide** (external microbicide)—Status: No sponsor is available to complete the approval process at the present time.

**Erythromycin=Aquamycin 100®** (oral antibacterial) —Status: Most technical sections submitted by University of Idaho; sponsor (Bimeda Inc.) needs to submit product chemistry; University of Idaho needs to submit hazard in the environment (to complete the Environmental Safety Technical Section); one label claim close to completion: control of mortality due to bacterial kidney disease in salmonids.

- On November 22, 2005, CVM accepted the risk assessment for microbial food safety for salmonids (GFI #152) from the University of Idaho.
- On October 2, 2006, the University of Idaho submitted to CVM the on the safety of residues in human food for all freshwater-reared salmonids (GFI #159).
- In January 2007, CVM accepted as complete the safety of residues in human food for all freshwater-reared salmonids (GFI #159).
- On January 4, 2007, CVM granted MUMS designation to Bimeda, the sponsor of AQUAMYCIN 100®, for the control of mortality in freshwater-reared salmonids due to bacterial kidney disease associated with *Renibacterium salmoninarum*.
- In May 2007, the University of Idaho submitted the final EA to CVM.

**Florfenicol=Aquaflor®** (oral antibacterial)—Status: The sponsor, SPAH, gained florfenicol (Aquaflor®) approval in the U.S. on October 24, 2005 to control mortality due to enteric septicemia of catfish (ESC) and **ON MARCH 19, 2007 FOR THE CONTROL OF MORTALITY IN FRESHWATER-REARED SALMONIDS DUE TO COLDWATER DISEASE CAUSED BY *FLAVOBACTERIUM PSYCHROPHILUM*; ONE CONDITIONAL APPROVAL OBTAINED ON APRIL 18, 2007 FOR THE CONTROL OF MORTALITY IN CATFISH DUE TO COLUMNARIS DISEASE ASSOCIATED WITH *FLAVOBACTERIUM COLUMNARE***; was an AFWA Project drug and now under development by the sponsor, UMESC, AADAP, and Mississippi State University; two other label claims close to completion: control of mortality due to (1) furunculosis in freshwater-reared salmonids and (2) systemic columnaris disease in freshwater-reared salmonids and catfish.

Progress on florfenicol (May 15, 2006 to May 14, 2007):

- **ON MARCH 19, 2007, CVM APPROVED THE AQUAFLO® SUPPLEMENTAL NADA FOR THE CONTROL OF MORTALITY DUE TO COLDWATER DISEASE IN ALL FRESHWATER-REARED SALMONIDS!**
- **ON APRIL 18, 2007, CVM GRANTED CONDITIONAL APPROVAL FOR AQUAFLO® FOR THE CONTROL OF MORTALITY DUE TO EXTERNAL COLUMNARIS DISEASE IN CATFISH!**
- On April 20, 2007, the final rule for the NADA approval for Aquaflor® appeared The Federal Register (Vol. 72, No. 76, Pages 19797-19798).

Current status of technical sections on florfenicol:

- *Product Chemistry*—Accepted from Schering-Plough Animal Health Corporation=SPAH.
- *Environmental Safety*—Accepted from SPAH for ponds and for flow-through systems.
- *Human Food Safety-Toxicology*—Accepted from SPAH.
- *Human Food Safety-Residue Chemistry*—human food safety package for catfish and all freshwater-reared salmonids—Accepted from SPAH; analytical method—Accepted from SPAH.
- *Human Food Safety-Microbial Food Safety*—accepted by CVM from SPAH.
- *Target Animal Safety*—Accepted from SPAH (conducted by UMESC) for channel catfish; Accepted from SPAH for salmonids.
- *Efficacy*—Accepted from SPAH for ESC (conducted by Mississippi State University); Accepted from SPAH (conducted by AADAP) for coldwater disease in salmonids and *Streptococcus iniae* in hybrid striped bass (December 9, 2004); UMESC validated methods to analyze for florfenicol in finfish feeds to support efficacy studies at AADAP.

**Formalin=Several commercial products** (external microbicide)—Status: Supplemental NADAs approved on June 18, 1998 and November 25, 2002 for control of certain fungi on the eggs of all finfish, certain external protozoa, and monogenetic trematodes on all finfish, and certain external protozoa on penaeid shrimp; was a Federal-State Aquaculture Drug Approval Partnership Project drug and now under development by the sponsors (Natchez Animal Supply Company, Western Chemical Inc., and Argent Chemical Laboratories), UMESC, and CVM's Office of Research; one additional label claim close to completion: control of mortality due to saprolegniasis on all freshwater-reared finfish.

Progress on formalin (May 15, 2006 to May 14, 2007): No progress to report.

Current status of technical sections on formalin:

- *Product Chemistry*—Accepted by CVM.
- *Environmental Safety*—Accepted by CVM.
- *Human Food Safety-Toxicology*—Accepted by CVM
- *Human Food Safety-Residue Chemistry*—Accepted by CVM.
- *Target Animal Safety*—Accepted by CVM.
- *Efficacy*—CVM informally accepted as supportive efficacy data for control of saprolegniasis on salmonids from the U.S. Fish and Wildlife Service (FWS) and UMESC efforts. CVM accepted from UMESC as supportive efficacy studies for the control of saprolegniasis on channel catfish (November 16, 2004) and from CVM Office of Research as pivotal efficacy studies for the control of saprolegniasis on rainbow trout (July 19, 2005).

**Hydrogen peroxide=35% PEROX-AID®** (external microbicide)—Status: **ON JANUARY 11, 2007, CVM APPROVED THE 35% PEROX-AID® ORIGINAL NADA FOR THE CONTROL OF MORTALITY DUE TO (1) SAPROLEGNIASIS ON ALL FINFISH EGGS, (2) BACTERIAL GILL DISEASE ON ALL FRESHWATER-REARED SALMONIDS, AND (3) EXTERNAL COLUMNARIS DISEASE ON ALL COOLWATER FISH AND CHANNEL CATFISH!** Low regulatory priority drug for use as a fungicide on fish and fish eggs was rescinded May 2, 2007; was an AFWA Project drug and now under development by

the sponsor (Eka Chemicals Inc.) and UMESC; one additional label claim close to completion: control of mortality due to (1) saprolegniasis on all finfish.

Progress on hydrogen peroxide (May 15, 2006 to May 14, 2007):

- On June 22, 2006, CVM accepted the EA for hydrogen peroxide from UMESC and determined that the drug has a Finding of No Significant Impact on the environment.
- On September 6, 2006, CVM accepted the All Other Information Technical Section for the first three broad label claims listed above from Eka Chemicals, Inc. in collaboration with the National Aquaculture NADA Coordinator.
- On October 3-4, 2006, Eka Chemicals, Inc. and Western Chemical Inc. (distributor for 35% PEROX-AID®) met with the National Aquaculture NADA Coordinator and UMESC to discuss the research and its relationship to the safe and effective use of the product when it is approved.
- On November 9, 2006, CVM accepted the 35% PEROX-AID® labeling for the first three broad label claims listed above from Eka Chemicals, Inc.
- On November 22, 2006, CVM accepted the Freedom of Information Summary for 35% PEROX-AID® for the first three broad label claims listed above from Eka Chemicals, Inc.
- On November 30, 2006, Eka Chemicals, Inc. submitted the original NADA package for the first three broad label claims listed above to CVM for approval.
- **ON JANUARY 11, 2007, CVM APPROVED THE 35% PEROX-AID® ORIGINAL NADA FOR THE CONTROL OF MORTALITY DUE TO (1) SAPROLEGNIASIS ON ALL FINFISH EGGS, (2) BACTERIAL GILL DISEASE ON ALL FRESHWATER-REARED SALMONIDS, AND (3) EXTERNAL COLUMNARIS DISEASE ON ALL COOLWATER FISH AND CHANNEL CATFISH!**
- On February 6, 2007, the final rule for the NADA approval for 35% PEROX-AID® appeared in The Federal Register (Vol. 72, No. 24, Pages 5329-5330).
- On May 2, 2007, CVM removed hydrogen peroxide from the list of Low Regulatory Priority aquaculture drugs because the drug is now the subject of an approved NADA for 35% PEROX-AID®. This means that 35% PEROX-AID® is the only hydrogen peroxide product that is legal to use.

Current status of technical sections on hydrogen peroxide:

- *Product Chemistry*—Accepted from Eka Chemicals, Inc. (February 11, 2004).
- *Environmental Safety*—Accepted from UMESC with a Finding of No Significant Impact (June 22, 2006).
- *Human Food Safety–Toxicology*—Accepted from Eka Chemicals, Inc. (March 22, 2000).
- *Human Food Safety–Residue Chemistry*—Accepted from Eka Chemicals, Inc. with no tolerances, regulatory methods, or withdrawal times needed for finfish and their eggs treated with hydrogen peroxide.
- *Human Food Safety–Microbial Safety*—GFI #52 (now GFI #159) accepted from Eka Chemicals, Inc. (June 6, 2005); GFI #152 accepted from Eka Chemicals, Inc. (September 16, 2005).
- *Human Food Safety*—Accepted FOI summary for human food safety (September 16, 2005).
- *Target Animal Safety*—Accepted from UMESC for all finfish (October 4, 2001) and from UMESC for all finfish eggs (March 17, 2000, August 16, 2002, and November 26, 2003).
- *Efficacy*—Accepted from UMESC for the control of mortality due to (1) saprolegniasis on all freshwater-reared finfish eggs (March 17, 2000, August 16, 2002, and February 10, 2004), (2)

bacterial gill disease on all freshwater-reared salmonids (October 12, 2000), (3) external columnaris disease on all coldwater fish (November 15, 2002 and November 21, 2003), and (4) external columnaris disease on channel catfish (November 21, 2003).

CVM accepted as pivotal efficacy data from UMESC for the control of mortality due to saprolegniasis on catfish but requested additional supportive data before this technical section can be considered as complete (November 24, 2004). CVM accepted as supportive efficacy data from UMESC for the treatment of external parasitic infestations on all salmonids (September 26, 2002).

**Oxytetracycline=TERRAMYCIN 200® FOR FISH** (OTC, oral antibacterial)—Status: Currently approved for control of certain systemic bacterial diseases in catfish, salmonids, and lobsters and as an oral marking agent in Pacific salmon; was an AFWA Project drug and now under development by the sponsor (Phibro Animal Health, formerly Pfizer, Inc.), UMESC, and AADAP; two label claims close to completion: control of mortality due to (1) systemic columnaris disease in steelhead trout and (2) systemic coldwater disease in all freshwater-reared salmonids.

Progress on oral oxytetracycline (May 15, 2006 to May 14, 2007):

- On June 6, 2006, the University of Arizona submitted documents on the safety of oxytetracycline (OTC) residues in penaeid shrimp in human food to CVM (GFI #159).
- On June 30, 2006, CVM accepted from the sponsor (Phibro Animal Health) the product chemistry package to change their oxytetracycline product (TERRAMYCIN® 200 for Fish) from the quaternary salt formulation to the dihydrate salt formulation.
- On July 18, 2006, AADAP submitted to CVM the OTC microbial food safety for freshwater-reared salmonids (GFI #152).
- On July 19, 2006 and August 25, 2006, Phibro Animal Health with the assistance of the National Aquaculture NADA Coordinator and UMESC submitted to CVM documents on the OTC safety of residues in all freshwater-reared finfish in human food to CVM (GFI #159).
- On August 15, 2006, CVM accepted the safety of OTC residues in penaeid shrimp in human food from the University of Arizona (GFI #159).
- On September 20, 2006, CVM accepted the OTC safety of residues in all freshwater-reared finfish in human food from Phibro Animal Health (GFI #159).
- On October 13, 2006, CVM requested a revision of the EA from UMESC.
- On November 28-30, 2006, the National Aquaculture NADA Coordinator met with Phibro animal Health to discuss the final requirements for approval and to go over the draft NADA package.
- On March 15, 2007, CVM accepted GFI #152 for all freshwater-reared salmonids from AADAP.

Current status of technical sections on oral oxytetracycline:

- *Product Chemistry*—Previously accepted by CVM under original NADA from Pfizer, Inc. (now owned by Phibro Animal Health). The sponsor obtained acceptance for the change to dihydrate salt formulation (June 30, 2006).
- *Environmental Safety*—Previously accepted by CVM under original NADA from Pfizer, Inc. (now owned by Phibro Animal Health). FINFISH: CVM is requiring a new EA for any new label claims. UMESC submitted an EA written to meet current guidelines and requirements to CVM (October 15, 2004). UMESC submitted an EA on oxytetracycline to CVM on April 3, 2006 AND A FINAL ea ON

October 13, 2007. PENAEID SHRIMP: University of Arizona—additional data needed to complete the EA as required on November 2, 2001.

- *Human Food Safety–Toxicology*—Previously accepted by CVM under original NADA from Pfizer, Inc. (now owned by Phibro Animal Health).
- *Human Food Safety–Microbial Food Safety*—FINFISH: Sponsor, AADAP, UMESC, and National Aquaculture NADA Coordinator—CVM accepted as complete from Phibro Animal Health GFI #159 (September 20, 2006); from AADAP GFI #152 (March 15, 2007). PENAEID SHRIMP: CVM accepted as complete from University of Arizona—GFI #159 (August 18, 2006).
- *Human Food Safety–Residue Chemistry*—FINFISH: Previously accepted by CVM for certain label claims under original NADA from Pfizer, Inc. for OTC for cold water species above 9°C and warm water species above 16°C. Recently, CVM accepted (1) residue chemistry studies submitted by UMESC for use of OTC below the label claim limit of 9°C which established a withdrawal time of three days for juvenile salmonids, (2) residue depletion studies submitted by UMESC for the use of OTC in juvenile cool water species with a zero withdrawal time, (3) a high performance liquid chromatography (HPLC) method developed by UMESC to detect OTC in feed and fish tissue, (4) a study completed by UMESC bridging the HPLC OTC detection method to the official microbial assay method, (5) extrapolated withdrawal times for salmonids (May 17, 2002), (6) liquid chromatographic determination of OTC in edible tissues of six species of fish (September 9, 2002), and (7) validation of an HPLC method in coho salmon and northern pike (September 9, 2002). UMESC petitioned CVM to shorten the withdrawal time for OTC in all freshwater fish species based on its residue depletion data and the new tolerance of 2 ppm. PENAEID SHRIMP: Accepted as complete from University of Arizona residue depletion study in penaeid shrimp (November 4, 1999).
- *Target Animal Safety*—FINFISH: Previously accepted by CVM for catfish, salmonids, and lobsters under original NADA from Pfizer, Inc. CVM accepted as complete from UMESC the target animal safety technical section for coolwater and scaled warmwater fish (December 19, 2003). PENAEID SHRIMP: University of Arizona submitted to CVM a target animal safety study in penaeid shrimp (August 2004); a new study needs to be completed.
- *Efficacy*—FINFISH: Previously accepted by CVM under original NADA from Pfizer, Inc. for OTC use on catfish, salmonids, and lobsters to control certain systemic bacterial diseases. CVM accepted as complete from AADAP the efficacy technical section for the use of OTC at 3.75 g/100 lb of fish for 10 days as effective in reducing mortality from (1) systemic columnaris disease in steelhead trout and (2) systemic coldwater disease in fingerling coho salmon. The efficacy technical section developed by UMESC from a data call-in was accepted as supporting data for control of (1) *Aeromonas* sp. in coolwater species, and (2) systemic columnaris disease in salmonids. PENAEID SHRIMP: Accepted as complete from University of Arizona efficacy data to control mortality due to NHP in penaeid shrimp (June 28, 2000).

**Oxytetracycline=several commercial products** (OTC, immersion antibacterial)—Status: No current sponsor for antibacterial use; one label claim close to completion: control of mortality due to external columnaris disease on coolwater and warmwater finfish.

Progress on immersion OTC (May 15, 2006 to May 14, 2007):

- In May 2007, UMESC submitted efficacy studies to CVM on the control of mortality in coolwater and warmwater finfish due to external columnaris disease.

Current status of technical sections on immersion OTC:

- *Product Chemistry*—Accepted by CVM.
- *Environmental Safety*—Accepted by CVM for marking by immersion from National Research Support Project-7 (NRSP-7).
- *Human Food Safety–Toxicology*—Accepted by CVM.
- *Human Food Safety–Residue Chemistry*—Accepted for all fish by CVM for marking by immersion from NRSP-7.
- *Target Animal Safety*—Accepted for all fish by CVM for marking by immersion from NRSP-7.

- **Efficacy**—On April 8, 2003, CVM responded to an October 28, 2002 submission from UMESC on the efficacy of OTC immersion treatment of bacterial diseases in and on coolwater fish. CVM commented that OTC immersion may be effective against bacterial diseases in a variety of species and the efficacy data may support future pivotal data. UMESC submitted efficacy studies for external columnaris disease on coolwater and warmwater fish (May 2007).

**Pet Fish Therapeutants** (various drugs and pesticides)—Status: Major effort to resolve non-food fish issues for these drugs through MUMS legislation.

**Potassium Permanganate=Cairox®** (external microbicide) —Status: Was an AFWA Project drug and now under development by the sponsor (Carus Chemical Company) and SNARC; one label claim in progress: control of mortality in channel catfish due to external columnaris disease.

Progress on potassium permanganate (May 15, 2006 to May 14, 2007):

- On September 12, 2006, CVM granted MUMS designations to Carus Chemical Company, the sponsor of Cairox®, for the following label claims: For the control of mortality in (1) freshwater-reared finfish due to external columnaris disease associated with *Flavobacterium columnare*, (2) freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, and (3) freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilum*.

Current status of technical sections on potassium permanganate:

- **Product Chemistry**—The sponsor, Carus Chemical Company, submitted product chemistry technical section for all fish to CVM on December 8, 1998; CVM asked for additional data; the sponsor provided additional data (March 2002) and CVM is asking for clarification (April 2002).
- **Environmental Safety**—The sponsor submitted a request for a categorical exclusion from an EA for all fish to CVM on February 23, 1998; CVM is requiring an EA. Efforts at Arkansas State University began in January 2002 on environmental fate and effects studies with funding from the Multi-State Conservation Grant Program. The studies were completed in November 2005.
- **Human Food Safety-Toxicology**—Accepted by CVM.
- **Human Food Safety-Residue Chemistry**—CVM accepted as complete from SNARC.
- **Target Animal Safety**—Planned on channel catfish.
- **Efficacy**—SNARC completed pivotal efficacy studies that demonstrate efficacy to prevent ichthyophthiriasis on channel catfish and tilapia. SNARC completed controlled efficacy studies for control of ichthyophthiriasis on channel catfish and tilapia. SNARC prepared an efficacy protocol for conducting efficacy studies on external columnaris disease in channel catfish.

**Praziquantel** (trematode and cestode control)—Status: Some interest on the part of potential sponsor in a NADA approval in the U.S. but needs positive marketing information and a completed mammalian safety technical section if considered for food finfish; has approval in several countries.

**Pyceze®** (external microbicide)—Status: Sponsor submitted an INAD/NADA letter of intent and summary of all major technical sections; met with CVM on development of data; early development stage.

**Romet®** (oral antibacterial)—Status: Romet-30® has approvals for control of ESC and furunculosis in salmonids; early development stage for extensions and expansions; sponsor resolved palatability for Romet-TC® (new label name for Type B medicated feed; previously called Romet-B®).

Progress on Romet® (May 15, 2006 to May 14, 2007): No progress to report.

Current status of technical sections on ROMET®:

- **Product Chemistry**—Accepted by CVM.

- *Environmental Safety*—Accepted by CVM.
- *Human Food Safety–Toxicology*—Accepted by CVM.
- *Human Food Safety–Residue Chemistry*—Accepted for catfish and salmonids by CVM.
- *Target Animal Safety*—Accepted for catfish and salmonids by CVM.
- *Efficacy*—Accepted for control of ESC and furunculosis in salmonids by CVM; palatability problems resolved by sponsor.

**Sarafloxacin** (oral antibacterial)—Status: Previously, most of the NADA technical sections were submitted by Abbott Laboratories and accepted by CVM for control of ESC with sarafloxacin. However, the Centers for Disease Control and Prevention (CDC) presented concerns about the use of all fluoroquinolones in animal health because of the perceived potential for developing pathogen resistance to drugs used in humans. It is doubtful that a new NADA on sarafloxacin or any fluoroquinolone will be allowed for aquaculture uses by CVM. Sarafloxacin was replaced by florfenicol as the oral antibacterial and model drug for crop grouping research in January 1998 by a unanimous vote of the AFWA Project stakeholders.

**Sea Lice Control** (various drugs and pesticides)—Status: Various drugs and pesticides (azamethiphos or Salmosan™, cypermethrin or Excis™) were previously pursued by the U.S. and Canada and none are currently active for approval. Uses of several drugs and pesticides are being challenged on the East coast, particularly in Maine. An INAD for Slice™ (emamectin benzoate) was allowed by CVM as a result of great need for a control that could not be challenged to the extent that the others have been.

**Trichlorfon** (external parasite control)—Status: Some interest on the part of potential sponsor in a NADA approval in the United States; has approvals in several countries. Several Special Local Need registrations were obtained in 1998 for control of predaceous insects.

## ANESTHETICS AND SEDATIVES

**Benzocaine**—Status: Major effort by AFWA Project for NADA approval terminated because of decision by AFWA Project stakeholders to select AQUI-S® as the candidate anesthetic in the U.S. public aquaculture sector; no known drug approval activities underway.

**Clove oil**—Status: Oil of cloves (eugenol) is considered Generally Recognized as Safe (GRAS) when used as a direct food additive (21CFR184.1257); however, to use eugenol as an anesthetic on fish, it must be approved by CVM for that purpose. A sponsor is required to proceed toward approval and no sponsor has come forward; no known drug approval activities underway. CVM provided guidance on the use of clove oil in GFI #150: Status of Clove Oil and Eugenol for Anesthesia of Fish.

- On April 17, 2006, AQUI-S New Zealand Ltd. requested a formal review of the information contained in GFI #150 on the status of clove oil and eugenol. The published data do not support the statements made in the document concerning the composition of clove oil.
- On April 24, 2007, CVM revised Guidance for Industry #150 dealing with concerns related to the use of clove oil (eugenol) as an anesthetic for fish by correcting information on its ingredients and safety.

**Isoeugenol=AQUI-S®**—Status: Was an AFWA Project drug and now under development by the sponsor (AQUI-S New Zealand Ltd.), UMESC, and AADAP; two label claims in progress: zero withdrawal anesthetic for sedation to handleable condition in (1) all freshwater finfish and (2) saltwater salmonids.

Progress on AQUI-S® (May 15, 2006 to May 14, 2007):

- CVM accepted from the Aquatic Animal Drug Approval Partnership Program (AADAP) efficacy studies on fingerling walleye (June 12, 2006), June suckers (July 7, 2006), and fingerling and juvenile kokanee salmon (July 7, 2006).

- On June 15, 2006, AQUI-S New Zealand Ltd. and the National Aquaculture NADA Coordinator met with National Toxicology Program (NTP) officials to discuss progress on the isoeugenol mammalian safety studies being conducted under NTP.
- On September 21, 2006, UMESC submitted a final report to Association of Fish and Wildlife Agencies (AFWA) on the development and validation of a determinative method to detect isoeugenol in fish tissues.
- On November 28, 2006, CVM accepted as complete from AADAP the effectiveness studies for all freshwater-reared finfish for sedation to handleable stage. Validation of the dose verification method is required before a technical section complete letter can be granted.
- On December 8, 2006, CVM accepted the target animal safety study on rainbow trout from AADAP.
- On January 31, 2007, UMESC submitted a response to CVM comments on the total residue depletion studies and a letter requesting the selection of the marker residue.
- On April 27, 2007, AADAP and UMESC announced they were suspending all research until the completion of the NTP review scheduled for February 2008 on studies conducted on mice and rats. The review had originally been scheduled for May 2007 but due to other priorities was delayed.

Current status of technical sections on AQUI-S®:

- *Product Chemistry*—The sponsor (AQUI-S New Zealand Ltd.) submitted studies on activity of AQUI-S® to CVM (October 2003); the complete manufacturing package is in progress.
- *Environmental Safety*—AQUI-S New Zealand Ltd. submitted a summary to CVM in the late 1990s and environmental biodegradation studies in freshwater and saltwater (November 24, 2003). The sponsor is conducting a series of ecotoxicity and physico-chemical studies in 2004 to 2006.
- *Human Food Safety–Toxicology*—AQUI-S New Zealand Ltd. conducted a review of the mammalian safety literature to determine whether to continue with the original active ingredient in light of NTP studies to test for its potential carcinogenicity. A 90-day feeding study demonstrated no carcinogenicity but NTP decided to proceed with a two-year study that was completed in Spring 2004; the final report will not be available until late 2006 or early 2007. AQUI-S New Zealand Ltd. concluded that the active ingredient is safe and presented these conclusions to CVM on November 18, 1999 and decided to proceed with the drug approval in the U.S. for the original active ingredient based on their assessment of scientific data that the active ingredient is not a carcinogen. The sponsor submitted a series of NTP studies to CVM: Teratology study (November 1, 2004; accepted June 13, 2005) and continuous breeding study (November 26, 2004; accepted June 24, 2005).
- *Human Food Safety–Residue Chemistry*—UMESC conducted a series of pilot studies to delineate the design of the total residue depletion study so that the exact amount of radiolabeled material needed for the study is known. UMESC submitted a pivotal total residue depletion study to CVM on March 14, 2006.
- *Target Animal Safety*—Pivotal target animal safety studies on salmonids were started in March 2005 by AADAP. AQUI-S New Zealand Ltd. submitted to CVM target animal safety studies on Atlantic salmon completed in Canada (July 6, 2004) and CVM declared them as supportive (May 17, 2005); Accepted rainbow trout from AADAP (December 8, 2006) .
- *Efficacy*—AQUI-S New Zealand Ltd. submitted to CVM pivotal efficacy studies on Atlantic salmon completed in Canada (July 6, 2004) and CVM declared them as supportive (May 17, 2005); Accepted from AADAP efficacy for handleable for all freshwater-reared finfish (November 28, 2006).

**Metomidate=AQUACALM®** (one label claim for use as a sedative during transport of ornamental (non-food) finfish)

- On November 13, 2006, CVM granted MUMS designation to Syndel Laboratories, LTD, the sponsor of AQUACALM®, for use as a sedative during transport of ornamental (non-food) finfish.

**MS-222**—Status: Two approved NADAs for MS-222 as an anesthetic with a 21-day withdrawal time.

### **SPAWNING AND GENDER MANIPULATION AIDS**

**Crude Carp Pituitary (CCP)**—Status: Interested parties proceeding toward NADA approval but sponsor, Stoller Fisheries, has decided not to pursue a response to CVM request for a revision of its product chemistry technical section.

Progress on CCP (May 15, 2006 to May 14, 2007): No progress to report.

Current status of technical sections on CCP:

- *Product Chemistry*—The sponsor submitted the product chemistry technical section for CCP to CVM on September 21, 1999. The sponsor received a response on November 22, 1999 from CVM that asked for more information. The sponsor has decided not to pursue a response.
- *Environmental Safety*—Accepted by CVM.
- *Human Food Safety-Toxicology*—Accepted by CVM
- *Human Food Safety-Residue Chemistry*—Accepted by CVM.
- *Target Animal Safety*—A literature review on target animal safety of CCP was completed, presented on August 5, 1998 in Bozeman, Montana, and submitted to CVM in summer 1999 by the Southeastern region of NRSP-7. On October 12, 2004, Southern Illinois University submitted the final report for the target animal safety study to NRSP-7 and this report was submitted to CVM.
- *Efficacy*—Accepted as complete from NRSP-7 by CVM as a spawning aid in freshwater-reared female finfish (July 17, 2002). CVM has requested additional information.

**Human Chorionic Gonadotropin (hCG)**—Status: Chorulon® (human chorionic gonadotropin) was approved on September 7, 1999 by CVM as a spawning aid by intramuscular injection for all fish and requires a prescription under the direction of a veterinarian.

**Luteinizing Hormone-Releasing Hormone analog (LHRHa)**—Status: Auburn University gained an INAD for LHRHa in the Spring 2003; early development stage.

**17  $\alpha$ -methyltestosterone (MT)=MASCULINIZING FEED FOR TILAPIA®**—Status: Sponsor, Rangen, Inc., is developing NADA package; INAD sponsors actively pursuing a NADA approval; one label claim close to completion: masculinization of female early life-stage tilapia.

Progress on MT (May 15, 2006 to May 14, 2007):

- In 2006, CVM Office of Research published a regulatory analytical method that will quantify and confirm the presence of MT in the muscles of tilapia, rainbow trout, and salmon.
- The lack of an internal standard for analyzing the MT-medicated feed for the target animal safety and efficacy studies delayed those studies until a standard was made. On June 5, 2006, AADAP received word that the internal standard was completed at Steraloids and it was being made available to the testing facility, CanTest, to begin the transfer validation.
- University of Wisconsin-Madison (UW-M) completed laboratory feed studies in summer 2006 and the final reports are to be submitted to CVM in 2006.

- UW-M completed the initial phase of the biodegradation study in water and will complete the analysis of the samples in 2006.
- Southern Illinois University began the target animal safety study on tilapia.

Current status of technical sections on MT:

- *Product Chemistry*—The sponsor, Rangen, Inc., submitted a product chemistry technical section on 17  $\alpha$ -methyltestosterone to CVM on November 8, 2000. CVM is requiring more information, stability studies, and an analytical method with greater recoveries. UW-M was selected as the contractor to complete these requirements and completed the laboratory phase of the studies in fall 2006. CVM accepted the analytical method to detect MT in feed (December 2, 2005).
- *Environmental Safety*—Auburn University received a response from CVM on November 8, 1999 regarding the revised EA for MT that requested additional information, a biodegradation study, and a more sensitive method to detect MT in water. UW-M was selected as the contractor to complete these requirements and is conducting the studies in fall 2006.
- *Human Food Safety-Toxicology*—Accepted by CVM.
- *Human Food Safety-Residue Chemistry*—Accepted by CVM.
- *Target Animal Safety*— Cornell University submitted to CVM an animal safety study on tilapia; CVM found a target animal safety study on percids by Southern Illinois University to be inadequate; literature review on other species completed and submitted by Auburn University. CVM recently determined that a target animal safety study on tilapia was needed and the North Central Regional Aquaculture Center (NCRAC) has agreed to fund this study; Southern Illinois University was selected to perform the target animal safety study on tilapia.
- *Efficacy*— Cornell University submitted to CVM a final report on the efficacy of MT to tilapia; Auburn University is coordinating a compassionate INAD on tilapia and completed and submitted the final report to CVM in December 2003; AADAP received authorization for a INAD to collect pivotal and supportive efficacy data on June 4, 2004.

**sGnRH<sub>a</sub> and domperidone=Ovaprim®**—Status: Sponsor recently submitted INAD letter of intent; early development stage.

- On July 27, 2006, CVM granted MUMS designation to Syndel Laboratories, LTD, the sponsor of Ovaprim®, for the induction of spawning in ornamental fish.

#### **CHEMICAL MARKING AGENTS**

**Calcein=SE-MARK®**—Status: Early development stage as chemical marking aid.

- On December 20, 2006, the sponsor, National Aquaculture NADA Coordinator, and AADAP met with CVM to discuss the data requirements for calcein approval.

**Oxytetracycline (immersion)** —Status: APPROVED: marking aid by immersion for all fish with four NADA sponsors.

- **ON MAY 9, 2007, THE FINAL RULE FOR THE GENERIC NADA APPROVAL FOR TETROXY AQUATIC® SPONSORED BY CROSS VETPHARM GROUP LTD FOR USE AS A SKELETAL MARKING AID IN FINFISH FRY AND FINGERLINGS APPEARED IN THE FEDERAL REGISTER (VOL. 72, NO. 89, PAGE 26289).**

**Strontium Chloride**—Status: Western Chemical Inc. is the sponsor; some work completed in Alaska; some efficacy studies underway under Western NRSP-7.

**PISCICIDES**—Rotenone and antimycin are used by hatcheries in resource agencies and private aquaculture facilities to help control diseases in cultured fish by removing undesirable fish in ponds and to help in the effective product of cultured fish.

- On July 12-14, 2006, selected members of Fisheries Management Chemicals Subcommittee (FMCS) of the American Fisheries Society (AFS) and UMESC met in La Crosse, Wisconsin with the registrant of antimycin, Aquabiotics Corporation, to discuss how to meet the reregistration requirements for fishery management.
- On September 28, 2006, the registrant, National Aquaculture NADA Coordinator, a FMCS representative, and UMESC participated in a conference call with the Environmental Protection Agency (EPA) to discuss the remaining requirements for the reregistration of antimycin.
- On March 31, 2007, EPA issued the Reregistration Eligibility Decision for rotenone. Comments are due July 23, 2007.

## PUBLIC INFORMATION AND MEETINGS

### Surveys on Unmet label Claim Needs

The National Aquaculture NADA Coordinator developed a survey the public aquaculture sector to determine the unmet label claim needs for the AFWA Project drugs. It was sent on September 21, 2005 under the authorization of Doug Hansen to state stakeholders who had funded the AFWA Project to determine if the AFWA Project is meeting their label claim needs. The final response was received by the NADA Coordinator on January 5, 2006. She tabulated and analyzed the results and provided a final report to the Drug Approval Working Group members on March 25, 2006. It was distributed to state stakeholders in July 2006.

The National Aquaculture NADA Coordinator developed a survey for the private aquaculture sector to determine the unmet label claim needs for all drugs. It was sent on July 26, 2006 to all the national aquaculture associations. Only 10 returns had been received by November 9, 2006.

### **AFWA Drug Approval Work Group (DAWG) for the Federal-State Aquaculture Drug Approval Partnership Project; known as the AFWA Project (includes nine drugs: AQUI-S®, chloramine-T, copper sulfate, florfenicol, formalin, hydrogen peroxide, oral oxytetracycline, immersion oxytetracycline, and potassium permanganate)**

The DAWG held a meeting on September 18, 2006 in Aspen, Colorado. The National Aquaculture NADA Coordinator provided documents before the meeting. The National Aquaculture NADA Coordinator indicated that approvals are very near because administrative NADAs will be submitted soon for initial approvals of AFWA Project drugs. She noted that there should be final submissions for original or supplemental approvals for (1) one drug with three label claims in 2006, (2) six drugs and 12 label claims in late 2006 through 2007, and (3) three drugs and four label claims in 2008 to 2009. CVM indicated that the past six months have been exceedingly productive toward drug approvals. AADAP, UMESC, SNARC and the National Aquaculture NADA Coordinator presented their work plans for 2007.

The DAWG held meetings on March 22-23, 2007 in Portland, Oregon. Past action items were finalized for (1) the Drug Approval Process Brochure, (2) the Unmet Needs Survey, and (3) the Public Fish Production Database. New approvals received announcements from the NADA Coordinator. The status of each drug was presented along with potential for efficacy studies on chloramine-T and hydrogen peroxide. NCRAC funding will be available for Aquaflor® and Terramycin 200® for Fish for motile aeromonad septicemia in coolwater and warmwater fish.

### **Annual Aquaculture Drug Approval Coordination Workshop**

On August 1-2, 2006, AADAP and UMESC hosted the 12<sup>th</sup> Annual Aquaculture Drug Approval Coordination Workshop in La Crosse, Wisconsin that centered on the progress being made on the drugs in the AFWA Project. The presentations included (1) perspectives by CVM's Office of minor Use and Minor Species Development and state natural resources agencies, (2) overviews from CVM, (3) status of the original AFWA Project drugs, (4) development of disease models, and (5) status of, and perspective on, non AFWA Project drugs.

### **Joint Subcommittee on Aquaculture (JSA) Working Group on Quality Assurance in Aquaculture Production**

The JSA Working Group on Quality Assurance in Aquaculture Production met on October 25, 2006 in Washington, DC. The topics of discussion were (1) updates on the National Aquaculture Drug Research Forum, Aquaculture Drug Approval Coordination Workshop, FAO/WHO Expert Consultation on Antimicrobial Resistance and Aquaculture, and the National Academy of Sciences report from the Institute of Medicine on Seafood Choices, (2) MUMS Indexing Federal Register notice, (3) effluents residues and aquaculture residues, (4) reregistration of aquatic pesticide products, (5) Good Aquacultural Product Practices, and (6) National Aquaculture NADA Coordinator reports on (a) actual and anticipated approvals for 2006-2009+, (b) effects of MUMS designation on sponsor participation, (c) results of unmet label claims from public and private surveys, and (d) microbial food safety submissions and acceptances.

### **Meeting on 35% PEROX-AID®**

On October 2-3, 2006, the sponsor of 35% PEROX-AID®, Eka Chemicals, Inc., and the new distributor, Western Chemical Inc. met in La Crosse, Wisconsin with the National Aquaculture NADA Coordinator and UMESC to discuss the final arrangements for an Administrative NADA on PEROX-AID® (hydrogen peroxide) for the first three broad label claims: (1) saprolegniasis on all finfish eggs, (2) bacterial gill disease on all freshwater-reared salmonids, and (3) external columnaris disease on all coolwater fish and channel catfish.

### **Designation Provision of the Minor Use and Minor Species Animal Health Act of 2004 (MUMS)**

The designation provision of the new Minor Use and Minor Species Animal Health Act of 2004 (MUMS) gives sponsors seven years of marketing exclusivity. There have been NADA approvals for two MUMS designations for Schering-Plough Animal Health's Aquaflor® and three MUMS designations for Eka Chemicals, Inc.'s 35%PEROX-AID®. So far, the MUMS Office has granted 44 designations, 40 for aquaculture uses to aquaculture drug sponsors who received extensive help from the National Aquaculture NADA Coordinator.

### **Funding Needs**

The National Aquaculture NADA Coordinator position stayed at 35 hours per week to maintain adequate funding. Contributions totaled \$122,035 for Year 12 (May 15, 2006 to May 14, 2007).

## **PUBLICATIONS, MANUSCRIPTS, PAPERS PRESENTED, AND SPECIAL REPORTS**

### **PUBLICATIONS**

AFS Task Force on Fishery Chemicals, Fish Management Chemicals Subcommittee. 2007. Fisheries News: Update on reregistration and use of piscicides rotenone and antimycin. Fisheries 32 (1): 6, 47.

Schnick, R.A. 2007. Fisheries News: Major aquaculture drug approval for 35% PEROX-AID®. Fisheries 32 (2): 58.

Schnick, R.A. 2007. News: Fisheries: Major aquaculture drug approval (Aquaflor®). Fisheries 32 (4): 162, 190.

## **PAPERS PRESENTED**

Schnick, R.A. 2006. Private aquaculture sector survey needed to complete the exciting progress toward drug approvals. National Association of State Aquaculture Coordinators, Little Rock, Arkansas, May 23-26, 2006.

Schnick, R.A. 2006. History of efforts toward aquaculture drug approvals. Center for Veterinary Medicine, Rockville, Maryland, June 5, 2006.

Schnick, R.A. 2006. Overview of Public Aquaculture Sector Survey to determine unmet label claims for IAWFA Project drugs. 12th Annual Aquaculture Drug Approval Coordination Workshop, La Crosse, Wisconsin, August 1-2, 2006.

Schnick, R.A. 2006. Introduction to non-AFWA projects for aquaculture drug approvals. 12th Annual Aquaculture Drug Approval Coordination Workshop, La Crosse, Wisconsin, August 1-2, 2006.

Schnick, R.A. 2006. Aquaculture NADA Coordinator's perspective on non-AFWA Project drugs. 12th Annual Aquaculture Drug Approval Coordination Workshop, La Crosse, Wisconsin, August 1-2, 2006.

Schnick, R.A. 2006. Update on AFWA Project Drugs. AFWA Drug Approval Working Group, Aspen, Colorado, September 18, 2006.

Schnick, R.A. 2006. Advances toward drug approvals for farmed fish. PennAqua 2006, Harrisburg, Pennsylvania, September 20-23, 2006.

Schnick, R.A. 2006. Advances in aquaculture drug approvals. NRSP-7, La Crosse, Wisconsin, October 10, 2006.

Schnick, R.A. 2006. Actual and anticipated NADA approvals for 2006-2009. JSA Working Group on Aquaculture Drugs, Biologics, and Pesticides Meeting, Washington, DC, October 25, 2006.

Schnick, R.A. 2006. Microbial Food Safety submissions & acceptances. JSA Working Group on Aquaculture Drugs, Biologics, and Pesticides Meeting, Washington, DC, October 25, 2006.

Schnick, R.A. 2006. Effect of MUMS designations on sponsor participation. JSA Working Group on Aquaculture Drugs, Biologics, and Pesticides Meeting, Washington, DC, October 25, 2006.

Schnick, R.A. 2006. Proposed actions to meet unmet label claims from the Public Aquaculture Sector Survey. JSA Working Group on Aquaculture Drugs, Biologics, and Pesticides Meeting, Washington, DC, October 25, 2006.

Schnick, R.A. 2007. Update on aquaculture drug approvals. North Central Regional Aquaculture Center Annual Meeting, Columbus, Ohio, February 9-11, 2007.

Schnick, R.A. 2007. Update on new drug approvals for catfish. Catfish Farmers of America Annual Meeting, Orange Beach, Alabama, February 15-18, 2007.

Schnick, R.A. 2007. Recent aquaculture drug approval successes. Aquaculture 2007, Producer Session "Aquaculture drug approval successes", San Antonio, Texas, February 28, 2007.

- Schnick, R.A. 2007. Progress on drug approvals. Aquaculture 2007, Striped Bass Growers Association Annual Meeting, San Antonio, Texas, February 28, 2007.
- Schnick, R.A. 2007. Progress on drug approvals for salmonids. Aquaculture 2007, US Trout Farmers Association Forum, San Antonio, Texas, February 27, 2007.
- Schnick, R.A. 2007. Progress on drug approvals for tilapia. Aquaculture 2007, American Tilapia Association Session, San Antonio, Texas, March 1, 2007.
- Schnick, R.A. 2007. Status of aquaculture drug approvals. NRSP-7 Spring Meeting, Rockville, Maryland, March 5-7, 2007.
- Schnick, R.A. 2007. AFWA Project Drugs: Remaining requirements and progress September 2006 to March 2007, Drug Approval Working Group Meeting, Portland, Oregon, March 22, 2007.
- Schnick, R.A. 2007. Thoughts on Administrative NADA process, Drug Approval Working Group Meeting, Portland, Oregon, March 22, 2007.
- Schnick, R.A. 2007. How Extension Specialists can help in the aquaculture drug approval process. 4<sup>th</sup> National Aquaculture Extension Conference, Cincinnati, Ohio, April 30 to May 4, 2007.
- Schnick, R.A. 2007. Dialog with Upper Midwest Environmental Sciences Center on Fisheries Management Chemicals and Drugs Program. Upper Midwest Environmental Sciences Center Partner Meetings, La Crosse, Wisconsin, May 10-11, 2007.

## **SPECIAL REPORTS**

- Schnick, R.A. 2006. Roz's Corner: AADAP Newsletter Contribution. Submitted to AADAP. June 9, 2006. 1 pp.
- Schnick, R.A. 2006. Eleventh annual report of activities—National Coordinator for Aquaculture New Animal Drug Applications (May 15, 2005 to May 14, 2006). Submitted to Ted Batterson, NCRAC for distribution. June 23, 2006. 29 pp.
- Schnick, R.A. 2006. Revised report (July 10, 2006): Tabulation and analysis of results from 2005 survey to determine unmet label claims for the AFWA Project drugs. Submitted to Steve Sharon, Chair, Drug Approval Working Group for distribution to 38 states. July 10, 2006. 16 pp.
- Schnick, R.A., J. Bowker, and J. Meinertz. 2006. Second Quarter 2006 Quarterly Report for Multistate Conservation Grant Number DC M-48-R-1 (AQUI-S®). Submitted to AFWA. July 24, 2006. 4 pp.
- Schnick, R.A. 2006. 2006 private aquaculture sector survey on unmet label claim drug needs. Submitted to the aquaculture associations for distributions to their members. July 26, 2006. 18 pp.
- Schnick, R.A. 2006. Draft Drug Alerts: Hydrogen peroxide and formalin. Submitted to Steve Sharon, Chair, Drug Approval Working Group for distribution to 50 state natural resources agencies. August 14, 2006. 2 pp.
- Schnick, R.A. 2006. Draft HALAMID® PHARMA GRADE label. Submitted to the sponsor, Axcentive SARL, for submission to CVM. August 14, 2006. 4 panels.
- Schnick, R.A. 2006. Draft of Technical Section submission on chloramine-T (HALAMID® PHARMA GRADE) related to Guidance for Industry #159 "Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI" (INAD #8086). Submitted to the sponsor, Axcentive SARL, for submission to CVM. August 21, 2006. 5 pp.

- Schnick, R.A. 2006. Draft of Technical Section submission on chloramine-T (HALAMID® PHARMA GRADE) related to Guidance for Industry #152: "Evaluating the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern" (INAD #8086). Submitted to the sponsor, Axcentive SARL, for submission to CVM. August 22, 2006. 6 pp.
- Schnick, R.A. 2006. Task Force on Fishery Chemicals Annual report to the AFS Governing Board, September 2006. Submitted to the AFS Executive Director. September 3, 2006. 4 pp.
- Schnick, R.A. 2006. Administrative New Animal Drug Application for 35% PEROX-AID®. Submitted to the sponsor. May 14, 2006 (revised September 14, 2006). 43 pp.
- Schnick, R.A. 2006. Responsibilities and acceptances for public partners for planned AFWA Project drug label claims (July 1994 to September 2006). Submitted to Steve Sharon, Chair, Drug Approval Working Group for September meeting. September 14, 2006. 4 pp.
- Schnick, R.A. 2006. AFWA Project Drugs: Remaining requirements and progress March to September 2006. Submitted to Steve Sharon, Chair, Drug Approval Working Group for September meeting. September 14, 2006. 9 pp.
- Schnick, R.A. 2005. Draft minutes to Drug Approval Working Group Meeting, Aspen, Colorado. Submitted to Steve Sharon, Chair, Drug Approval Working Group. September 23, 2006 (sent out January 4, 2007). 10 pp.
- Schnick, R.A. 2005. Letter requesting assistance on efficacy studies for coolwater and warmwater species using chloramine-T and hydrogen peroxide. Submitted to Steve Sharon, Chair, Drug Approval Working Group. September 25, 2006. 2 pp.
- Schnick, R.A., J. Bowker, and J. Meinertz. 2006. Third Quarter 2006 Quarterly Report for Multistate Conservation Grant Number DC M-48-R-1 (AQUI-S®). Submitted to AFWA. October 20, 2006. 5 pp.
- Schnick, R.A. 2006. Roz's Corner: AADAP Newsletter Contribution. Submitted to AADAP. November 9, 2006. 1 pp.
- Schnick, R.A. 2006. Twelfth mid-year report of activities—National Coordinator for Aquaculture New Animal Drug Applications (May 15, 2006 to November 9, 2006). Submitted to Ted Batterson, NCRAC for distribution. November 20, 2006. 19 pp.
- Schnick, R.A. 2006. Template for MUMS annual reports. Provided to Sponsors of MUMS designations. November 22, 2006. 1 pp.
- Schnick, R.A., J. Bowker, and J. Meinertz. 2007. Fourth Quarter 2006 Quarterly Report for Multistate Conservation Grant Number DC M-48-R-1 (AQUI-S®). Submitted to AFWA. January 15, 2007. 4 pp.
- Finlayson, B., and R.A. Schnick. 2007. Comments on the EPA's risk assessments and related documents for the piscicide antimycin as noticed in *Federal Register* (Vol. 72, No. 10, January 17, 2007, pages 1990-1992). Sent to EPA. March 15, 2007. 3 pp.
- Schnick, R.A. 2007. News Releases: Major drug approval for 35% PEROX-AID®. Sent to aquaculture magazines. February 3, 2007. 1 pp.
- Schnick, R.A. 2007. Template for Technical Section: All Other Information. Provided to DAWG. March 19, 2007. 1 pp.

Schnick, R.A. 2007. AFWA Project Drugs: Remaining requirements and progress September 2006 to March 2007. Submitted to DAWG. March 20, 2007. 4 pp.

Schnick, R.A. 2007. Roz's Corner: AADAP Newsletter Contribution. Submitted to AADAP. April 4, 2006. 1 pp.

Schnick, R.A. 2007. 2007. News Releases: Major drug approval (Aquaflor®). Sent to aquaculture magazines. April 5, 2007. 1 pp.

Schnick, R.A., J. Bowker, and J. Meinertz. 2007. First Quarter 2007 Quarterly Report for Multistate Conservation Grant Number DC M-48-R-1 (AQUI-S®). Submitted to AFWA. April 27, 2007. 5 pp.