ATTACHMENT B

NATIONAL COORDINATOR FOR AQUACULTURE
NEW ANIMAL DRUG APPLICATIONS (NADAs)

LEAD INSTITUTION: North Central Regional Aquaculture Center
Michigan State University

FUNDING LEVEL: $9,000

This request is for partial support for the National Coordinator for Aquaculture NADAs.

BACKGROUND AND JUSTIFICATION

The Joint Subcommittee on Aquaculture (JSA) recognized in the 1990s that investigation and approval of safe therapeutants for use by the aquaculture industry to help manage diseases was one of the highest priorities currently facing the industry. At that time, only a few approved compounds were available to the industry and further development of the aquaculture industry is severely constrained by a lack of approved drugs essential for treating over 50 known aquaculture diseases. The U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM) has afforded the aquaculture industry throughout the U.S. with a "window of opportunity" to seek approval of drugs to be used legally in their production practices. The need for additional drugs is great, but securing data necessary to satisfy the requirements of CVM for drug approval is time consuming, costly, and procedures are rigorous. The Investigational New Animal Drug/New Animal Drug Applications (INAD/NADA) process is the one method that allows the industry to provide CVM with data on efficacy and also aid producers in their production practices.

The JSA's Working Group on Quality Assurance in Aquaculture Production previously identified the need for a National Coordinator for Aquaculture INADs. This position was supported through Cooperative Agreement No. 92-COOP-1-8021 with funds from U.S. Department of Agriculture's Cooperative State Research, Education. And Extension Service (USDA/CSREES) beginning September 1, 1992. Dr. Robert Ringer, Professor Emeritus of Michigan State University, was hired on a part-time basis (0.14 FTE) to serve as the INAD Coordinator. Dr. Ringer continued as the INAD Coordinator for a second year, September 1, 1993 - August 31, 1994, working on a part-time basis (0.14 FTE). Funds to support his second year's activities were provided by CSREES and CVM through the Cooperative Agreement. The North Central Regional Aquaculture Center (NCRAC) also provided support for his activities.

During Dr. Ringer's second year, the JSA's Working Group on Quality Assurance in Aquaculture Production identified the need for a National Coordinator for Aquaculture NADAs. The NADA Coordinator would build upon those activities undertaken and developed by the National INAD Coordinator, continuing to develop a collaborative working relationship between the private aquacultural sector and various federal agencies, particularly the CVM, the U.S. Department of Interior's (USDI) Fish and Wildlife Service (USFWS), and the USDI's Geological Survey's (USGS) Biological Resources Discipline (formerly the National Biological Service). The National Coordinator serves as a conduit between an INAD/NADA applicant and CVM. The National Coordinator for Aquaculture NADAs helps to alleviate time demands on CVM staff, thus allowing more time to process a greater number of applications as well as increasing the breadth of research endeavors within the industry. The grouping of INAD applicants should help to alleviate redundancy, amalgamate efforts, and increase the amount of efficacy data, all of which should result in greater progress toward developing available, approved therapeutic and production drugs.

On May 15, 1995, Ms. Rosalie (Roz) Schnick, recently retired Registration Officer from the USGS National Biological Service's Upper Mississippi Science Center (now the Biological Resources Discipline's Upper Midwest Environmental Science Center = UMESC), was hired on a three-quarter time basis as the National Coordinator for Aquaculture NADAs. Funds to support her position came from 15 different public and private sector sources. Because of her performance and success as the National Coordinator for Aquaculture NADAs, additional monies became available and on May 15, 1996, her position was

increased to a full-time basis through Year 6 (May 15, 2000 to May 14, 2001). Given carry-over of private funds from previous years and the amount of funds that were pledged for 2001-2002, Schnick's position was reduced to a three-quarter time level for Year 7: May 15, 2001 to May 14, 2002. For Year 8 (May 15, 2002 to May 14, 2003) carry-over and pledged funds allowed the position to return to full-time. For Year 9 (May 15, 2003 to May 14, 2004) carry-over and pledged funds required that the position be reduced to three-quarter time as of October 1, 2003. For Year 10 (May 15, 2004 to May 14, 2005) carry-over and pledged funds (see Table 1) will enable the position to increase to 87.5% time.

Coordination

The National Coordinator for Aquaculture NADAs has been based at Michigan State University under the aegis of NCRAC. The Coordinator has worked closely and collaboratively with the following: USDA/CSREES; Regional Aquaculture Center (RAC) Program; CVM; JSA's Working Group on Quality Assurance in Aquaculture Production; NRSP-7 (formerly IR-4) Minor Use Animal Drug Program; UMESC; USDA's Agricultural Research Service National Aquaculture Research Center at Stuttgart, Arkansas; other aquaculture industry representatives; pharmaceutical/chemical companies involved with aquaculture; Cooperative Extension Services, Sea Grant Marine Advisory Services and RAC Extension programs; other aquaculture coordinators, state, regional and national.

Tasks

Tasks for the National Coordinator are as follows.

(1) Serve as an information conduit between INAD/NADA applicants and CVM;

(2) Identify and encourage prospective INAD participants to become involved in specific investigational studies and NADA approval-related research;

(3) 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;

(4) Guide prospective and current INAD holders on the format for INAD exemption requests and related submissions to CVM;

(5) Identify existing data and remaining data requirements for NADA approvals;

(6) Review, record, and provide information on the status of INADs and NADAs;

(7) Provide liaison and coordination among all the federal agencies involved in the INAD/NADA process; and

(8) Provide public education related to training and guidance in obtaining INAD exemptions and pursuing NADA approval.

Funds to Support the National Coordinator

The funds to support the National Coordinator for Aquaculture NADA's position have come from a variety of public and private sources. During 2004-2005 a number of government agencies, private associations, and other organizations have pledged almost $106,000 for the NADA Coordinator's position. Those sources of funds are presented in Table 1.

Table 1. Funds pledged for support of the National Coordinator for Aquaculture NADAs for 2004-2005.

Source	Amount
CVM[1, 2]	$37,037
USDI/USGS[1, 3]	$9,200
USDI/USFWS[1, 3]	$9,200
NCRAC	$9,000
American Veterinary Medical Association	$10,000
Catfish Farmers of America	$2,500
Florida Tropical Fish Farms Association, Inc.	$2,500
Striped Bass and Hybrid Producers Association	$2,000
National Aquaculture Association	$2,000
AFS - Fish Health Section	$1,000
Axcentive	$4,976
Aqui-S	$5,000
Alabama Catfish Producers	$1,000
Kent Sea Tech Corporation	$2,000
Aquacenter	$2,500
Aquarium Pharmaceuticals	$2,000
National Ornamental Goldfish Growers Association	$1,500
Schering-Plough	$2,500
	$105,913

[1]Funds to be provided through Cooperative Agreement No. 2001-39233-10593
[2]Amount received ($40,000) less USDA's 8% administrative fee for an interagency transfer
[3]Amount received ($10,000) less USDA's 8% administrative fee for an interagency transfer

The Board of Directors of NCRAC, based on input from the Center's Industry Advisory Council, indicated at both the 2003 and 2004 Annual Program Planning Meetings that funds should be made available for activities that would lead to aquaculture drug approvals. The top priority drugs as identified by NCRAC were 17α-Methyltestosterone (MT) and AQUI-S®. These drugs had been identified in various NCRAC white papers (e.g., Tilapia, Salmonids) as being critical for the aquaculture industry in the 12-state North Central Region. Therefore, not only did the NCRAC Board approve funds for projects on both of those drugs, they also approved funds to support the National Coordinator for Aquaculture NADAs for coordinating and supervising the research efforts on those drug projects as well as for gaining approval of other drugs critical to the industry.

To date, $26,976 from the private sector has already been received for Ms. Schnick's tenth year of activity (May 15, 2004 - May 14, 2005) as the National Coordinator for Aquaculture NADAs.

Summary of Accomplishments to Date of the National Coordinator for Aquaculture NADAs

A cumulative Progress Report for the National Coordinator's activities since 1992 is contained in Attachment 1 to this proposal.

Work Planned

The National NADA Coordinator will continue to coordinate efforts to obtain approvals for high priority aquaculture drugs through interactions with the JSA's Working Group on Quality Assurance in Aquaculture Production, FDA, and all the various potential sponsors.

Budget

The budget that has been established for the tenth 12-month period (May 15, 2004 - May 14, 2005) for the National Coordinator for Aquaculture NADAs is presented in Table 2 below.

Table 2. Proposed tenth year budget for the National Coordinator for Aquaculture NADAs: May 15, 2004 - May 14, 2005.

	Budget
Salary (0.875 FTE)	$73,551
Fringe Benefits	$24,001
Total Salary and Fringe Benefits	$97,552
Nonexpendable Equipment	$0
Materials and Supplies	$1,500
Travel	$11,000
Other Direct Costs	$2,500
TOTAL COSTS	$112,552

This request is for $9,000 for the partial support of the costs for the National Coordinator for Aquaculture NADAs during the tenth 12-month period: May 15, 2004 - May 14, 2005. A completed CSREES-2004 budget form for this amount of money is presented on the next page. On page 5 is a budget narrative for the various components of the proposed budget.

UNITED STATES DEPARTMENT OF AGRICULTURE
COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE

OMB Approved 0524-0039
Expires 03/31/2004

BUDGET

ORGANIZATION AND ADDRESS
North Central Regional Aquaculture Center
Michigan State University
East Lansing, MI 48824-1222

PROJECT DIRECTOR(S)
Ted R. Batterson

USDA AWARD NO.

	CSREES FUNDED WORK MONTHS			Duration Proposed Months: 12 **Funds Requested by Proposer**	Duration Proposed Months: ____ **Funds Approved by CSREES** (If different)	Non-Federal Proposed Cost-Sharing/ Matching Funds (If required)	Non-federal Cost-Sharing/ Matching Funds Approved by CSREES (If Different)
A. Salaries and Wages	Calendar	Academic	Summer				
1. No. of Senior Personnel							
a. ___ (Co)-PD(s)							
b. ___ Senior Associates	1.0			$6,016			
2. No. of Other Personnel (Non-Faculty)							
a. ___ Research Associates-Postdoctorates							
b. ___ Other Professionals							
c. ___ Paraprofessionals							
d. ___ Graduate Students							
e. ___ Prebaccalaureate Students							
f. ___ Secretarial-Clerical							
g. ___ Technical, Shop and Other							
Total Salaries and Wages →				$6,016	$0	$0	$0
B. Fringe Benefits (If charged as Direct Costs)				$1,925			
C. Total Salaries, Wages, and Fringe Benefits (A plus B) →				$7,942	0	$0	$0
D. Nonexpendable Equipment (Attach supporting data. List items and dollar amounts for each item.)							
E. Materials and Supplies				$500			
F. Travel							
G. Publication Costs/Page Charges							
H. Computer (ADPE) Costs							
I. Student Assistance/Support (Scholarships/fellowships, stipends/tuition, cost of education, etc. Attach list of items and dollar amounts for each item.)							
J. All Other Direct Costs (In budget narrative, list items and dollar amounts and provide supporting data for each item.)				$558			
K. Total Direct Costs (C through I) →				$9,000	0	$0	$0
L. F&A/Indirect Costs. (If applicable, specify rate(s) and base(s) for on/off campus activity. Where both are involved, identify itemized costs in on/off campus bases.)							
M. Total Direct and F&A/Indirect Costs (J plus K) →				$9,000	0	$0	$0
N. Other →							
O. Total Amount of This Request →				$9,000	0	$0	$0

P. Carryover -- (If Applicable) . . . . . **Federal Funds: $** **Non-Federal funds: $** **Total $**

Q. Cost Sharing/Matching (Breakdown of total amounts shown in line O)
Cash (both Applicant and Third Party) →
Non-Cash Contributions (both Applicant and Third Party) →

NAME AND TITLE (Type or print)	**SIGNATURE** (required for revised budget only)	**DATE**
Project Director		
Authorized Organizational Representative		
Signature (for optional use)		

Form CSREES-2004 (12/2000)

Budget Narrative

A. Salaries and Wages. This amount ($6,016) would provide 1.0 month of salary for the National Coordinator for Aquaculture NADAs at 0.875 FTE.

B. Fringe Benefits. The fringe benefit loading rate for FY 2003-04 is 32%.

E. Materials and Supplies. Annual costs: $500 for general office supplies such as pens, paper, toner cartridges, and software upgrades.

I. All Other Direct Costs. Telephone ($325), fax ($165), and postage ($68) charges incurred by the National Coordinator for Aquaculture NADAs for conducting activities associated with that position.

PROGRESS REPORT FOR THE NATIONAL COORDINATOR FOR AQUACULTURE NADAs

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:

(1) Serve as an information conduit between INAD/NADA applicants and the U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM);

(2) Identify and encourage prospective INAD participants to become involved in specific investigational studies and NADA approval-related research;

(3) 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;

(4) Guide prospective and current INAD holders on the format for INAD exemption requests and related submissions to CVM;

(5) Identify existing data and remaining data requirements for NADA approvals;

(6) Review, record, and provide information on the status of INADs and NADAs;

(7) Provide liaison and coordination among all the federal agencies involved in the INAD/NADA process; and

(8) Provide public education related to training and guidance in obtaining INAD exemptions and pursuing NADA approval.

PROGRESS AND PRINCIPAL ACCOMPLISHMENTS

THERAPEUTANTS

Amoxicillin (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.

On November 11, 2003, Kent Sea Tech Corporation submitted to CVM an efficacy study on amoxicillin to control Streptococcus infections in hybrid striped bass. The study had been performed at the Harry K. Dupree National Aquaculture Research Center (SNARC).

Chloramine-T (external antibacterial)—Status: Was a Federal-State Aquaculture Drug Approval Partnership Project drug and now under development by the sponsor (Axcentive bv; formerly Akzo Nobel Chemicals, Inc.), UMESC, and AADAPP; two label claims close to completion: control of mortalities associated with (1) bacterial gill disease on all freshwater-reared salmonids and (2) external columnaris disease on walleyes in flow-through systems.

Progress on chloramine-T (May 15, 2003 to November 9, 2003):

- On July 16, 2003, Axcentive bv submitted the proprietary environmental assessment (EA) on chloramine-T to CVM. The Upper Midwest Environmental Sciences Center (UMESC) developed the EA for the sponsor with funds from the company. The National Aquaculture NADA Coordinator helped the sponsor with the submission.

- On May 14, 2003, the National Aquaculture NADA Coordinator provided the sponsor with information on recent efficacy studies and the current status of the approval process for chloramine-T.

- On July 11, 2003, CVM reinstated the slaughter authorization for the use of chloramine-T under the U.S. Fish and Wildlife Service's (FWS) Investigational New Animal Drug (INAD) exemption. The CVM decision was based on the acceptance of mammalian safety data from Axcentive bv.

Current status of technical sections on chloramine-t:

- *Product Chemistry*—The sponsor, Axcentive bv (a 100% daughter company of PNP Holding bv, Barneveld, The Netherlands) is committed to developing the product chemistry technical section and submitting it to CVM into INAD #8086.
- *Mammalian Safety*—The sponsor is addressing this technical section. CVM declared that p-TSA is not genotoxic based on proprietary data submitted by Axcentive bv (July 19, 2002). CVM accepted additional proprietary mammalian safety data from Axcentive bv; based on those data, CVM declared that the safe concentration of p-TSA in edible tissue of fish is 1 ppm (April 9, 2003).
- *Environmental Safety*—CVM accepted 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 environmental assessment that was submitted by Axcentive bv on July 16, 2003 to CVM under INAD #8086.
- *Human Food Safety*—CVM accepted (1) residue chemistry studies by UMESC for total residue depletion and metabolism of chloramine-T in several species of fish; p-TSA was established as the major metabolite in fish and declared as a marker residue for chloramine-T in juvenile rainbow trout, (2) simple colorimetric procedure by UMESC for use in efficacy studies for determining chloramine-T concentrations in treatment waters, (3) research by UMESC that bridges the proposed HPLC analytical method for p-TSA with an outdated, labor intensive method previously used to quantify p-TSA in fish tissue (January 13, 2003), and (4) determinative method in multiple species (April 24, 2003). Through an interagency agreement with UMESC, CVM's Office of Research developed a confirmatory method for p-TSA in fish tissue to satisfy an all fish label claim. UMESC submitted a FOI summary on human food safety to CVM. CVM declared that the safe concentration of p-TSA in edible tissue of fish is 1 ppm (April 9, 2003).
- *Target Animal Safety*—CVM accepted as complete from the Aquatic Animal Drug Approval Partnership Program (AADAPP) the target animal safety technical section on freshwater-reared salmonids (September 13, 2002). UMESC submitted target animal safety data on several species of coolwater and warmwater fish to CVM (August 28, 2002).
- *Efficacy*—CVM accepted as complete from AADAPP the efficacy technical section for control of mortalities associated with bacterial gill disease on all freshwater-reared salmonids at 12 to 20 mg/L for one hour. UMESC submitted efficacy data on the control of mortalities associated with external columnaris disease on walleye (January 28, 2003).

Copper Sulfate (external microbicide)—Status: Was a Federal-State Aquaculture Drug Approval Partnership Project drug and now under development by the sponsor (Phelps Dodge Refining Corporation) and SNARC; one label claim close to completion: control of Ichthyophthirius on channel catfish in earthen ponds with no outflows.

Progress on copper sulfate (May 15, 2003 to November 9, 2003):

- The representative for Phelps Dodge Refining Corporation is now David Fisher.

- SNARC had the data audit completed on the target animal safety study on channel catfish and is in the process of developing the final report for submission.

Current status of technical sections on copper sulfate:

- *Product Chemistry*—CVM accepted as complete from the sponsor, Phelps Dodge Refining Corporation.

- *Mammalian Safety*—CVM accepted as complete from the sponsor, Phelps Dodge Refining Corporation; FOI summary written by CVM on March 3, 2000.
- *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 addressed the use of copper sulfate in ponds was completed and will be incorporated into a revised EA and submitted to CVM.
- *Human Food Safety*—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 additional target animal safety studies with a histopathology component are requested by CVM for an all fish label claim. SNARC performed such a study on channel catfish and will submit it to CVM.
- *Efficacy*—CVM accepted as complete from SNARC the efficacy technical section for control of Ichthyophthirius on all fish. SNARC also conducted pivotal efficacy studies to control fungi on catfish eggs.

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

- On September 2, 2003, the sponsor, Syngenta Crop Protection, Inc., held a conference call with NRSP-7 and the to discuss the product chemistry issues and potential ways of resolving them.

- On October 2, 2003, Syngenta Crop Protection, Inc. declared that the senior management could not support the development of their diquat product for aquaculture use because of the requirement to manufacture its product under Good Manufacturing Practices.

Enrofloxacin (oral antibacterial)—Status: INADs inactive in the United States because of fluoroquinolone and antimicrobial resistance issues; no sponsor interest.

Erythromycin (oral antibacterial)—Status: A sponsor is available for erythromycin—Bimeda Inc.; most technical sections submitted except sponsor product chemistry; risk assessment needed on potential for disease resistance in humans and hazard in the environment (to complete the Environmental Safety and Human Food Safety Technical Sections); near NADA approval for bacterial kidney disease in salmonids if can resolve the antimicrobial resistance issue.

- Recently, Bimeda Inc. agreed to become the NADA sponsor of erythromycin when the data packages are accepted by CVM.

- Studies are underway at the University of Idaho to (1) understand the extent of erythromycin resistant microflora in the GI tract of fish following treatment with erythromycin and (2) address the fate of erythromycin in sediment ponds with a history of erythromycin treatment. A risk assessment document will follow these studies.

Florfenicol (oral antibacterial)—Status: The sponsor, Schering-Plough Animal Health, gained florfenicol (Aquaflor®) approval in Canada in August 1997 to control furunculosis in Atlantic salmon; sponsor is developing data for aquaculture approval for control of diseases in salmonids and catfish; was a Federal-State Aquaculture Drug Approval Partnership Project drug and now under development by the sponsor, UMESC, and AADAPP; three label claims close to completion: control of (1) enteric septicemia in catfish, (2) coldwater disease in freshwater-reared salmonids and (3) furunculosis in freshwater-reared salmonids.

Progress on florfenicol (May 15, 2003 to November 9, 2003):

- On August 7, 2003, CVM accepted as complete the AADAPP efficacy data for the control of coldwater disease in all freshwater-reared salmonids.

- In the fall 2003, CVM accepted as complete the sponsor's target animal safety data on salmonids.

- On November 8, 2003, the National Aquaculture NADA Coordinator provided the sponsor with information on veterinarians who could prescribe Aquaflor® when it gains approval as a Veterinary Feed Directive drug for its use to control enteric septicemia in catfish.

Current status of technical sections on florfenicol:

- *Product Chemistry*—Accepted by CVM.
- *Mammalian Safety*—Accepted by CVM.
- *Environmental Safety*—submitted by sponsor.
- *Human Food Safety*—human food safety package for catfish—accepted by CVM; for salmonids—submitted by sponsor; microbial food safety for all fish—accepted by CVM.
- *Target Animal Safety*—CVM accepted as complete from Schering-Plough Animal Health (and conducted by UMESC) the target animal safety technical section on channel catfish; salmonids—accepted.
- *Efficacy*—enteric septicemia in catfish from the sponsor—accepted; coldwater disease in salmonids from AADAPP—accepted; UMESC validated methods to analyze for florfenicol in finfish feeds to support efficacy studies at AADAPP; AADAPP submitted efficacy studies to CVM on systemic columnaris disease and furunculosis in salmonids and streptococcal septicemia in hybrid striped bass.

Formalin (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 mortalities associated with saprolegniasis on all fish.

Progress on formalin (MAY 15, 2003 TO November 9, 2003):

- Recently both the CVM Office of Research and UMESC completed pivotal efficacy studies for control of saprolegniasis on salmonids and channel catfish. Final reports are being developed for submission to CVM that would request a "all fish" label claim.

- The National Aquaculture NADA Coordinator worked extensively with a sponsor on a manufacturer for formalin.

Current status of technical sections on formalin:

- P*roduct Chemistry*—Accepted by CVM.
- *Mammalian Safety*—Accepted by CVM.
- *Environmental Safety*—Accepted by CVM.
- *Human Food Safety*—Accepted by CVM.
- *Target Animal Safety*—Accepted by CVM.
- *Efficacy*—CVM informally accepted supporting efficacy for control of saprolegniasis on salmonids from FWS and UMESC efforts.

Fumagillin (microsporidiosis control)—Status: No recent sponsor activity; several efforts to collect efficacy data in public and private sector; early development stage.

Hydrogen peroxide (external microbicide)—Status: Currently considered as a low regulatory priority drug for use as a fungicide on fish and fish eggs but CVM has encouraged the development of a NADA; was a Federal-State Aquaculture Drug Approval Partnership Project drug and now under development by the sponsor (Eka Chemicals Inc.) and UMESC; four label claims close to completion: control of mortalities from (1) saprolegniasis on all finfish eggs, (2) saprolegniasis on all finfish, (3) bacterial gill disease on all freshwater-reared salmonids, and (4) external columnaris disease on all freshwater-reared coolwater finfish and channel catfish.

Progress on hydrogen peroxide (MAY 15, 2003 TO November 9, 2003):

- On June 25, 2003, the National Aquaculture NADA Coordinator revised the hydrogen peroxide label to reflect the latest thinking on the label claims that can be supported and submitted it to the sponsor.

- On June 30, 2003, Eka Chemicals, Inc. submitted a revised product chemistry package to CVM to answer the remaining questions on manufacture of hydrogen peroxide.

- In November 2003, CVM accepted as complete the efficacy data from UMESC for the control of mortalities associated with external columnaris disease on coolwater fish and channel catfish.

- UMESC recently completed pivotal efficacy studies to control mortalities associated with saprolegniasis on rainbow trout and channel catfish and is in the process of writing up the final reports.

- UMESC is conducting the pivotal 21-day Daphnia study requested by CVM to complete the Environmental Safety Technical Section.

Current status of technical sections on hydrogen peroxide:

- *Product Chemistry*—Sponsor, Eka Chemicals, Inc., submitted product chemistry technical section on July 12, 1999, a revised package on June 30, 2002, and another revised package on June 30, 2003 after gaining clarification from CVM in a meeting on March 13, 2003.
- *Mammalian Safety*—Accepted by CVM. The FOI summary was written by CVM on March 22, 2000.
- *Environmental Safety*—A model was developed by UMESC to estimate discharged environmental concentrations based on UMESC hatchery survey and a point source dilution model from the U.S. Geological Survey. UMESC wrote an environmental assessment to support an all fish label claim and submitted it to CVM on March 14, 2000 and the final review by CVM was completed on June 24, 2002. CVM required a 21-day chronic toxicity study on daphnia and reformatting of the environmental assessment.
- *Human Food Safety*—Accepted by CVM. The FOI summary was written by CVM on March 22, 2000--no tolerances, regulatory methods, or withdrawal times are needed for finfish and their eggs treated with hydrogen peroxide.
- *Target Animal Safety*—CVM accepted as complete the target animal safety technical section on all finfish from UMESC and the target animal safety technical section for all finfish eggs from UMESC.
- *Efficacy*—CVM accepted as complete from UMESC the efficacy technical sections for the control of mortalities associated with (1) saprolegniasis on all salmonid eggs by a 15-minute treatment at 500 mg/L of hydrogen peroxide, (2) saprolegniasis on all coldwater and coolwater finfish eggs, (3) bacterial gill disease on all freshwater-reared salmonids by a 60-minute treatment at 50 mg/L or 30-minute treatment at 100 mg/L, (4) external columnaris disease on all coldwater by a 60-minute treatment at 50 mg/L, and (5) external columnaris disease on channel catfish by 60-minutes treatments of 50, 75, and 100 mg/L. CVM accepted from UMESC the following as supporting data: (1) 60-minute treatments to control mortalities associated with external columnaris disease in yellow perch that allowed an all coolwater fish label claim when combined with the pivotal efficacy study with walleye and (2) treatment of external parasitic infestations on all salmonids. UMESC submitted efficacy reports on the control of saprolegniasis on a variety of warmwater finfish eggs (February 25, 2003); UMESC completed pivotal efficacy studies to control mortalities associated with saprolegniasis on rainbow trout and channel catfish.

MelaFix™ (external microbicide)—Status: Have sponsor; early development stage

Oxytetracycline (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 a Federal-State Aquaculture Drug Approval Partnership Project drug and now under development by the sponsor (Phibro Animal Health, formerly Pfizer, Inc.), UMESC, and AADAPP; two label claims close to completion: control of mortalities associated with (1) systemic columnaris disease in selected freshwater-reared salmonids and (2) systemic coldwater disease in all freshwater-reared salmonids.

Progress on oral oxytetracycline (MAY 15, 2003 TO November 9, 2003):

- The National Aquaculture NADA Coordinator interacted with the sponsor to ensure that they were committed to an NADA when all the technical sections for supplemental NADAs are accepted and complete. CVM provided updates on oral OTC requirements.

- In October 2003, CVM accepted the Freedom of Information (FOI) as complete for the control by oral OTC of coldwater disease in all freshwater-reared salmonids.

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).
- *Mammalian Safety*—Previously accepted by CVM under original NADA from Pfizer, Inc. (now owned by Phibro Animal Health).
- *Environmental Safety*—Previously accepted by CVM under original NADA from Pfizer, Inc. (now owned by Phibro Animal Health). CVM is requiring a new EA for any new label claims. UMESC is in the process of writing the EA. UMESC is preparing under contract with the University of Wisconsin-Madison a model to describe the fate of oxytetracycline released into the environment from aquaculture facilities. Validation of the estimated model concentrations will be conducted at an aquaculture facility and the results will be submitted as an amendment to the environmental assessment report.
- *Human Food Safety*—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) an 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. UMESC submitted a letter package addressing the antimicrobial resistance issues with human food safety; CVM replied that a microbial food safety assessment is required.
- *Target Animal Safety*—Previously accepted by CVM for catfish, salmonids, and lobsters under original NADA from Pfizer, Inc. Target animal safety studies conducted according to Good Laboratory Practice regulations are required for cool water fish because there are no adequate pivotal and supporting efficacy studies on these additional species to demonstrate that OTC is safe. UMESC conducted these studies and submitted them to CVM (February 19, 2003).
- *Efficacy*—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 AADAPP the efficacy technical section the use of OTC at 3.75 g/ 100 lbs of fish for 10 days as effective in reducing mortalities 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.

Oxytetracycline (OTC, immersion antibacterial and marking aid)—Status: No current sponsor for antibacterial use; however, potential immersion OTC sponsor available for marking; four label claims close to completion: (1) marking all fish and control of mortalities associated with (2) bacterial gill disease, (3) external columnaris disease, and (4) systemic columnaris disease on coolwater and warmwater fish.

Progress on immersion OTC (MAY 15, 2003 TO November 9, 2003):

- UMESC is conducting pivotal efficacy studies on coolwater and warmwater fish for control of mortalities associated with (1) bacterial gill disease, (2) external columnaris disease, and (3) systemic columnaris disease.

- Potential sponsor submitted to CVM a supplemental NADA for OTC use as a marking aid that is in the final stages of approval.

Current status of technical sections on immersion OTC:

- *Product Chemistry*—Accepted by CVM.
- *Mammalian Safety*—Accepted by CVM.
- *Environmental Safety*—Accepted by CVM for marking by immersion from NRSP-7.
- *Human Food Safety*—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. Pivotal efficacy studies underway by UMESC on coolwater and warmwater fish for control of (1) bacterial gill disease, (2) external columnaris disease, and (3) systemic columnaris disease.

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

Potassium Permanganate (external microbicide)—Status: Was a Federal-State Aquaculture Drug Approval Partnership Project drug and now under development by the sponsor (Carus Chemical Company) and SNARC; label claim in progress: control of Ichthyophthirius on channel catfish in earthen ponds with no outflows

Progress on potassium permanganate (MAY 15, 2003 TO November 9, 2003):

- The National Aquaculture NADA Coordinator worked with the sponsor on the product chemistry revision.

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).
- *Mammalian Safety*—Accepted by CVM.
- *Environmental Safety*—The sponsor submitted a request for a categorical exclusion from an environmental assessment for all fish to CVM on February 23, 1998; CVM is requiring an environmental assessment. Efforts at Arkansas State University began in January 2002 on environmental fate and effects studies with funding from the Multi-State Conservation Grant Program.
- *Human Food Safety*—CVM accepted as complete from SNARC the human food safety technical section.
- *Target Animal Safety*—SNARC completed a target animal safety study on channel catfish.
- *Efficacy*—SNARC completed pivotal efficacy studies that demonstrate efficacy to prevent Ichthyophthirius on channel catfish and tilapia. SNARC completed controlled efficacy studies for control of Ichthyophthirius on channel catfish and tilapia. A pivotal efficacy study is planned when seasonal water temperatures are optimal for control of Ichthyophthirius on channel catfish.

Praziquantel (trematode and cestode control)—Status: Some interest on the part of potential sponsor in a NADA approval in the United States but needs positive marketing information; 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 enteric septicemia in catfish 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, 2003 TO November 9, 2003):

- The sponsor resolved the palatability problems with Romet-TC® Type B medicated feed and submitted information to CVM. In November 2003, CVM declared that no supplemental NADA would be required.

- The National Aquaculture NADA Coordinator worked extensively with the sponsor and CVM to help in the process of gaining acceptance by CVM of the resolution of the palatability problems with Romet-TC®.

Current status of technical sections on ROMET®:

- *Product Chemistry*—Accepted by CVM.
- *Mammalian Safety*—Accepted by CVM.
- *Environmental Safety*—Accepted by CVM.
- *Human Food Safety*—Accepted for catfish and salmonids by CVM.
- *Target Animal Safety*—Accepted for catfish and salmonids by CVM.
- *Efficacy*—Accepted for control of enteric septicemia in catfish 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 enteric septicemia in catfish 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 IAFWA Project stakeholders.

Sea Lice Control (various drugs and pesticides)—Status: Various drugs and pesticides (azamethiphos or Salmosan™, cypermethrin or Excis™) are being pursued by the United States and Canada and are at various stages of registration and 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 obtained in 1998 for control of predaceous insects.

ANESTHETICS

AQUI-S®—Status: Was a Federal-State Aquaculture Drug Approval Partnership Project drug and now under development by the sponsor (AQUI-S New Zealand LTD.), UMESC, and AADAPP; label claim in progress: zero withdrawal anesthetic in salmonids

Progress on AQUI-S® (May 15, 2003 TO November 9, 2003):

- From May 29 to June 3, 2003, the National Aquaculture NADA Coordinator hosted a representative from AQUI-S® New Zealand prior to the meeting with CVM and discussed strategies for approval. Both saw a presentation by UMESC on the status of the residue chemistry studies on AQUI-S®.

- On June 3, 2003, the sponsor and its U.S. representative along with UMESC and the National Aquaculture NADA Coordinator met with CVM to discuss the data requirements for product chemistry and human food safety of AQUI-S®. A major topic of discussion was the need to clarify the ratio of isomers in the formulation before any human food safety studies begin.

- On July 29, 2003, the U.S. representative of the sponsor, UMESC, AADAPP, and the National Aquaculture NADA Coordinator met in Bozeman, Montana to discuss the potential need for a large amount of radiolabeled material and how to fund the purchase of the material. UMESC is conducting a series of pilot studies to further delineate the design of the total residue depletion study so that the exact amount of radiolabeled material needed for the study is known.

- AADAPP submitted three efficacy studies on AQUI-S® for the following species: (1) shortnose sturgeon on September 4, 2003, (2) coho salmon on October 2, 2003, and (3) largemouth bass on October 17, 2003.

- The National Aquaculture NADA Coordinator is working with the sponsor to develop a Research and Development Plan for the approval of AQUI-S® in the United States. The plan should be in place soon.

- The National Aquaculture NADA Coordinator and UMESC are collaborating on a preliminary proposal for funding the radiolabeled material for the total residue depletion study on rainbow trout, a surrogate for all salmonids.

- The National Aquaculture NADA Coordinator is working on a white paper for AQUI-S®.

Current status of technical sections on AQUI-S®:

- *Product Chemistry*—Accepted elsewhere; no current activity for U.S.
- *Mammalian Safety*—The sponsor (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 National Toxicology Program (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 will be completed in Spring 2004. The sponsor 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 original active ingredient based on their assessment of scientific data that the active ingredient is not a carcinogen.
- *Environmental Safety*—The sponsor submitted a summary to CVM and has completed environmental biodegradation studies in freshwater and saltwater that will soon be submitted to CVM for review.
- *Human Food Safety*— UMESC is conducting a series of pilot studies to further delineate the design of the total residue depletion study so that the exact amount of radiolabeled material needed for the study is known. UMESC is planning to conduct a pivotal total residue depletion study after the pilot studies are completed and radiolabeled material has been obtained. The National Aquaculture NADA Coordinator and UMESC are collaborating on a preliminary proposal for funding the radiolabeled material for the total residue depletion study on rainbow trout, a surrogate for all salmonids.
- *Target Animal Safety*—Preliminary toxicity studies have been completed at UMESC on a variety of fish species but UMESC will not perform any other studies because funds were diverted to fulfill the need for human food safety studies. Pivotal target animal safety studies on salmonids will be performed by AADAPP. AADAPP will soon submit a protocol for these studies to CVM. The

sponsor is preparing to submit to CVM target animal safety and efficacy studies on Atlantic salmon completed in Canada.
- *Efficacy*—Preliminary efficacy studies were completed at UMESC on a variety of fish species. Pivotal efficacy studies will be performed by AADAPP on a variety of fish species but UMESC will not perform any other studies because funds were diverted to fulfill the need for human food safety studies. The sponsor is ready to submit to CVM pivotal efficacy studies on Atlantic salmon completed in Canada. AADAPP has submitted eight efficacy studies on a variety of species from January 1, 2003 to November 9, 2003.

Benzocaine—Status: Major effort by IAFWA Project for NADA approval terminated because of decision by IAFWA 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.

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, 2003 to November 9, 2003):

- The sponsor has not decided to pursue a response to CVM request for a revision of its product chemistry technical section on CCP.

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 not decided to pursue a response.
- *Mammalian Safety*—Accepted by CVM.
- *Environmental Safety*—Accepted by CVM.
- *Human Food Safety*—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. Mississippi State University completed target animal safety studies on CCP and is in the process of submitting them to CVM.
- *Efficacy*—Accepted as complete from NRSP-7 by CVM as a spawning aid in freshwater-reared female finfish (July 17, 2002).

Human Chorionic Gonadotropin (hCG)—Status: September 1999 NADA approval in the United States. 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. This approval is significant because it is the first original NADA approval since 1986 when formalin was first approved for fish and because it was approved for all fish.

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

17 α-methyltestosterone (MT)—Status: Sponsor, Rangen, Inc., is developing NADA package; INAD sponsors actively pursuing a NADA approval; one label claim close to completion: gender manipulation aid for tilapia

Progress on MT (May 15, 2003 to November 9, 2003):

- The National Aquaculture NADA Coordinator developed the announcement for biodegradation and stability studies to be funded by the North Central Regional Aquaculture Center that was sent to prospective contractors on August 29, 2003. A potential contractor was selected and is in the process of developing the protocols for the studies.

- On August 1, 2003, Cornell University submitted to CVM two final reports on MT: (1) use of MT for sex reversal (masculinization) of early life stage tilapia and (2) animal safety of MT to tilapia.

- The National Aquaculture NADA Coordinator continued to work toward a MT INAD for ornamentals with the University of Florida and CVM.

Current status of technical sections on MT:

- *Product Chemistry*—The sponsor, Rangen, Inc., submitted a product chemistry technical section on MT to CVM on November 8, 2000. CVM is requiring more information, stability studies, and an analytical method with greater recoveries.
- *Mammalian Safety*—Accepted by CVM.
- *Environmental Safety*—Auburn University received a response from CVM on November 8, 1999 regarding the revised environmental assessment for MT that requested additional information, a biodegradation study, and a more sensitive method to detect MT in water.
- *Human Food Safety*—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.
- *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 is in the process of completing the final report for submission to CVM; North Central Regional Aquaculture Center representatives are coordinating a compassionate INAD on percids.

Ovaplant™ and **Ovaprim™**—Status: Sponsor recently submitted INAD letter of intent; early development stage.

CHEMICAL MARKING AGENTS

Calcein—Status: Have sponsor (Western Chemicals Inc.); early development stage.

Oxytetracycline (immersion)—Status: Public Master File from NRSP-7 accepted by CVM; one label claim close to completion: marking aid by immersion for all fish

- A potential sponsor has submitted a supplemental NADA for this label claim and it is in the final stages of approval.

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

PISCICIDES--Both rotenone and antimycin are used by hatcheries in resource agencies and private aquaculture facilities to control diseases in cultured fish and undesirable fish in ponds.

- The National Aquaculture NADA Coordinator hosted a meeting July 23-27, 2003 to discuss (1) a training course on the use of piscicides, (2) Standard Operating Procedures manual for antimycin.

- Members of the Fish Management Chemicals Subcommittee (FMCS) provided a training course on the use of piscicides on October 27-31, 2003.

PUBLIC INFORMATION, WORKSHOPS AND PRESENTATIONS

Federal-State Aquaculture Drug Approval Partnership Project (IAFWA Project)–includes eight drugs: AQUI-S®, chloramine-T, copper sulfate, florfenicol, formalin, hydrogen peroxide, oxytetracycline, and potassium permanganate)

AADAPP hosted the 9th Annual INAD Workshop on July 30-31, 2003 that centered on the progress being made on the drugs in the Federal-State Aquaculture Drug Approval Partnership Project (a project under the auspices of the International Association of Fish and Wildlife Agencies=IAFWA; project known as the IAFWA Project). The presentations included (1) progress being made on the IAFWA Project drugs, (2) public fish production database availability, (3) overviews of activities by AADAPP, SNARC, USDA's Agriculture Research Service (ARS), UMESC, CVM's Office of Research, CVM's Aquaculture Drugs Team, Washington offices for FWS, USGS/BRD, ARS, (4) other drugs under development including erythromycin, calcein, N-Halamine, Romet®, Pyceze®, MinnCare®, diquat, and (5) update on the Minor Use Minor Species (MUMS) legislation. As a result of the meeting, the public fish production database was made available on the website for the National Aquaculture NADA Coordinator (http://ag.ansc.purdue.edu/aquanic/jsa/aquadrugs/index.htm).

The IAFWA Drug Approval Working Group (DAWG) held a meeting on September 10, 2003 in Madison, Wisconsin. The National Aquaculture NADA Coordinator provided a report on (1) the status of IAFWA Project drugs toward initial approval, (2) funding needs for the position, and (3) future plans for expanding and extending existing label claims. Each research facility (i.e., AADAPP and UMESC) provided a status report for the current research year. CVM reported that, from the agency's perspective, great progress has been made on the IAFWA Project drugs. The USGS prepared a draft Memorandum of Understanding for the IAFWA Project agencies (USGS, ARS, FWS, IAFWA, and Michigan State University). In a post-DAWG meeting, the group discussed the (1) format of future DAWG meetings, (2) funding needs for AQUI-S®, (3) funding the public sector activities of the National Aquaculture NADA Coordinator, and (4) future research efforts.

When Bob Miles retired as IAFWA Resources Director in July 2003, Eric Schwaab replaced him.

Funding Needs

The National Aquaculture NADA Coordinator is in the process of finalizing a white paper on the funding needs for this position. The paper includes (1) the justification for funding from the public aquaculture sector, (2) a two-year budget, (3) scheduled activities, and (4) potential products for the period of October 1, 2003 to September 30, 2006. The National Aquaculture NADA Coordinator went to three-quarter time due to lack of funds starting October 1, 2003.

EPA Effluent Guidelines Plan

The Aquaculture Effluents Task Force (AETF) was formed to coordinate and facilitate input of science-based information to assist in the development of national effluent limitation guidelines and standards for aquaculture facilities by EPA. AETF, in this time period, (1) provided EPA with documents of the judicious use of drugs and chemicals and (2) held a teleconference with EPA and the different subgroups on May 27, 2003 to discuss remaining issues and set a course of action on effluents. EPA officials met with CVM to work toward a Memorandum of Agreement to distinguish their respective legal authorities and establish an effective mechanism to address the discharge of drugs. The Drugs and Chemicals and Aquatic Animal Pathogens Technical Subgroup (1) responded to EPA questions on drugs on May 21, 2003 and (2) provided EPA on July 10, 2003 with actual volume figures for antibiotic sales in the US in 2001 and 2002 to counteract the impression that tons of antibiotics are used in US aquaculture [Note: The National Aquaculture NADA Coordinator was one of the authors].

EPA developed a draft Notice of Data Availability (NODA) and distributed copies to federal agencies in September 2003. The NODA will be published in the Federal Register in the fall 2003. The final rule is scheduled for signature by EPA in June 2004.

Minor Use Minor Species Legislation

A bill originally entitled "Minor Animal Species Health and Welfare Act of 2000" was renamed and reintroduced into Congress as "Minor Use Minor Species Animal Health Act" in 2001, 2002, and now in 2003. It was reintroduced in the U.S. Congress into the House as (HR-2079 and into the Senate (S-741). The MUMS Act will facilitate and accelerate the approvals of aquaculture drugs. The bill includes provisions for early life stages that should help expedite the approvals of aquaculture drugs that are of interest to public and private fish production.

The National Aquaculture NADA Coordinator sent e-mails to state fish chiefs on July 3, 2003 to urge them to support the MUMS legislation and counteract the misinformation being transmitted by opponents to the bill.

MUMS legislation passed the Senate HELP Committee in November 2003 and there is hope that passage in the full Senate will occur soon.

On October 22, 2003, the National Aquaculture NADA Coordinator met with CVM's Aquaculture Drugs Team to (1) provide historical background to the efforts to gaining approval of drugs for aquaculture and (2) provide the status of drug approvals from the industries' perspective. The new CVM reviewer, Ruth Barratt, attended the meeting.

Technical Committee/Research Reappointment

The National Aquaculture NADA Coordinator was reappointed to the Technical Committee/Research Subcommittee of the North Central Regional Aquaculture Center.

PUBLICATIONS, MANUSCRIPTS, PAPERS PRESENTED, AND SPECIAL REPORTS

PUBLICATIONS

MacMillan, J.R., R.A. Schnick, and G. Fornshell. In press. U.S. aquaculture. Alliance for the Prudent Use of Antibiotics, Facts about Antibiotics in Animals and their Impact on Resistance (FAAIR) Project..

PAPERS PRESENTED

Schnick, R.A. 2003. Progress toward aquaculture drug approvals. National Association of State Aquaculture Coordinators, Seattle, Washington, June 11-14, 2003.

Schnick, R.A. 2003. Overview of progress toward aquaculture drug approvals. USFWS 9th Annual INAD Coordination Workshop, Bozeman, Montana, July 30-31, 2003.

Schnick, R.A. 2003. Initial or supplemental New Animal Drug Application (NADA) approvals for Federal-State Aquaculture Drug Approval Partnership Project. USFWS 9th Annual INAD Coordination Workshop, Bozeman, Montana, July 30-31, 2003.

Schnick, R.A. 2003. Chemical and drug use in aquaculture. International Association for Food Protection, New Orleans, Louisiana, August 10-13, 2003.

Schnick, R.A. 2003. Overview of progress toward aquaculture drug approvals. American Veterinary Medical Association Aquaculture and Seafood Advisory Committee, Chicago, Illinois, September 5-6, 2003.

Schnick, R.A. 2003. Status of each IAFWA Project drug toward initial approval. Drug Approval Working Group Meeting, Madison, Wisconsin, September 10, 2003.

Schnick, R.A. 2003. Possible future label claim needs. Drug Approval Working Group Meeting, Madison, Wisconsin, September 10, 2003.

Schnick, R.A. 2003. Future activities and funding needs for the National Coordinator for Aquaculture New Animal Drug Applications. Drug Approval Working Group Meeting, Madison, Wisconsin, September 10, 2003.

Schnick, R.A. 2003. Progress toward aquaculture drug approvals. NRSP-7 Fall Meeting, Rockville, Maryland, September 15-16, 2003.

Schnick, R.A. 2003. Historical efforts to gain drug approvals. Aquaculture Drugs Team, Center for Veterinary Medicine, Rockville, Maryland, October 22, 2003.

Schnick, R.A. 2003. Overview Federal-State Aquaculture Drug Approval Partnership Project. Joint Subcommittee on Aquaculture, Silver Spring, Maryland, October 23, 2003.

SPECIAL REPORTS

Schnick, R.A. 2003. National Coordinator for Aquaculture New Animal Drug Applications (NADAs). Eighth annual report of activities, May 15, 2002 to May 14, 2003. Submitted to Ted Batterson, North Central Regional Aquaculture Center, East Lansing, Michigan. June 6, 2003. 20 pp.

Schnick, R.A. 2003. Draft label claim for 35% hydrogen peroxide (Perox-Aid®). Submitted to Eka Chemicals Inc. June 25, 2003. 5 pp.

MacMillan, J.R., R.A. Schnick, and G. Fornshell. 2003. Volume of antibiotics sold (2001 and 2002) in US domestic aquaculture industry. Submitted to Gary Jensen for forwarding to EPA. July 10, 2003. 6 pp.

Schnick, R.A. 2003. 2003 annual report of the AFS Task Force on Fishery Chemicals. Submitted to the Governing Board and AFS President, Fred Harris, Bethesda, Maryland. July 13, 2003. 9 pp.

Schnick, R.A. 2003. Call for Statements of Interest: Drug Approval Research on 17 α-methyltestosterone. Submitted to Ted Batterson, North Central Regional Aquaculture Center for distribution to potential contractors. August 29, 2003. 4 pp.

Schnick, R.A. 2003. Minutes to Drug Approval Working Group Meeting, Madison, Wisconsin, September 10, 2003. Submitted to Drug Approval Working Group. October 15, 2003. 13 pp.

Schnick, R.A. 2003. Status of drug approval for 17 α-methyltestosterone. Forwarded to interested parties. October 2, 2003. 4 pp.

Schnick, R.A. 2003. Initial or supplemental New Animal Drug Application (NADA) approvals for Federal-State Aquaculture Drug Approval Partnership Project. Handout to selected CVM staff. October 31, 2003. 10 pp.