

Memorandum of Agreement

Between the Federal Agencies

**DEPARTMENT OF THE INTERIOR, U.S. GEOLOGICAL SURVEY;
DEPARTMENT OF THE INTERIOR, U.S. FISH & WILDLIFE SERVICE;**

and the

Non-Governmental Organization

INTERNATIONAL ASSOCIATION OF FISH AND WILDLIFE AGENCIES;

and the designated

National Coordinator for Aquaculture New Animal Drug Applications (NADA)

OBJECTIVES:

This Memorandum of Agreement establishes and describes responsibilities and facilitates cooperation between the Department of the Interior's U.S. Fish and Wildlife Service (FWS), the Department of the Interior's U.S. Geological Survey (USGS), the National Coordinator for Aquaculture New Animal Drug Applications (NCANADA), and the International Association of Fish and Wildlife Agencies (IAFWA) to collaborate on research, field tests, data collection, data analysis, and data submittals to the U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM) for approval of priority drugs for use in public and private aquaculture in the United States. The USGS, FWS, NCANADA and IAFWA are herein referred to as Partners.

APPROACH:

In 1994, USGS, FWS, and the IAFWA, on behalf of 38 participating states, developed a 5-year cooperative initiative to fund and carry out research directed both toward gaining approval of eight high priority aquaculture drugs (seven therapeutants and one anesthetic) and to demonstrate the concept of crop grouping. The initiative was formally named the Federal-State Aquaculture Drug Approval Partnership Project, but has been referred to as the IAFWA Project. The focus of the IAFWA Project was to conduct research and submit technical section data to CVM for approval of priority aquaculture drugs. The research targeted development of New Animal Drug Application (NADA) approvals or extensions of existing NADA approvals for the aforementioned eight priority drugs. In 1999, the agreement between the aforementioned parties, which later included the U.S. Department of Agriculture's Agriculture Research Service, was extended for three years in order to complete data requirements and address changes in program direction. The IAFWA Project concluded in September 2002.

During the eight years of effort, three label claims were approved and tremendous progress was made in advancing 17 new label claims for six drugs to the point of near completion and approval by the CVM. State partners within the IAFWA Project, as well as other public agencies and private aquaculture interests in the U.S., identified the need to complete the label claim process and gain final approval of these important aquaculture drugs, and the need of additional research on other promising aquaculture drugs. Building on the project's unique and important eight-year foundation, the aforementioned agencies and the IAWFA, which represents the States' interest through its Drug Approval Working Group (DAWG) of the Fisheries and Water Resources Policy Committee,

are establishing a new partnership to follow through on the final label claim process and to obtain additional new animal drug approvals for aquaculture use. Work conducted by the Partners relative to the stated objectives of this Memorandum of Agreement, is herein collectively referred to as work under the "Project".

Signatories to this agreement will collaborate in joint efforts to ensure that efficient administrative and scientific efforts are conducted to accomplish the objectives of this agreement.

STATEMENT OF MUTUAL INTEREST:

All Partners are actively engaged in either the conduct or coordination of independent research projects designed to obtain approval of priority drugs for use in aquaculture. The focus of this agreement is to address both the immediate tactical and long-term strategic drug needs of the aquaculture community. The Partners agree that meeting the objectives will benefit all Partners, and will strengthen and enhance ongoing research within the scope of this agreement.

The focus of this agreement includes, but is not limited to the:

1. development of a coordinated multi-entity effort;
2. establishment of both short and long-term work plans; short-term plans will have a specific focus (e.g., an NADA for a specific, or potentially narrow, label claim);
3. development of methods for timely communication of progress and status (including impediments) among Partners;
4. development and submission of drug-specific data sets to CVM to support NADAs for use in aquaculture production;
5. development of mechanisms for the dissemination of Project progress and status to the aquaculture community; and
6. assistance in the establishment of effluent standards to ensure responsible use of drugs and chemicals in aquaculture.

THE PARTNERS AGREE TO:

Collaborate in joint efforts to ensure that efficient administrative and scientific efforts are conducted to accomplish the objectives of this Memorandum of Agreement. General responsibilities of individual Partners are as follows, specific responsibilities are outlined in Table 1.

The Department of the Interior's U.S. Fish and Wildlife Service will:

- a. Provide funding support and program guidance to the Aquatic Animal Drug Approval Partnership (AADAP) Program, Bozeman, MT for aquaculture drug approval coordination activities, Investigational New Animal Drug (INAD) exemptions' administration, aquaculture-related drug research, data analysis, and data submission using appropriated funds (as available).
- b. Specifically, the AADAP will perform the following types of coordination, administration and research activities as jointly agreed upon by the DAWG and all Partners:
 - assist jointly with other Partners in the coordination of efforts toward approval of all initial IAFWA Project drugs;

- assist jointly with other Partners in the coordination of efforts toward future supplemental NADA approvals of IAFWA Project drugs;
- assist jointly with other Partners in the coordination of NADA efforts for specific, non-IAFWA Projects drugs that are of interest to public and/or private sector aquaculture;
- continue to interact directly with pharmaceutical sponsors to determine data requirements, establish data generation and submission timelines, and exchange information as necessary to facilitate completion of NADAs;
- perform pivotal efficacy studies;
- perform target animal safety studies;
- prepare data summaries, as required by FDA, to assist the FDA in preparation in Freedom of Information (FOI) summaries;
- coordinate and administer compassionate INADs for data generation and use by federal, state, tribal and private aquaculture agencies/facilities;
- coordinate information transfer and dissemination with respect to Project progress and status; and
- submit data and final study reports to CVM.

The Department of the Interior's U. S. Geological Survey will:

- a. Provide funding support and program guidance to the Upper Midwest Environmental Sciences Center (UMESC), La Crosse, WI, and other Science Centers as appropriate, for aquaculture-related drug research, data analysis, and data submission using appropriated funds (as available).
- b. Specifically, the UMESC will perform the following types of research activities, relative to initial IAFWA Project drugs and new aquaculture drugs as jointly agreed upon by the DAWG and all Partners:
 - assist jointly with other Partners in the coordination of efforts toward approval of all initial IAFWA Project drugs, and future supplemental NADA approvals;
 - assist jointly with other Partners in the coordination of NADA efforts for specific, non-IAFWA Projects drugs that are of interest to public and/or private sector aquaculture;
 - continue to interact directly with pharmaceutical sponsors to determine data requirements, establish data generation and submission timelines, and exchange information as necessary to facilitate completion of NADAs;
 - conduct research to develop and validate disease models to support and perform laboratory-based clinical efficacy studies;
 - perform target animal safety studies;
 - perform human food safety studies (e.g., total and marker residue depletion studies) on Project drugs;
 - develop environmental assessments of aquaculture drug safety;

- develop, conduct, and validate appropriate aquaculture environmental drug fate and effect research and drug effluent models;
- conduct research to support the concept of crop grouping of fishes;
- prepare data summaries, as required by FDA, to assist the FDA in preparation of Freedom of Information (FOI) summaries; and
- submit data and final study reports to CVM.

The National Coordinator for Aquaculture New Animal Drug Applications will:

- a. continue coordinating efforts toward initial NADA approvals of IAFWA Project drugs; identifying current status and remaining data requirements for the approval of these drugs;
- b. continue coordinating the efforts toward future supplemental NADA approvals of IAFWA Project drugs;
- c. coordinate NADA efforts for specific, non-IAFWA Project drugs that are of interest to public and/or private sector aquaculture; identifying current status and remaining data requirements for the approval of these drugs;
- d. serve as liaison and information conduit between various researchers and CVM;
- e. coordinate with pharmaceutical sponsors to maintain current, and generate new, interest in NADAs, aid sponsors in developing the final NADA packages for submission; and seek the support and participation of sponsors to provide product chemistry data, product labeling, and financial support for NADA development; and
- f. on a semi-annual basis, review, assemble and provide consolidated information on the Project's status to the DAWG.

The International Association of Fish and Wildlife Agencies will:

- a. represent the states' aquaculture drug interests and needs;
- b. represent the interests of state natural resource agencies in drug development for public aquaculture and provide advice through the DAWG;
- c. via an independent peer review panel, provide or assist in potential funding (when possible) for aquaculture drug research through the Multi-State Conservation Grants Program and/or other funding sources;
- d. ensure that Drug Approval Multi-State Conservation Grants are reviewed by an independent panel on an annual basis; and
- e. work to partially fund the National Coordinator for Aquaculture New Animal Drug Applications, who receives guidance from the DAWG.

Table 1 Specific Roles and Responsibilities of the Collaborators to the Memorandum of Agreement to Establish Joint Efforts and Facilitate Coordination of Research for the Approval of Priority Drugs for Use in Public and Private Aquaculture in the United States

Agency/Organization	Specific Roles and Responsibilities	Obligation ¹
USFWS AADAP	Assist jointly with other Partners in the coordination of efforts toward approval of all initial IAFWA Project drugs	Shared
	Assist jointly with other Partners in the coordination of efforts toward future supplemental NADA approvals of IAFWA Project drugs	Shared
	Assist jointly with other Partners in the coordination of NADA efforts for specific, non-IAFWA Projects drugs that are of interest to public and/or private sector aquaculture	Shared
	Continue to interact directly with pharmaceutical sponsors to determine data requirements, establish data generation and submission timelines, and exchange information as necessary to facilitate completion of NADAs	Shared
	Perform pivotal field efficacy studies	Primary
	Perform target animal safety studies	Shared
	Prepare data summaries, as required by FDA, to assist the FDA in preparation of Freedom of Information (FOI) summaries	Shared
	Coordinate and administer compassionate INADs for data generation and use by federal, state, tribal and private aquaculture agencies/facilities	Primary
	Coordinate information transfer and dissemination with respect to Project progress and status	Primary
	Submit data and final study reports to CVM	Shared
USGS UMESC	Assist jointly with other Partners in the coordination of efforts toward approval of all initial IAFWA Project drugs, and future supplemental NADA approvals;	Shared
	Assist jointly with other Partners in the coordination of NADA efforts for specific, non-IAFWA Projects drugs that are of interest to public and/or private sector aquaculture	Shared
	Continue to interact directly with pharmaceutical sponsors to determine data requirements, establish data generation and submission timelines, and exchange information as necessary to facilitate completion of NADAs	Shared
	Conduct research to develop and validate disease models to support and perform laboratory-based clinical efficacy studies	Primary
	Perform target animal safety studies	Shared
	Perform human food safety studies (e.g., total and marker residue depletion studies) on Project drugs	Primary
	Develop environmental assessments of aquaculture drug safety	Primary
	Develop, conduct, and validate appropriate aquaculture environmental drug fate and effect research and drug effluent models	Primary
	Conduct research to support the concept of crop grouping of fishes	Primary
	Prepare data summaries, as required by FDA, to assist the FDA in preparation of Freedom of Information (FOI) summaries	Shared
Submit data and final study reports to CVM	Shared	
IAFWA	Represent the states' aquaculture drug interests and needs	Primary
	Oversee Project direction and provide guidance through the Drug Approval Working Group (DAWG)	Primary
	Provide/assist in potential funding for drug research through the Multi-State Conservation grants program and/or other funding sources	Primary
	Ensure that Drug Approval Multi-State Conservation Grants are reviewed by an independent panel on an annual basis	Primary
	Work to support a position for a National Coordinator for Aquaculture New Animal Drug Applications, who receives guidance from the DAWG	Primary
National Coordinator for Aquaculture NADAs	Continue coordinating efforts toward initial NADA approvals of IAFWA Project drugs, identify current status and remaining data requirements for the approval of these drugs	Primary
	Continue coordinating the efforts toward future supplemental NADA approvals of IAFWA Project drugs	Shared
	Coordinate NADA efforts for specific, non-IAFWA Project drugs that are of interest to public and/or private sector aquaculture; identify current status and remaining data requirements for the approval of these drugs	Shared
	Serve as liaison and information conduit between researchers and CVM	Primary
	Coordinate with pharmaceutical sponsors to maintain current, and generate new, interest in NADAs; aid sponsors in developing the final NADA packages for submission; seek support and participation of sponsors to provide product data, labeling, and financial support for NADA development	Primary
	Bi-annually review, assemble, and provide consolidated information on the status of Project efforts to the DAWG	Primary

Footnotes: 1. Primary obligations are those for which the identified entity has lead responsibility. Shared obligations are those for which two of more entities share lead responsibilities and will work collaboratively.

MUTUAL AGREEMENTS:

1. This Memorandum of Agreement establishes the cooperative management and research framework for the Project.
2. No funds will be obligated or authorized under this agreement. Identification of funding will be the responsibility of each Partner within the guidelines of their respective Agency/Department or organization. Nothing in this agreement shall be contrary to the provisions of the Anti-Deficiency Act.
3. Specific obligations to be accomplished under this Memorandum of Agreement will be accomplished by each Partner in accordance with their respective organization's or Agency/Department's rules and regulations.
4. All Partners shall provide office space, laboratory space and equipment needed for the completion of identified Project work.
5. Table 1 delineates specific responsibilities of all Partners as being either "primary" or "shared". Primary responsibilities indicate that the identified party has the lead responsibility for that function. Shared responsibilities indicate that two or more parties have shared lead responsibility and will work cooperatively on these functions.
6. The details of the cooperative work shall be planned and executed jointly by the applicable Partners. Outlines covering working plans and procedural methods shall be prepared jointly subject to revision by joint action as work progress requires. Copies of these plans, as required, will be filed with applicable Partners.
7. A report of the results of the research and experimental work shall be submitted by all Partners each year to the DAWG and the National Coordinator for Aquaculture NADAs.
8. Patents and Inventions: Partners will comply with the laws, regulations, policies and guidelines of their respective Department/Agency or organization.

REVISION AND TERMINATION:

This Memorandum of Agreement may be revised as necessary by the mutual consent of the signatories via the adoption of a written amendment signed and dated by the parties. Any party may terminate their involvement in this Memorandum of Agreement by providing 60 days notice to the DAWG committee. This Memorandum of Agreement will expire five years from the date of signing by all parties.

SIGNATORIES TO THE MEMORANDUM OF AGREEMENT:

This Memorandum of Agreement may specifically be expanded to include other Partners, with the mutual consent of current Partners, via a written amendment signed and dated by all parties.

SIGNATURES:

On witness thereof, this Memorandum of Agreement is effective as of the last date shown below.



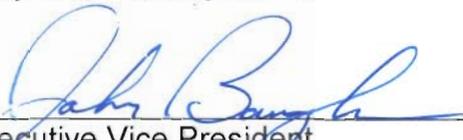
Director
DOI, U.S. Fish & Wildlife Service

10/25/05
Date



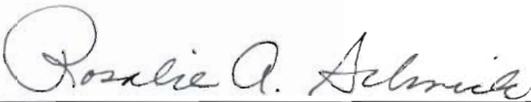
Associate Director
DOI, U.S. Geological Survey

11/22/05
Date



Executive Vice President
International Association of Fish and Wildlife Agencies

12/6/05
Date



National Coordinator for Aquaculture New Animal Drug Applications

1/3/06
Date