

**Agreement #NMFSAFWAOAQ-1-2020**

**Memorandum of Agreement**

*Between the Federal Agencies*

**DEPARTMENT OF COMMERCE, NATIONAL OCEANIC  
AND ATMOSPHERIC ADMINISTRATION, NATIONAL MARINE FISHERIES SERVICE;  
DEPARTMENT OF THE INTERIOR, U.S. FISH & WILDLIFE SERVICE;  
DEPARTMENT OF THE INTERIOR, U.S. GEOLOGICAL SURVEY**

*and the*

*Non-Governmental Organization*

**ASSOCIATION OF FISH AND WILDLIFE AGENCIES**

**I. OBJECTIVES:**

This Memorandum of Agreement (MOA) establishes and describes responsibilities, and facilitates cooperation among the Department of Commerce's National Oceanic and Atmospheric Administration–National Marine Fisheries Service (NOAA-NMFS), the Department of the Interior's (DOI) U.S. Fish and Wildlife Service (FWS) and U.S. Geological Survey (USGS), and the Association of Fish and Wildlife Agencies (AFWA), to coordinate and collaborate on research and data submittals to the U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) for approval of priority drugs for use in public aquaculture in the United States. NOAA-NMFS, the FWS, the USGS, and AFWA are herein referred to as Partners. This agreement supersedes any previous agreement among the parties for this purpose.

**II. AUTHORITIES:**

Authority is granted for this agreement under the provisions of the National Aquaculture Act of 1980 (as amended at 16 USCS §§ 2801-2810(2011)). NOAA-NMFS is authorized to enter into this agreement pursuant to section 5(a) of the National Aquaculture Act (16 U.S.C. 2804(a)) and the Fish and Wildlife Coordination Act (16 U.S.C. 661 *et seq.*) The FWS is authorized to enter this agreement under provisions of the Fish and Wildlife Coordination Act (16 U.S.C. 661 *et seq.*) and the Fish and Wildlife Act of 1956 (16 U.S.C. 742f. *et seq.*). The USGS authority to enter into this MOA is pursuant to Public Law 99-591 that bestows permanent authority on the USGS to “prosecute projects in cooperation with other agencies, Federal, State, and private” (43 U.S.C. 36c), and the USGS Organic Act of March 3, 1879, as amended (43 U.S.C. 31 *et seq.*).

**III. BACKGROUND:**

In 1994, AFWA (at the time, known as the International Association of Fish and Wildlife Agencies), on behalf of 38 participating States, developed a 5-year cooperative initiative with the FWS and the USGS to fund and carry out research directed toward gaining approval of eight high priority aquaculture drugs (seven therapeutic agents and one anesthetic) identified by State and Federal agencies. The initiative was formally named the Federal-State Aquaculture Drug Approval Partnership Project but has been since referred to as the “AFWA Project.” The focus of the AFWA Project was to coordinate and conduct research for submission of data to the CVM for approval of priority aquaculture drugs. The research targeted development of New Animal Drug Applications (NADAs) or extensions of existing NADAs for the eight priority aquaculture drugs. In 1999, the AFWA Project, which later included the U.S. Department of Agriculture's Agricultural Research Service (USDA-ARS), was extended for three years

to complete data requirements and address changes in program direction. This phase of the AFWA Project concluded in September 2002.

Between 1999 and 2002, the partners were able to finalize three aquaculture drug label claims and advance 17 others for CVM approval. Building upon the AFWA Project's success since its inception in 1994, a new AFWA Project MOA was established and signed in 2005 to continue these collaborative efforts under the leadership of the Drug Approval Working Group (DAWG) of AFWA's Fisheries and Water Resources Policy Committee. The DAWG functions as a coalition of State and Federal agency interests that facilitates sharing of information and identifies common objectives focused on the development of aquatic animal drugs and therapeutic agents for CVM approval. State members (typically five, one serving as Chair) are selected by the AFWA Fisheries and Water Resources Policy Committee to represent the diversity of aquaculture settings across State natural resource agencies. Federal members of the DAWG include representatives of NOAA-NMFS, FWS, USGS, FDA-CVM, and USDA-ARS.

The primary objectives of the DAWG are to: (1) prioritize pathogens or diseases that cause serious challenges to State and Federal aquaculture programs and for which there is currently no effective drug to control that disease/pathogen, and (2) facilitate coordination of research by Federal agencies to develop data required to obtain approval of drugs that may control important diseases/pathogens of fish reared by Federal and State aquaculture programs. By coordinating through the DAWG, Federal Partners are better able to identify important pathogens which need to be controlled (and thus make more informed decisions on priority drugs), to identify treatment regimens that are reasonable given current technology available to most Federal or State aquaculture programs, and generally to make more informed decisions on how best to focus their aquaculture drug-related research.

The most recent MOA, which went into effect in October 10, 2012, and expired on October 12, 2017, modified the 2005 MOA to address; 1) the dissolution (in April 2010) of the non-government affiliated position of the National Coordinator for Aquaculture New Animal Drug Applications (a signatory of the 2005 MOA), and 2) the identified need to include representation by NOAA-NMFS. This new MOA is being established to continue, under the leadership of the DAWG, the important collaborative freshwater and marine aquatic animals (invertebrate and vertebrate) drug approval work described above.

Work conducted by the Partners relative to the stated objectives of this MOA (as defined below in the Statement of Mutual Interest), is herein collectively referred to as work under the AFWA Project. This MOA establishes the cooperative management and research framework for the AFWA Project. Signatories to this agreement will collaborate in joint efforts to encourage the conduct of efficient, coordinated administrative and scientific efforts that support the objectives of the AFWA Project.

#### **IV. STATEMENT OF MUTUAL INTEREST:**

All Partners are actively engaged in the conduct or coordination of drug registration research or have agency management responsibilities for aquaculture. The Partners recognize the need to coordinate their efforts to efficiently obtain approval of priority drugs for use in public and private aquaculture. The focus of this MOA is to address both the immediate and long-term drug and therapeutic needs of the aquaculture community. The Partners agree that meeting the following specific objectives will benefit all Partners as well as the United States aquaculture community in general. Meeting these specific objectives will strengthen and enhance ongoing research and collaboration among the Partners within the scope of this MOA.

The specific objectives of this agreement include, but are not limited to, the coordination and maintenance of multi-entity effort that;

1. Establishes short- and long-term work plans; short-term plans will have a specific focus, such as securing a NADA for a specific drug label claim, long-term plans will focus on the selection of priority drugs;
2. Develops an agreement on methods required for the timely communication of progress and status among Partners;
3. Submits drug-specific data sets to the CVM to support NADAs for priority drugs for use in U.S. aquaculture;
4. Communicates to the aquaculture community the AFWA Project progress and methods to safely and judiciously use aquaculture drugs; and
5. Identifies and develops potential funding sources to support aquaculture drug research including the responsible management of funding sources (other than agency appropriated funds) through a collaborative process.

## **V. RESPONSIBILITIES OF THE PARTNERS:**

The Partners agree to collaborate in joint efforts to encourage the conduct of efficient administrative and scientific efforts in order to accomplish the objectives of this MOA. General responsibilities of individual Partners are as follows.

### **A. NOAA-NMFS will endeavor to:**

1. Coordinate and perform research to support the management of aquatic animal health in United States aquaculture. The primary focus of NOAA-NMFS's activities will be marine aquaculture but may extend to freshwater aquaculture as situations dictate;
2. Specifically, NOAA-NMFS will seek to perform the following types of coordination, administration, and research activities as jointly discussed and agreed upon within the DAWG and among all Partners:
  - a. Coordinate with other Partners and pharmaceutical sponsors on efforts to develop the steps in the process required to obtain new (or supplemental) approvals of current or future AFWA Project priority drugs;
  - b. Coordinate with pharmaceutical sponsors to maintain current, and generate new, interest in NADAs; aid sponsors in developing final NADA packages for submission; and seek the support and participation of sponsors to provide data relevant to NADA technical sections, product labeling, and financial support for NADA development. 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;
  - c. Perform (as expertise is available) drug approval related studies associated with NADAs;
  - d. Submit final study reports to the CVM and assist the CVM in the preparation of Freedom of Information Act (FOIA) summaries; and

- e. Assist in information transfer and dissemination of AFWA Project progress and status among Partners and to the aquaculture community.
- f. Conduct research in cooperation with partners to identify or test novel compounds that may be useful for the prevention or control of infectious diseases of aquatic animals.

B. The FWS will endeavor to:

1. Strengthen and enhance ongoing research and collaboration among the Partners for aquaculture drug approval activities. Through the Aquatic Animal Drug Approval Partnership (AADAP) Program, Bozeman, Montana, the FWS will conduct activities such as Investigational New Animal Drug (INAD) exemptions administration; aquaculture-related drug research, data analysis, and data submission; and transfer and dissemination of aquaculture drug-related information, to the extent that resources and funding are available;
2. Specifically, the FWS will seek to perform the following types of coordination, administration, and research activities as jointly discussed and agreed upon within the DAWG and among all Partners:
  - a. Coordinate with other Partners and pharmaceutical sponsors on efforts to develop the steps in the process required to obtain new (or supplemental) approvals of current or future AFWA Project priority drugs;
  - b. Coordinate with pharmaceutical sponsors to maintain current, and generate new, interest in NADAs; aid sponsors in developing final NADA packages for submission; and seek the support and participation of sponsors to provide data relevant to NADA technical sections, product labeling, and financial support for NADA development. 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;
  - c. Perform (as expertise is available) drug approval related studies associated with NADAs;
  - d. Submit final study reports to the CVM and assist the CVM in the preparation of FOIA summaries;
  - e. Coordinate and administer INADs for data generation and use by Federal, State, and tribal agencies, as well as private aquaculture facilities;
  - f. Coordinate information transfer and dissemination of AFWA Project progress and status among Partners and to the aquaculture community; and
  - g. Conduct research in cooperation with partners to identify or test novel compounds that may be useful for the prevention or control of infectious diseases of aquatic animals.

C. The USGS will endeavor to:

1. Coordinate and perform research to support the management of aquatic animal health in United States aquaculture. The Upper Midwest Environmental Sciences Center (UMESC) in, La Crosse, Wisconsin, and other USGS Science Centers with expertise will conduct research, including analysis and submission of data, to evaluate the use of drugs and other materials needed to support the health of aquatic animals reared in freshwater and marine aquaculture;
2. Specifically, UMESC, and other USGS Science Centers as appropriate, will seek to perform the following types of coordination, administration, and research activities as jointly discussed and agreed upon within the DAWG and among all Partners:
  - a. Coordinate with other Partners and pharmaceutical sponsors on efforts to develop the steps in the process required to obtain new (or supplemental) approvals of current or future AFWA Project priority drugs;
  - b. Coordinate with pharmaceutical sponsors to maintain current, and generate new, interest in NADAs; aid sponsors in developing final NADA packages for submission; and seek the support and participation of sponsors to provide data relevant to NADA technical sections, product labeling, and financial support for NADA development. 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;
  - c. Perform (as expertise is available) drug approval related studies associated with NADAs;
  - d. Submit final study reports to the CVM and assist the CVM in the preparation of FOIA summaries; and
  - e. Assist in information transfer and dissemination of AFWA Project progress and status among Partners and to the aquaculture community.
  - f. Conduct research in cooperation with partners to identify or test novel compounds that may be useful for the prevention or control of infectious diseases of aquatic animals.

D. AFWA will endeavor to:

1. Represent the interests of State natural resource agencies in drug development for public aquaculture and provide leadership through the DAWG;
2. Support aquaculture drug approval activities for the AFWA Project priority drugs. AFWA may also serve as the fiscal agent for funds developed or obtained to support the drug approval process;
3. Appoint an AFWA member of the Fisheries and Water Resources Committee to serve as Chairman of the DAWG;

4. Organize and convene a biannual meeting of the DAWG;
5. Coordinate efforts to develop the steps in the process required to obtain new (or supplemental) approvals of current or future AFWA Project priority drugs;
6. Coordinate information transfer and dissemination of AFWA Project progress and status among Partners and to the aquaculture community; and
7. Serve as a liaison and information conduit among collaborative researchers.

## **VI. SPECIAL PROVISIONS:**

- A. Nothing in this MOA may be construed to obligate NOAA-NMFS, the FWS, the USGS, or the United States to any current or future expenditure of resources in advance of the availability of appropriations from Congress. Nor does this MOA obligate NOAA-NMFS, the FWS, the USGS, or the United States to spend funds on any particular project or purpose, even if funds are available.
- B. This MOA in no way restricts NOAA-NMFS, the FWS, or the USGS from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals.
- C. The Partners will comply with the Federal Advisory Committee Act to the extent it applies.
- D. Specific obligations to be accomplished under this MOA will be accomplished by each Partner in accordance with their respective Agency/Department's or organization's statutory authority, regulations, policies, and availability of funding.
- E. As funding permits, all Partners shall endeavor to provide office space, laboratory space, and equipment needed for the completion of identified AFWA Project work.
- F. The details of the cooperative work shall be planned and executed in conjunction with the applicable Partners. Outlines covering work plans and procedural methods shall be shared and discussed among the Partners.
- G. A report of the results of the research and experimental work shall be provided by all Partners biannually to the DAWG.
- H. Patents and inventions: Partners will comply with the laws, regulations, policies, and guidelines of their respective Department/Agency or organization.
- I. All Partners will obtain prior approval of all press releases, published advertisements, or other statements intended for the public that refer to this agreement or to NOAA-NMFS, the FWS, or the USGS, the Departments of the Interior or Commerce, or the name or title of any employee of either Department in connection with this MOA.
- J. Nothing in this MOA may be interpreted to imply that the United States, the Departments of the Interior or Commerce, NOAA-NMFS, the FWS, or the USGS, endorse any product, service or policy of AFWA. AFWA will not take any action or make any statement that suggests or implies such an endorsement.

## **VII. REVISION AND TERMINATION:**

This MOA may be revised as necessary by the mutual consent of the signatories via the adoption of a written amendment signed and dated by the Partners. Any Partner may terminate their involvement in this MOA by providing 60 days' notice to other signatories. This MOA will expire five years from the signing date of the last Partner to sign the MOA.

## **VIII. SIGNATORIES TO THE MOA:**

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

### **SIGNATURES:**

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

 4/20/2023

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Director, DOI, U.S. Fish & Wildlife Service

JAMES D.  
APPLEGATE

Digitally signed by JAMES D.  
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Date: 2023.01.17 13:05:35 -05'00'

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Director, DOI, U.S. Geological Survey

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Assistant Administrator for Fisheries  
National Marine Fisheries Service/NOAA, Department of Commerce

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Executive Director, Association of Fish and Wildlife Agencies