

AGREEMENT

between

THE U.S. FISH AND WILDLIFE SERVICE

and

(AGENCY/ORGANIZATION)¹

I. INTRODUCTION

The (Agency/Organization), hereinafter referred to as the XXXX, joins with the U.S. Fish & Wildlife Service (Service) to develop, implement, manage, and maintain national investigational new animal drug (INAD) exemptions required for the use of certain drugs, therapeutants, and chemicals that are needed for disease control and product quality in aquaculture programs, in compliance with U. S. Food and Drug Administration (FDA) regulations and responsibilities set forth under 21 CFR 511 and section 512(j) of the Federal Food, Drug and Cosmetic Act. Therefore, this Agreement is made, and entered into, between the Service and the XXXX.

II. PURPOSE

This Agreement establishes obligations to be met and procedures to be followed by the Service and all Cooperators to establish and maintain cooperative INADs to enable the use of certain drugs and chemicals under the compassionate INAD process as set forth by the FDA. This Agreement defines general and specific obligations of the parties and summarizes the roles of the Service and Cooperators. The goal of this Agreement is to consolidate the INAD process, eliminate duplication of effort, reduce workloads and costs, ensure needed drugs, chemicals, and therapeutants are made available to all aquaculture programs in the United States, ensure compliance with FDA guidelines, and ensure the submission of data that is necessary for future drug approval and labeling.

All INAD exemptions under the National INAD Project will be developed and administered by a National INAD Project Coordinator (Coordinator) and staff at the Service's National INAD Office, Bozeman, MT. National INAD Project oversight and direction, including funding oversight will be provided by the Service's INAD Sponsor, through the Chief, Division of National Fish Hatcheries.

¹ Where the term "Agency/Organization" appears in the heading and the first line of the "Introduction", insert the standard name of the participating agency or organization; thereafter insert the short title or standard abbreviation in the remainder of this Agreement wherever this term indicates.

III. PERIOD OF PERFORMANCE

The period of performance of this Agreement begins on the date of signing of this Agreement by both parties and extends for an indefinite period thereafter as mutually agreed upon by the signatory parties. This Agreement becomes effective upon the date of signature by the Service Sponsor.

IV. AUTHORITY

U. S. Fish and Wildlife Service: This Agreement is hereby made and entered into by and between the Service and the **XXXX** under the authority of the Economy Act 31 U.S.C. 1535, the Intergovernmental Cooperation Act 31 U. S. C. 6505, the Fish and Wildlife Coordination Act 16 U.S.C. 661-667, and the Fish and Wildlife Act 16 U.S.C. 742 F.

(Agency/Organization): This Agreement is hereby made and entered into by and between the MDFWP and the Service under the authority of the

(Note: Use this space to list the statutes (if applicable) authorizing the Agency/Organization to enter into an agreement of this kind.)

V. DEFINITIONS

For purposes of this Agreement, the term --

- A. "Agreement" means this signed Agreement between the U.S. Fish and Wildlife Service and an agency/organization to join together under the U.S. Fish & Wildlife Service's National INAD Project to develop, implement, manage, and maintain national investigational new animal drug exemptions required for the use of certain drugs, therapeutants, and chemicals that are needed for disease control and product quality in aquaculture programs, in compliance with U. S. Food and Drug Administration (FDA) regulations and responsibilities set forth under 21 CFR 511 and section 512(j) of the Federal Food, Drug and Cosmetic Act;
- B. "Annual" means the time period of January 1 through December 31;
- C. "Chief, Division of National Fish Hatcheries" means the Service office or representative responsible for providing leadership, direction, funding oversight, and concurrence on Service INAD activities;
- D. "Coordinator" means the National INAD Project Coordinator, who is Chief of the Service's National INAD Office and who is responsible for developing and

- administering national INAD exemptions for the use of unapproved therapeutants needed to control certain fish diseases and maintain product quality;
- E. "Cooperators" means those Federal, State, Tribal, university, and private aquaculture programs signing this Agreement to participate in the National INAD Project;
 - F. "FDA" means the U. S. Food and Drug Administration;
 - G. "Fish" means any fish or fish eggs of any size, age, or species;
 - H. "Hatchery" means any geographically distinct fish cultural facility where fish or fish eggs are held or reared at any time during the Period of Performance of this Agreement;
 - I. "INAD" means compassionate investigational new animal drug exemption as defined by the FDA;
 - J. "INAD Project Officer" means the Cooperator's representative who is responsible for providing oversight and administration of, and compliance with, National INAD Project Agreement requirements, including any FDA-imposed requirements for drug or chemical accountability, data collection, reporting or restrictions on drug withdrawal periods following the treatment of fish, or environmental restrictions on the discharge of therapeutants in hatchery effluents;
 - K. "National INAD Project" means the U.S. Fish and Wildlife Service program established to coordinate and administer the activities of Federal, State, Tribal, university, and private aquaculture programs with respect to participation on Service compassionate investigational new animal drug exemptions that are required for the use of certain drugs, therapeutants, and chemicals needed for disease control and product quality management;
 - L. "National INAD Project Office" means the Bozeman National INAD Office;
 - M. "Project Area" means the entire geographic area of the United States of America, and includes all 50 States of the United States of America, all United States of America Territories, and all Native American Tribes located within the 50 States of the United States of America and all United States of America Territories;
 - N. "Service" means the U.S. Fish and Wildlife Service; and
 - O. "Service's INAD Sponsor" means the Assistant Director - Fisheries or his/her representative responsible for providing administrative oversight of Service INAD activities.

VI. OBLIGATIONS OF THE PARTIES

A. THE ~~XXXX~~ SHALL:

1. Ensure that the individual signing this Agreement is an official directly responsible for the administration or oversight of all Cooperator employees that will be using therapeutants in compliance with all conditions specified in this Agreement and in any INAD exemption including any FDA-imposed requirements for drug or chemical accountability, data collection, reporting or restrictions on drug withdrawal periods following the treatment of fish, or environmental restrictions on the discharge of therapeutants in hatchery effluents.
2. During the “open season” sign-up period, from October 15 to December 31, notify the Coordinator of the facilities and fish species to be listed in each INAD during the coming calendar year (January 1 through December 31).
3. Pay to the Service the required funding amount identified by the Service for each hatchery to be listed on each individual INAD exemption. A summary of the costs and payment conditions are addressed in Section IX.
4. Designate to the National INAD Project Coordinator, and keep current, the name, address, telephone and facsimile numbers of the individual assigned the duties of ~~XXXX~~ INAD Project Officer and the names of all individuals designated as monitors and as investigators for clinical field trials and meeting the criteria for monitors set forth in the FDA guidelines for the *Conduct of Clinical Investigations: Responsibilities of Clinical Investigators and Monitors for Investigational New Animal Drug Studies* dated October 1992 or later.
5. Provide in a timely manner, all required site data, fish stock information, fish release or use information relative to human food safety, anticipated drug levels in hatchery effluents, National Pollutant Discharge Elimination System (NPDES) data, and other information necessary for FDA approval of National INAD exemption applications.
6. Monitor the use of investigational new animal drugs at their hatcheries in accordance with INAD Study Protocols including proper storage, labeling, handling, dispensing, inventory control, record keeping, and reporting of data relating to the use and control of investigational new animal drugs in clinical investigations authorized by National INAD Project INAD exemptions sponsored by the Service.

7. Indemnification -

- a. The **XXXX** hereby indemnifies and holds harmless the National INAD Project Coordinator; Chief, Division of National Fish Hatcheries; Service Sponsor; and Service from all claims and liabilities of any person or entity resulting from acts or omissions by the MDFWP arising under or relating to this Agreement.
- b. The Service hereby indemnifies and holds harmless the **XXXX** from all claims and liabilities of any person or entity resulting from acts or omissions by the Service arising under or related to this Agreement.

8. Insurance -

- a. Each *non-governmental party* to this Agreement shall acquire and maintain general liability, directors and officers, and employment practices insurance in the amount of \$1,000,000 for acts and omissions arising out of or related to this Agreement.

B. THE SERVICE SHALL:

Administer and manage the National INAD Project under the direction and supervision of the Service's INAD Sponsor; and, maintain a National INAD Project Coordinator and sufficient staff to manage and administer INADs for Cooperators in the project area, prepare applications for INAD exemptions, and collect and submit to the FDA any necessary reports.

1. In regard to project management, the National INAD Project Coordinator shall, among other required activities:
 - Hold an "open season" from October 15 to December 31 each year to allow Cooperators an opportunity to provide information on facilities and fish species to be listed in each INAD during the coming calendar year (January 1 through December 31).
 - Work with all National INAD Project Cooperators to implement the obligations of this Agreement;
 - Maintain liaison between National INAD Project Cooperators and the FDA;

- Develop, and submit to the FDA, National INAD Project INAD requests and reports;
 - Comply with all FDA regulations pertaining to the administration and implementation of INADs;
 - Serve as administrator for each National INAD;
 - Maintain liaison with the Service's INAD Sponsor and Chief, Division of National Fish Hatcheries;
 - Interact with scientists performing research studies on therapeutants covered by National INAD Project INADs to ensure the earliest possible FDA approval of New Animal Drug Applications (NADAs);
 - Communicate national needs and priorities to the National New Animal Drug Approval Coordinator, the FDA, and the Joint Subcommittee on Aquaculture to advance the drug approval and labeling process; and,
 - Supervise staff required to carry out National INAD Project responsibilities.
2. In regard to project administration, the National INAD Project Coordinator shall provide office space, equipment and personnel support for administration of the National INAD Project which will be funded by Cooperator payments.

VII. COMPLIANCE

Compliance with FDA accountability, record keeping, and data collection and submission is paramount. Prompt payment of funding and submission of information required for INAD management by Cooperators is also essential. Non-compliance with these requirements can jeopardize the National INAD Project and FDA's renewal of INADs. In the event of confirmed non-compliance, this Agreement shall be immediately terminated by the Service and no further use of investigational new animal drugs will be allowed under the INADs covered by this Agreement. For the purposes of this paragraph, non-compliance includes, but is not limited to, the non-payment of required funding amounts, misuse of therapeutants, non-compliance with data record keeping or data submission guidelines, or non-compliance with human food safety, worker safety, or environmental protection specifications in INAD exemptions granted by the FDA.

VIII. PROJECT OFFICERS

A. NATIONAL INAD PROJECT OFFICER for the **XXXX** is:

_____ (Name, Title)
_____ (Agency/Organization)
_____ (Address)
_____ (City, State, Zip)
_____ (Area code/Phone)
_____ (Fax Number)
_____ (E-mail address)

B. NATIONAL INAD PROJECT COORDINATOR for the Service is:

Dr. Dave Erdahl
National INAD Office
Bozeman Fish Technology Center
U. S. Fish and Wildlife Service
4050 Bridger Canyon Road
Bozeman, MT 59715
Ph. 1-406-587-9265 Ext. 125; FAX: 1-406-582-0242
E-mail: dave_erdahl@fws.gov

IX. FUNDING AND PAYMENTS

With the exception of the initial sign-up period of January 1, 1999 through April 1, 1999, Cooperators will be billed in advance by the Service as described in Section VI. A. 3. of this Agreement. Cost for participation by non-Service entities on Service INADs will be \$400 per INAD per facility per calendar year. In addition, there will be a one-time \$100 initiation fee for all participating facilities. This fee also applies to the re-entry of facilities that have previously withdrawn from National INAD Project enrollment. Upon both parties acknowledging their concurrence with this Agreement, the Service will issue an advance billing for the work to be performed. Payments must be received in order to initiate the services.

Although it is not anticipated at this time, cost for participation in subsequent calendar years may be subject to change. Additionally in subsequent years, a \$100 late fee may be assessed for payment received after January 31.

If actual program costs change from as described above, the attached Amendment form will be used. An Amendment to the Agreement's cost structure requires the written concurrence of both parties.

X. MODIFICATION

This Agreement may not be waived, discharged or modified in any manner other than by written agreement of the parties.

XI. TERMINATION

This Agreement may be terminated by either party without cause 60 days following written notice to the other party.

XII. CONCURRENCE

FOR THE (AGENCY/ORGANIZATION)

By: _____ Date: _____
(Signature)

(Title)

FOR THE U.S. FISH AND WILDLIFE SERVICE

By: _____ Date: _____
(Signature)

Assistant Director — Fisheries
(Title)

AMENDMENT

to the

AGREEMENT

between

THE U.S. FISH AND WILDLIFE SERVICE

and

(AGENCY/ORGANIZATION)

The following sections of the Agreement are amended:

IX. FUNDING AND PAYMENTS

The original estimated costs of participation by non-Service entities on Service INADs are amended to reflect the following changes as summarized below:

1. _____
2. _____
3. _____
4. _____

Cooperators will be billed in advance by the Service as described in Section VI. A. 3. of this Agreement. Upon both parties acknowledging their concurrence with this Agreement, the Service will issue an advance billing for the work to be performed. Payments must be received in order to initiate the services.

CONCURRENCE TO THE AMENDMENT

FOR THE (AGENCY/ORGANIZATION)

By: _____ Date: _____
(Signature)

(Title)

FOR THE U.S. FISH AND WILDLIFE SERVICE

By: _____ Date: _____
(Signature)

Assistant Director — Fisheries
(Title)