

AGREEMENT
between
THE U.S. FISH AND WILDLIFE SERVICE
and

(AGENCY/ORGANIZATION)

I. INTRODUCTION

The _____ (Agency/Organization), hereinafter referred to as the Cooperator, joins with the U.S. Fish & Wildlife Service (Service) to participate in the Service's National Investigational New Animal Drug (INAD) Program. INAD exemptions held by the Service allow for the legal use of specific, but currently unapproved, drugs that are critically needed for use in aquaculture and fisheries management programs throughout the U.S. INAD exemptions are authorized by the U.S. Food and Drug Administration (FDA), and require user compliance with FDA regulations and responsibilities set forth under 21 CFR 511 and section 512(j) of the Federal Food, Drug and Cosmetic Act. By participating in the National INAD Program, the Cooperator agrees to maintain INAD regulatory compliance as set forth by the FDA, and to assist the Service in generating efficacy and safety data to be used to support FDA approval of drugs being used under INAD exemption.

II. PURPOSE

This Agreement establishes obligations to be met and procedures to be followed by the Service and Cooperator to establish and maintain cooperative INADs to enable the use of certain drugs and chemicals under the 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 Cooperator. The goal of this Agreement is to consolidate the INAD process; eliminate duplication of effort; reduce workloads and costs; and ensure needed drugs are made available to aquaculture and fisheries management facilities in the United States in compliance with FDA regulations. This effort will also result in the submission of data to FDA that is necessary for future drug approval and labeling.

All INAD exemptions under the National INAD Program will be developed and administered by the Service's Aquatic Animal Drug Approval Partnership (AADAP) program, under the direction of the National INAD Program Administrator (Administrator). National INAD Program oversight and direction will be provided by the Service's Fish and Aquatic Conservation Program.

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.

IV. AUTHORITY

U. S. Fish and Wildlife Service: This Agreement is hereby made and entered into by and between the Service and the Cooperator 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 Cooperator 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.)

The two fillable spaces above are NOT required information. They are only applicable if there are statutes authorizing the Agency/Organization to enter the agreement.

V. DEFINITIONS

For purposes of this Agreement, the term --

- A. "Agreement" means this signed Agreement between the U.S. Fish and Wildlife Service and the Cooperator to join together under the U.S. Fish & Wildlife Service's National INAD Program to develop, implement, manage, and maintain national-scope INAD exemptions that allow for the use of certain critically needed drugs by aquaculture and fisheries management facilities throughout the U.S; and ensure all INAD exemptions are 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. "Administrator" means the Aquatic Animal Drug Approval Partnership Program's Branch Chief, who is responsible for developing and administering the National INAD Program to ensure the availability of drugs that are critically needed for use in aquaculture and fisheries management programs throughout the U.S.;
- C. "Cooperator" means the Federal, State, Tribal, university, or private aquaculture and/or fisheries management entity signing this Agreement to participate in the National INAD Program;

- D. "FDA" means the U. S. Food and Drug Administration;
- E. "Fish" means any fish or fish eggs of any size, age, or species;
- F. "INAD" means investigational new animal drug exemption as defined by the FDA;
- G. "INAD Program Officer" means the Cooperator's representative who is responsible for providing oversight and administration of, and compliance with, National INAD Program Agreement requirements, including any FDA-imposed requirements for drug accountability, data collection, data reporting or restrictions on drug withdrawal periods following the treatment of fish, or environmental restrictions on the discharge of drug residues in effluent;
- H. "National INAD Program" means the U.S. Fish and Wildlife Service program established to coordinate and administer the activities of Federal, State, Tribal, university, and private aquaculture and fisheries management entities with respect to participation in Service held investigational new animal drug exemptions that are required for the use of certain critically needed drugs by aquaculture and fisheries management facilities throughout the U.S.;
- I. "Program 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; and
- J. "Service" means the U.S. Fish and Wildlife Service.

VI. OBLIGATIONS OF THE PARTIES

A. The Cooperator 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 drugs in compliance with all conditions specified in this Agreement and in any INAD exemption including any FDA-imposed requirements for drug accountability, data collection, data reporting, restrictions on drug withdrawal periods following the treatment of fish, or environmental restrictions on the discharge of drug residues in hatchery effluents.
2. Pay to the Service the required funding amount identified by the Service for each aquaculture or fisheries management facility participating on each individual INAD exemption.

3. Designate to the National INAD Program Administrator, and keep current, the name, address, telephone number and email address of the individual assigned the duties of INAD Project Officer and the names of all individuals designated as Study Monitors and as Investigators for clinical field trials, and ensure that these individuals meet the criteria 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.
4. 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 effluents, National Pollutant Discharge Elimination System (NPDES) data, and other information necessary for FDA approval of National INAD exemption applications.
5. Monitor the use of investigational new animal drugs at their aquaculture and fisheries management facilities in accordance with INAD Study Protocols including proper drug 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 Program INAD exemptions sponsored by the Service.
6. 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 Program; maintain a National INAD Program Administrator and sufficient staff to manage and maintain INADs for Cooperators in the project area; prepare applications and/or amendments for both new and existing INAD exemptions; and collect and submit to the FDA all required treatment data and other mandatory facility, site, and/or watershed related information.

The National INAD Program Administrator shall:

- Allow Cooperators to sign-up for individual INADs at any time throughout the year;
- Work with all National INAD Program Cooperators to fully implement the obligations of this Agreement;

- Serve as liaison between National INAD Program Cooperators and the FDA;
- Develop and submit to the FDA all National INAD Program INAD requests, amendments, and reports;
- Comply with all FDA regulations pertaining to the administration and implementation of INADs;
- Serve as administrator for each individual INAD available under the National INAD Program;
- Interact with scientists and other collaborators performing research studies on drugs covered by National INAD Program INADs to ensure the earliest possible FDA approval of New Animal Drug Applications;
- Supervise staff required to carry out National INAD Program responsibilities; and
- Maintain liaison with the Service's Fish and Aquatic Conservation Program at Service Headquarters.

C. Indemnification

1. The Cooperator shall indemnify, save and hold harmless and defend the Department of the Interior, the Service, and its agents and employees from and against any and all liabilities, obligations, losses, damages, judgments, claims, actions, suits, penalties, fines, costs, and expenses (including reasonable attorney' fees and experts' fees) of any kind and nature arising out of acts or omissions of the Cooperator, its employees, agents and contractors (including any contractors' subcontractors). This includes injury to people (including injury resulting in death) and damage to property in connection with activities under this agreement.
2. The liability of the United States arising out of any conduct under this Agreement shall be governed by the Federal Tort Claims Act, 28 USC 2671 et seq.

VII. COMPLIANCE

Compliance with National INAD Program and FDA requirements for drug accountability, record keeping, and data collection and submission is paramount. Prompt payment of funding and submission of all information required for National INAD Program management by Cooperator

is also essential. Non-compliance with these requirements can jeopardize the National INAD Program and FDA's renewal of INADs.

Notwithstanding Section XI of this Agreement, in the event of confirmed non-compliance by a Cooperator, this Agreement shall be immediately terminated by the Service and no further use of investigational new animal drugs will be allowed by the Cooperator 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 drugs, non-compliance with data record keeping or data submission guidelines, or non-compliance with human food safety, worker safety, or environmental protection specifications as described in INAD Study Protocols and authorized by the FDA.

VIII. PROJECT OFFICERS

A. NATIONAL INAD PROGRAM OFFICER for the Cooperator is:

This person is usually the INAD monitor or someone that is familiar with the INAD Program from your agency/company.

(Name, Title of Cooperator)

(Agency/Organization)

(Address of facility)

(City, State, Zip)

(Area code/Phone)

(Email address)

B. NATIONAL INAD PROGRAM ADMINISTRATOR for the Service is:

Dr. Marilyn Blair
Aquatic Animal Drug Approval Partnership
U.S Fish and Wildlife Service
4050 Bridger Canyon Road
Bozeman, MT 59715
Phone: (406) 994-9904
Email: marilyn_j_blair@fws.gov

IX. FUNDING AND PAYMENT

Cooperator cost for participation in the National INAD Program by non-Service entities will be \$700 per INAD per aquaculture or fisheries management facility per calendar year. Under this fee structure, there will be no restrictions on the number of times drug treatment may be initiated under an INAD, nor on the number of fish treated. Cooperator will be invoiced immediately following National INAD Program sign-up. Payment must be received before drug treatment is authorized.

INAD payment will not be prorated for participants that enroll later in the calendar year. INAD payment will not be refunded for non-INAD use (i.e., if INAD drug treatment is not actually conducted).

Cost for participation in subsequent calendar years may be subject to change. If program costs change from those described above, this section of the Agreement will need to be amended, with the written concurrence of both parties, to incorporate the new fee structure.

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 Cooperator:

By: _____
(Signature)

(Title)

Date: _____

Job title of Cooperator and date agreement was signed. This is someone that is authorized to sign an agreement between your agency/company and the USFWS.

For the Service: The following will be filled out by AADAP

By: _____
(Signature)

Date: _____

National INAD Program Administrator, U.S. Fish and Wildlife Service