

National INAD Program

U.S. Fish and Wildlife Service, Aquatic Animal Drug Approval Partnership, 4050 Bridger Canyon Road,
Bozeman, MT 59715

STANDARDS FOR THE U.S. FISH AND WILDLIFE SERVICE'S NATIONAL INAD PROGRAM

PURPOSE:

The U.S. Fish and Wildlife Service's National INAD Program provides the means through which Federal, State, Tribal, and private agencies or organizations (Cooperators) located throughout the United States are allowed to use certain critical drugs necessary to maintain the health and fitness of aquatic species under Investigational New Animal Drug (INAD) exemptions. INAD exemptions are granted by the U.S. Food and Drug Administration, and are a critical tool used by fisheries managers to meet current day management objectives. INAD exemptions also contribute important drug efficacy and safety data that are used to support the future approval of new drugs for use in aquatic species.

NAME AND AFFILIATIONS:

SECTION 1. *Name:* The name of this program shall be the U.S. Fish and Wildlife Service's National INAD Program, hereafter described as the National INAD Program. The acronym "INAD" stands for Investigational New Animal Drug exemption, a process of the U. S. Food and Drug Administration that authorizes and controls the transport, possession, and use of unapproved drugs. The National INAD Program is administered by the U.S. Fish and Wildlife Service's Aquatic Animal Drug Approval Partnership (AADAP) Program located in Bozeman, MT.

SECTION 2. *Affiliations:* The National INAD Program is an official program of the U.S. Fish and Wildlife Service (Service). The National INAD Program was established to facilitate consolidation of the INAD exemption process, protect aquatic animal health, eliminate duplication of effort, reduce workloads and costs, ensure compliance with FDA regulations, and ensure the submission of efficacy and safety data necessary to support future drug approval and labeling. The National INAD Program is a cost reimbursable program established under the direction and supervision of the Service's INAD Sponsor to ensure critically needed drugs are available to all fisheries management/aquaculture programs in the United States. The INAD Sponsor (assisted by Cooperator funding) provides full administrative support for the office and staff of the National INAD Program.

PROJECT AREA, PARTICIPATION, AND FUNDING:

SECTION 1. *Program Area:* The 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.

SECTION 2. *Participation:* Participation in the National INAD Program is completely voluntary. Participants may include any public, tribal, private, or university entity located in the Program Area. Participation in the National INAD Program shall be by virtue of a written and signed Cooperative Agreement that explicitly describes FDA and National INAD Program requirements with respect to participation under Service sponsored INAD exemptions.

SECTION 3. *Funding:* The Service will assess and collect cost reimbursable funds from each non-Service agency or fisheries organization based on the number of individual facilities enrolled, and the number of individual INAD exemptions listed per facility. Cost reimbursable funding amounts will be set by the Service, and will be based on the anticipated total number of non-Service facilities participating, and the number of INADs listed for these facilities during the coming calendar year. Cost reimbursable funds will cover the actual expenses of the National INAD Program and may include, but are not limited to, funding requirements for program administrative support, data processing, evaluation, and submission, and general operating expenses. Cost reimbursable funds for a new calendar year are payable to the Service's INAD Sponsor upon receipt of an invoice. During the first year of an agencies/organizations participation in the National INAD Program, cost reimbursable funds are not refundable after June 30th of that year. For subsequent years, cost reimbursable funds will be due by December 31st of the preceding calendar year, and will not be refundable after that date.

OBJECTIVES, IMPLEMENTATION, AND COMPLIANCE:

SECTION 1. *Objectives:* The objectives of the National INAD Program are to provide a means through which Federal, State, Tribal, and private agencies or organizations located throughout the United States are 1) allowed to use certain critical drugs necessary to maintain the health and fitness of aquatic species under Investigational New Animal Drug (INAD) exemptions, and 2) contribute important drug efficacy and safety data needed to support the future approval of new drugs for use in aquatic species.

SECTION 2. *Implementation:* The National INAD Program shall establish and maintain an office and employ a professionally qualified Coordinator and necessary support staff to develop and manage the National INAD Program, ensure drug accountability, and meet all data collection and reporting requirements of the FDA.

SECTION 3. Compliance: Participants recognize the responsibilities incumbent on all parties to properly use, account for, and safe-guard investigational new animal drugs and to comply with study protocol requirements in the collection and submission of "source data" and other reports as directed. The office of the Coordinator shall monitor compliance with INAD requirements and act promptly to notify appropriate participant designated Program Officers (Program Officers are the Cooperator representatives that administer and oversee participants National INAD Program INAD activities) of deficiencies, obtain relief of such deficiencies, or suspend the authorized use of an INAD compound until such deficiencies are corrected or INAD participation for that facility is terminated.

SPONSOR:

SECTION 1. General Powers: The Service's INAD Sponsor, the Branch Chief -- Aquatic Animal Drug Approval Partnership, is the financial management and decision-making official for the National INAD Program and his/her decisions will be final. The Chief -- Division of Fisheries and Aquatic Resource Conservation, is responsible for providing leadership, direction, funding oversight, and concurrence on Service INAD activities. The Sponsor is responsible for implementing and administering day-to-day Service INAD activities, as well as establishing annual INAD-participation funding amounts and an annual budget for the National INAD Program. Further, the Sponsor and his/her representatives shall act on the recommendations of Cooperator Project Officers to approve the addition or termination of INAD exemptions, formulate INAD management and participation policy, conduct routine business of the National INAD Program, and work with the FDA, researchers, and others involved in the pursuit of new aquaculture drug approvals. However, final National INAD Program policy decisions shall rest solely with the Sponsor and his/her representatives.

SECTION 2. Annual Meeting: Each year, the Service will schedule an annual meeting for participants of the National INAD Program. A single representative to this meeting may be designated by each entity signing a National INAD Program cooperative agreement. The purpose of the meeting will be to discuss past performance, current status, and future direction of the National INAD Program. Participation at the annual meeting is invited but not mandatory.

AMENDMENTS TO THE STANDARDS

SECTION 1. Amendments to the Standards: Amendments to the Standards may be made by the Sponsor or his/her representatives. Any proposed amendment made in writing by any Cooperator will be given due consideration by the Sponsor or his/her representatives, and if warranted, the Standards will be amended accordingly. Proposed amendments should be directed to the National INAD Program Coordinator.