



U.S. Fish & Wildlife Service

The National Fish Hatchery System

The Aquatic Animal Drug Approval Partnership

New Animal Drug Approvals for Aquatic Species

Public and private aquaculture in the United States has struggled for many years because of a severe shortage of U.S. Food and Drug Administration (FDA) approved drugs and therapeutants for use in aquatic species.

Currently, only a handful of drugs is approved for use in aquatic species, and use of these compounds is restricted to only certain species and life stages. This situation has jeopardized the health and fitness of aquatic species held in captivity, many of which are key to restoration, recovery, and management activities by the Service and its many partners. Improved health and fitness of released animals serves not only to conserve valuable aquatic resources, but also enhances overall ecosystem diversity and fitness.



The Service's Aquatic Animal Drug Approval Partnership (AADAP) was established within the Service's National Fish Hatchery System to ensure continued progress towards obtaining FDA-approved and EPA-compliant new animal drug approvals for use in Federal, State, Tribal and private aquaculture programs throughout the United States.



The successful control of treatable diseases in all animals (including humans) requires that the health-care professionals have more than one drug available for any given disease, as reliance on a single drug may quickly lead to that drug becoming ineffective. Private and public aquaculturists in the U.S. now raise more than 100 species of aquatic animals. Unfortunately, FDA-approved drugs do not exist to legally treat the vast majority of these species. The AADAP will provide the means to assist all Federal, State, Tribal and private aquatic animal culturists meet their animal disease management needs. The AADAP will focus efforts on a prioritized list of new FDA-approved drugs that will be available to all qualified animal

health professionals (private or public).

The AADAP is a broad, partner-based national program. More specifically, the AADAP will lead a coordinated effort to generate data, analyze results, compile final study reports, disseminate information and data, and manage all other aspects of requisite data submissions to FDA in support of new animal drug approvals for aquatic species. The AADAP will also be responsible for coordinating drug approval activities to ensure hatchery compliance with EPA discharge regulations as they relate to drugs and chemicals.

The AADAP builds on a long-standing partnership between the Service's National INAD Office (NIO) in Bozeman, Montana and over 50 Federal, State, Tribal and/or private agencies or



organizations. The NIO administers the Service's highly successful National INAD Program, whereby both Service and non-Service participant facilities are allowed to use needed drugs and therapeutants under limited experimental conditions. The NIO's ongoing research program also generates important FDA-required data to support new animal drug approvals in cooperation with its partners.

The AADAP, with strong support and encouragement of our partners, will continue and expand on the work of the NIO, and will lead a concerted national effort to assemble the complex data packages that must be submitted to FDA to obtain a new aquatic animal drug.



Not only do AADAP activities fully support the Secretary of Interior's strategies, but they also reflect good common sense and public responsibility:

- # *conservation* - healthier fish are released to the environment and available to the public;
- # *cooperation* - partnership activities with other Federal, State, Tribal and private entities;
- # *consultation* - AADAP was developed jointly with the International Association of Fish and Wildlife Agencies and other Federal, State, Tribal and private partners;
- # *communication* - all activities will be coordinated and focused on partner-based objectives, and disseminated through a newsletter and web-page;

- # *customer value* - all new drug approvals obtained via the AADAP will be available for use by all fish culturists, not just those working at Service facilities;
- # *integration* - the AADAP integrates resources and expertise from other Federal, State, Tribal and private organizations to accomplish common goals;
- # *accountability* - all AADAP activities and generated research will be publicly available via a web-page; and
- # *modernization* - the AADAP will use the latest technologies and sound science to achieve goals and objectives.

The AADAP was developed to be consistent with the Service's seven Fisheries Vision focus areas, which in turn were developed to be consistent with the Secretary's strategies:

- # *Partnerships and Accountability;*
- # *Aquatic Species Conservation and Management;*
- # *Public Use;*
- # *Cooperation with Native Americans;*
- # *Leadership in Science and Technology;*
- # *Aquatic Habitat Conservation and Management; and*
- # *Workforce Management.*



The Service shares stewardship responsibilities for the care and preservation of our Nation's aquatic heritage with our State, Tribal and other partners. As our Nation grows, so do both direct and indirect pressures on those valuable resources. As a consequence, we

must work ever more diligently and effectively with our partners to maintain and enhance our aquatic ecosystems for the continued benefit of the American public. Captive propagation and the carefully managed release of aquatic species will continue to be an important tool in our work. To ensure the success of such



releases, and to maintain the strength and fitness of these populations and that of the ecosystems in which they interact, it is imperative that animals in our care remain as healthy as possible at all times.



The AADAP, in its role of obtaining new approved drugs and chemicals for aquatic species, is integral to the Service's successful stewardship of our natural resources for the enjoyment of all Americans.

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