

The Aquaculture Drug Approval Process



Meeting the Needs of Public & Private Fish Culture

This brochure describes the general path to *approval of an aquaculture drug*. Each drug is different - the path may vary depending on the type of compound, the route of administration, and the intended use.



All photographs courtesy of the USFWS →

How Does a Therapeutic or Production Need Become a Drug for Development?

Antibacterials Antifungals



Antiparasitics Spawning Aids

Anesthetics

Fisheries biologists, hatchery managers, veterinarians, researchers, and aquaculture specialists identify needed therapeutics and production aids.

Once needs are identified, likely drugs and chemicals are investigated as potential products. A few - based on their effectiveness, safety, relative cost, and other factors - are advanced for further study.

The Federal-State Aquaculture Drug Approval Partnership Project (known as the Association of Fish and Wildlife Agencies or AFWA Project) is the largest and most extensive aquaculture drug approval project in the US. Beginning in 1994, the project has covered the development of eight drugs.

The National Coordinator for Aquaculture New Animal Drug Applications (NADA's) helps coordinate the development of these drugs and posts a list of drugs under development on the website:

<http://aquanic.org/jsa/aquadrugs/index.htm>

Who Regulates Aquaculture Drugs and How Do They Do It?



The Food & Drug Administration's **Center for Veterinary Medicine (CVM)** approves NADA's for animal drugs.

There are five major technical sections that must be addressed for each drug.

Effectiveness

Target Animal Safety

Human Food Safety

Environmental Safety

Chemistry, Manufacturing, & Controls

For a list of *approved drugs for use in aquaculture* check out FDA/CVM's Aquaculture page at:

<http://www.fda.gov/cvm/drugsuseaqua.htm>

Investigational New Animal Drug (INAD) File

Sponsors seeking to develop data to support a new drug open an INAD file with FDA/CVM and agree to abide by the new animal drug regulations before beginning *safety and effectiveness trials*.



Preliminary work is done to *determine a safe and effective treatment regimen* for a specific drug claim, "for the control of mortality associated with..."

Substantial evidence of effectiveness must be demonstrated under **field** and/or **laboratory** conditions.



These **pivotal studies** must be conducted under *stringent conditions* and include *dose verification* and *rigorous statistical analysis of results*.

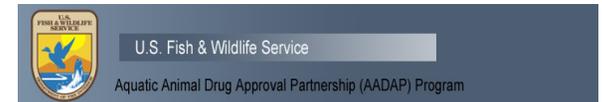


The drug must be shown to have a *margin of safety* under a *variety of conditions* often for *multiple species*.

All drugs must be *safe for their intended use and application*, and *safe for the environment*. Drugs must be *manufactured for stability, purity, and potency*. If intended for use on **any life stage of food fish**, the *edible products must be free from any harmful residues that might be harmful to humans*.

New Animal Drug Application

The **New Animal Drug Application (NADA)** is the culmination of complete data fulfilling all the technical sections. It often represents years of work and many \$\$\$. For eight aquaculture drugs a significant contribution has been made by the AFWA Project by state and federal entities that need medications to fulfill their mission of conservation and protection of fisheries resources.



US Fish and Wildlife Service, Aquatic Animal Drug Approval Partnership (AADAP) Program
<http://fisheries.fws.gov/aadap/#>



US Geological Survey,
Fishery Drug and Development Program
http://www.umesc.usgs.gov/aquatic/aquaculture_drug.html



US Department of Agriculture, Stuttgart National Aquaculture Research Center
<http://www.ars.usda.gov/Research/docs.htm?docid=7816>