

# **NAA Aquatic Animal Therapeutant, Chemical and Vaccine Policy**

## Background

Good aquatic animal health management is essential for successful aquatic animal production and should be based on integrated health management practices. These practices emphasize disease prevention and include the management of host, pathogen, and environment. Vaccines can be a useful tool to prevent disease. To help maintain a healthy environment, water treatment chemicals may be used. Disease may nevertheless occur. Therapeutants may be used to alleviate animal stress and help treat disease.

The number of therapeutants or vaccines federally approved for use in aquatic animal production is limited. The U.S. aquaculture industry is relatively small. Programs must be developed that encourage vaccine and therapeutant development.

## Policy

NAA encourages:

1. Use of federally approved vaccines, therapeutants, and water treatment chemicals by all aquatic animal producers.
2. Cooperative approaches to obtaining additional vaccine, therapeutants, or water treatment approvals for use in production and maintenance of aquatic species.
3. Educational programs that inform producers about fish health management practices and proper use of therapeutants and other aquatic animal remedies to treat aquatic animal disease.
4. Development of preventive measures (e.g. vaccines, improved breeding practices and management practices) to diminish the needs for disease treatments.
5. Development and approval of therapeutants that are efficacious, environmentally safe and economical.

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# Drug Approvals

## Background

Drugs may occasionally be used in the farming of aquatic animals. Infectious diseases, as in other plants and animals can occur. Many of the disease causing agents affecting farmed aquatic animals are normal inhabitants of water and are opportunistic pathogens. When vaccines are not available to control these agents, various disinfection procedures, water treatment chemicals, or therapeutic drugs may be used. Other drugs might be used to modulate spawning cycles or to anesthetize the fish. Regardless of the drugs purpose, it is imperative that fish safety, human safety, and environmental safety be ensured. This requires that drugs be used in accordance with federal requirements.

In the United States there are very few drugs specifically approved for use in farmed aquatic animals. The reason for this is that there is little economic incentive for pharmaceutical companies to seek US drug approval under the Food, Drug and Cosmetic Act. Drug approvals are estimated to cost several million dollars for each animal species or drug use claim. To help foster drug approvals in the US, the position of National Coordinator for Aquaculture New Animal Drug Applications (NADA Coordinator) was created. This position is funded through a variety of governmental and non-governmental groups including domestic aquaculturists and the NAA. It is imperative that drugs suitable for use by the commercial aquaculture industry be developed. The NADA Coordinator can help ensure commercial aquaculture interests are represented in discussions with federal and state agencies similarly seeking drug approvals. In doing so, a coordinated and partnered approach to drug approval efforts can be facilitated thereby ensuring limited resources are focused on the most important drug approvals.

## Policy

The NAA Supports:

1. The National Coordinator for Aquaculture New Animal Drug Applications (NADA Coordinator)
2. The coordinated efforts of federal, state and private industry to obtain additional drug approvals.