



Aquaculture and Aquaculture Drugs Basics



Have you ever wondered where the fish in the pond in your local park may come from, where the fish you buy at the pet store are from, or where the fish at your local grocery store come from? What happens if they get sick, are there medicines available for them? Read below to answer these questions and to find out more about the up-and-coming field of aquaculture.

What is aquaculture?

Think of aquaculture as aquatic animal and plant farming where people manage producing, raising, and caring for aquatic animals in controlled environments such as tanks, ponds, and offshore cages. Fish farming may involve reproducing, raising, and harvesting the animals. Both saltwater and freshwater fish are grown in the United States for people's food, for repopulating ponds, rivers, and streams, and for the aquarium trade.

Finfish such as catfish, salmon, trout, and tilapia, and shellfish like oysters, clams, and shrimp are routinely farmed for human food and represent an important source of the world's animal protein. Currently, almost half of the

fish eaten by people globally is from commercial aquaculture. But, not all aquaculture involves a commercial venture. Federal and state agencies grow a wide range of fish species -- trout, salmon, bluegill, largemouth bass, walleye, channel catfish, redbreast, and others -- to boost fish populations in the wild.

Ornamental fish are grown and kept for display in home or public aquaria, and in ornamental garden ponds, but they are not food. Ornamental fish raised and sold in the United States include tetras, barbs, and danios generating millions of dollars in the commercial trade each year.

How does CVM keep fish safe and healthy?

Fish, like other animals, can get sick. Bacteria, fungi, parasites, viruses, and poor water quality can cause disease. Fish producers and fish hatchery managers worry about diseases because they can kill many fish quickly. FDA's Center for Veterinary Medicine (CVM) works to ensure that safe and effective drugs are available to treat fish diseases and that treated food fish are safe for people and other animals to eat. CVM works with other government agencies, aquaculture groups, and fish health professionals to promote the proper use of legal drugs and through educational outreach encourages research to support the approval of safe and effective fish drugs.

How are new animal drugs approved for aquaculture?

Sponsors of new animal drugs are typically drug companies or chemical firms. Once sponsors identify a new drug they would like FDA to approve, they can contact CVM to discuss approval requirements. After certain initial legal requirements are met, the sponsors start effectiveness and safety studies on the test drug. In some cases, public agencies, like the U.S. Fish and Wildlife Service, U.S. Geological Survey, and U.S. Department of Agriculture, may request their own investigational exemption for a specific drug in order to help sponsors provide the required effectiveness and safety data on the drug. Sponsors may involve fish producers and public hatcheries in the studies and data collection.

CVM evaluates the sponsor's collected drug data based on the following five main areas called major technical sections:

- Target Animal Safety
- Effectiveness
- Human Food Safety (for food fish)
- Chemistry, Manufacturing, and Controls
- Environmental Impact

There are also two other areas called minor technical sections:

- Labeling
- All Other Information

When sponsors have the required drug data supporting the areas listed above, they submit a New Animal Drug Application (NADA) to CVM. Human food safety data do not need to be submitted for non-food animals. CVM reviews the data in the NADA to make sure the proposed drug is safe and that it works as it should. If CVM determines the data show the drug is safe and effective when used according to the label directions, CVM approves the drug. To learn more, please visit CVM's Web site on the drug approval process (<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/FDAandtheVeterinarian/ucm077383.htm>).

Do aquaculture drugs affect the environment?

The National Environmental Policy Act (NEPA) of 1969 requires CVM to consider any effects a proposed drug may have on the environment before a drug is approved. Some sponsors are required to conduct studies and prepare an Environmental Assessment (EA) to show their drug will not harm the environment. In some situations, CVM requires special drug labeling or restricted use to make sure the drug does not harm the environment. To learn more, please visit CVM's Web site on environmental assessments (<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/default.htm>).

Are treated fish safe to eat?

To protect consumers' health, when deciding whether to approve a new animal drug, CVM looks at the potential for problems with human food safety.

Aquaculture drugs for food fish must meet human food safety standards for approval. When a fish producer or hatchery manager uses an approved drug for food fish as directed on the label, the treated fish are safe to eat.

What drugs can be used in aquaculture?

CVM classifies horses, dogs, cats, cattle, pigs, turkeys, and chickens as major species. Fish and other aquatic animals are examples of minor species. Sponsors may legally sell unapproved drugs for minor species under two other drug categories: conditionally-approved drugs and indexed drugs.

Under the Minor Use and Minor Species (MUMS) Animal Health Act of 2004, CVM may grant a conditional approval for a minor species drug. For a conditional approval, CVM evaluates the drug data for each technical section. If CVM accepts the safety data and decides the drug will likely work, then the drug is conditionally-approved. Sponsors can then legally market their drug for up to five years to gain back some of their research costs, while at the same time conducting formal studies showing the drug's effectiveness.

Under the MUMS Act, indexing is a legal way for drug manufacturers to sell certain unapproved drugs for minor species. Indexing is available for only some of the fish drugs: those for non-food fish, and those for early, non-food life stages of food fish. The review process for indexed drugs is somewhat different than for an approval; an outside panel of experts looks at the drug's safety and effectiveness information.

For more in-depth information about the MUMS Act, indexing, or conditional drug approvals, visit the MUMS (<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/default.htm>) and the Animal Health Literacy Campaign (<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm189540.htm>) Web pages. The

“Drug Indexing” section of the MUMS Web page has a link to the list of indexed drugs, The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm125452.htm>). For a list of approved aquaculture drugs, visit CVM’s approved aquaculture drugs (<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/Aquaculture/ucm132954.htm>) Web page.

How are approved drugs used?

Each drug is approved for certain species, for certain diseases or benefits, and for certain dosages. Since only a few drugs are approved for use in fish, veterinarians sometimes need to use drugs approved for other animals or people. The Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994 allows veterinarians to prescribe approved new animal or human drugs for uses other than those on the approved label. This is called “extra-label use.” The FDA defines extra-label use as the:

Actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease and other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from labeled withdrawal time based on these different uses.

Veterinarians must follow the regulations when treating fish with a drug in an extra-label manner. For further information on extra-label drug use in animals, please visit CVM’s Resources for You, FDA and the Veterinarian (<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/FDAandtheVeterinarian/ucm077390.htm>). Refer to the “What drugs can be used in aquaculture” section above for a link to the list of approved aquaculture drugs.

How can I tell if a drug is approved, conditionally- approved, or indexed?

There are two ways to tell a drug's approval status. First, look at the drug's label. An approved drug has a six-digit New Animal Drug Application (NADA) number on its label. A conditionally-approved drug's label states "Conditionally approved by the FDA pending a full demonstration of effectiveness under application number ###-###," whereas an indexed drug's label states "Indexed by FDA." The second way to tell a drug's approval status is to look it up on CVM's "Animal Drugs @ FDA " (<http://www.accessdata.fda.gov/scripts/animaldrugsatfda/>), "Drug Indexing" (<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm070206.htm>), or "Aquaculture" (<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/Aquaculture/default.htm>) sites. The sites contain lists of all FDA-approved or indexed drugs for fish.

What should I do if my pet fish is sick?

If your pet fish becomes sick, you should first check the water quality. Often, poor water quality is the cause of the problem.

Most pet store drugs have not been evaluated or approved by CVM and are not legally marketed. (See the section above entitled "How can I tell if a drug is approved?") Therefore, you don't know whether those products contain the correct amount of drug or whether they are safe and effective.

Many people also don't realize that some veterinarians see fish as patients, and can help you diagnose your fish's problem and recommend a treatment plan. Remember, certain drugs require a veterinarian's involvement.

What can I do if my fish has a bad reaction to a drug or doesn't respond to treatment?

Besides approving safe and effective new animal drugs, CVM also monitors approved drugs on the market to make sure they still work and are safe. CVM encourages you to report instances, known as adverse drug experiences

(ADEs), when fish have bad reactions to a drug, or when the drug does not work. For instructions on how to report an ADE, please see the brochure entitled “ADE Reporting for Fish Drugs: Information for Fisheries on How to Report Adverse Drug Events” (<http://www.fda.gov/downloads/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/UCM117767.pdf>) on the CVM’s Animal Health Literacy Campaign Web site.

