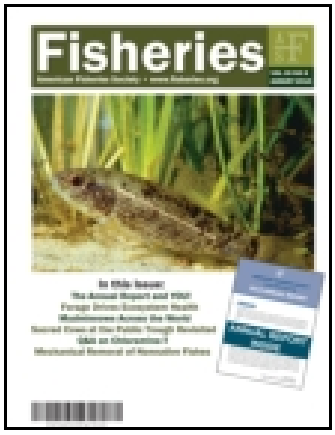

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Q&A: Halamid® Aqua (Chloramine-T) Approved by FDA to Treat Fish Diseases—What It Means for Fisheries

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Q&A: Halamid® Aqua (Chloramine-T) Approved by FDA to Treat Fish Diseases—What It Means for Fisheries

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Axcentive SARL announced recently that the U.S. Food and Drug Administration (FDA) has approved Halamid® Aqua (100% chloramine-T) as a new therapeutic drug for use in fish. Halamid® Aqua is an important weapon in the arsenal fisheries professionals use to combat fish diseases, and its approval is a major advance in fish health management. Below, Jesse Trushenski, president of the Fish Culture Section, discusses the approval with Western Division Vice President James Bowker, who has played a leadership role in fish drug approval efforts for the past 20 years.

What is chloramine-T and what is it used for?

Chloramine-T is a chlorine-releasing product that's used as a sanitizing agent in hospitals, other medical and dental facilities, laboratories, and veterinary facilities. Chloramine-T kills microbes through nonselective, oxidative processes. In other words, it's a disinfectant and not an antibiotic. Chloramine-T kills gram-negative bacteria, including the fish pathogens associated with bacterial gill disease and columnaris. After more than 20 years in development, Halamid® Aqua (100% chloramine-T) has been approved by the FDA to control mortality in freshwater-reared salmonids caused by bacterial gill disease and in Walleye and freshwater-reared warmwater finfish caused by columnaris.

This seems like very good news for fish culture and fish health types, but why does it matter to "Joe Fish Biologist"?

Whether it's for creating new fishing opportunities or restoring imperiled species, fish culture and hatchery-reared fish are central to fisheries management. Many fish pathogens are ubiquitous and, like all of us, when fish are crowded together like they are in intensive rearing systems, they become more susceptible to infections. When disease outbreaks occur, it's essential that we have a well-stocked medicine chest to treat the infections, ensure that production goals are met, and ensure that fish are healthy when they are released into our waters. Stocking healthy fish should not only matter to Joe Fish Biologist but to anglers and all those interested in fisheries conservation.

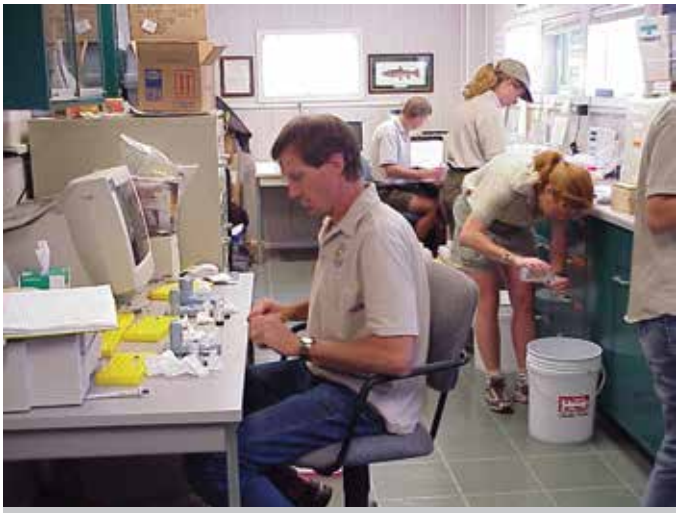
Billions of fish are stocked in the United States annually, mostly for sportfishing, but also for restoration and recovery of threatened and endangered fish. FDA-approved fish drugs, like Halamid Aqua, help culturists safely and effectively control mortality in the hatchery. That means that time and money are not wasted on rearing fish that succumb to disease. We all know that resources are limited in fisheries conservation; Halamid Aqua isn't a silver bullet, but judicious use of chloramine-T and other approved drugs can help hatcheries operate more effectively.

Twenty-plus years seems like a long time for a drug to be in development. What did it take to secure this approval?

That's a question that has been asked for…well, about 20 years! Approval of a chloramine-T product has been the number one priority of the Association of Fish and Wildlife Agencies Drug Approval Working Group since its inception, and it has been a long road. The FDA takes a precautionary approach to drug approvals and proving a drug is safe and effective requires volumes of data generated under strict regulatory oversight. Chloramine-T was the first Association of Fish and Wildlife Agencies drug priority we tackled collectively, and we charted new territory in the process. Without the commitment of the sponsor, several research entities, and the National New Animal Drug Application Coordinator, Halamid Aqua would never have been approved.

What have you learned during the development of chloramine-T? Will the process always be this laborious?

We learned from our mistakes. We now communicate more frequently with the FDA, and we have learned to ask the right questions. We've become experts in the drug approval process and have developed expertise in the related fisheries disciplines, and that has made the process much less laborious and lengthy. For example, we're currently working toward an approval for an immediate-release fish sedative, and we anticipate that this drug will be approved in less than half the time it took for Halamid Aqua.



AADAP staff collecting data in support of the Halamid Aqua approval. Photo credit: U.S. Fish and Wildlife Service.

Does this mean that the fisheries medicine chest is now full?

Unfortunately, no. Several more fish drugs are still critically needed, including another antibiotic to better address issues such as antimicrobial resistance. We've got a handful of options for freshwater fish, but the medicine chest for marine fish is empty.

Congratulations and thanks are due to all those who have contributed to this approval over the years. What can fisheries professionals do to express our gratitude for those who toil in the field of aquatic animal drug approvals?

Thank you. First, it is critical that fisheries professionals use only FDA-approved drugs and that they use them judiciously. Second, make a commitment to help groups like the U.S. Fish and Wildlife Service Aquatic Animal Drug Approval Partnership Program to conduct field effectiveness trials. If you don't help prove a drug is effective in treating a disease in your fish, it's unlikely that it will be approved for that use. Opportunities to conduct scientifically valid, statistically defensible field effectiveness trials are the biggest limiting factor in getting drugs approved for new uses. Halamid Aqua is now approved for a few uses, but by helping us conduct the necessary experiments, you can help expand the label, enabling use by more fisheries professionals in need.