

Aquatic Animal Drug Approval Partnership - AADAP Update

A Branch of the Fish and Aquatic Conservation Program

The AADAP Update provides recent news and updates from the Aquatic Animal Drug Approval Partnership program and its partners. For questions or to offer feedback, email [Jim Bowker](#).

Notice of change to federal rule regarding access to antibiotic drugs and consequences for fish hatcheries

The FDA has issued a new rule that all antibiotics will be accessible only with veterinary oversight. This rule was adopted to address concerns related to use of antibiotics in food-producing animals (including fish) and the development of antimicrobial resistance. Starting January 1, 2017:

1. All in-feed treatments of FDA approved antibiotics will require a Veterinary Feed Directive (VFD). These include Aquaflor, Terramycin 200 for Fish, Romet 30, and Romet TC. The FDA prohibits end-users from top-coating antibiotics on medicated feed. Products that were previously “over the counter” will no longer be used extra-label as prescribed by a veterinarian as this type of use of a VFD drug is now prohibited.
2. All immersion treatments with FDA approved antibiotics will require a veterinary prescription. This includes products like Oxymarine, Pennox343, and Terramycin 343 for marking skeletal tissue of fish.

The new rule does not apply to approved drugs that are not antibiotics (if used according to the label), such as Halamid Aqua (chloramine-T), 35% Perox Aid (hydrogen peroxide), Parasite-S (formalin); drugs used under a compassionate INAD authorization; or low regulatory priority/deferred regulatory status drugs

What does this mean for you? You'll need to establish a valid veterinarian-client-patient relationship (VCPR) and work with your veterinarian and local fish health specialist to obtain prescriptions/VFDs for the affected drugs. Be aware that the definition and requirements of a valid VCPR vary by state.

We anticipate challenges relative to timely coordination with veterinarians and treatment application. Experience with Aquaflor (always a VFD drug) suggests that VFDs can be issued and medicated feed acquired to allow treatment within 2-3 days of diagnosis. However, efficiency of this process is going to be highly dependent on veterinarian availability and laying the groundwork ahead of time may avoid lengthy delays to fish treatment. If a hatchery does not already work with a veterinarian, consult with a fish health center to identify qualified veterinarians. Working with the veterinarian and fish health specialist, develop a plan for rapid disease diagnosis, prescription/VFD issuance and drug acquisition to ensure prompt treatment of sick fish. Be aware that keeping an inventory of drug/medicated feed on site for immediate treatment following diagnosis will be difficult or prohibited. Unused product on hand after January 1, 2017 will have to be disposed of in an appropriate manner.

This new rule also affects those that use oxytetracycline products to mark skeletal tissue of fish and starting Jan 1, 2017, a veterinarian will need to prescribe this treatment. At this time, there may be some uncertainty relative to the use of antibiotics for such use and whether such use calls within this new rule. AADAPs interpretation is that marking fish with oxytetracycline hydrochloride will require a veterinary prescription.

If you have further questions, please contact your Fish Health Center or the Aquatic Animal Drug Approval Partnership Program.