United States Department of the Interior

FISH AND WILDLIFE SERVICE
Washington, D.C. 20240

In Reply Refer To
FWS/AFAC/DNC 063882

AUG 19 2016

Memorandum

To: Fish and Aquatic Conservation Assistant Regional Directors

From: Assistant Director – Fish and Aquatic Conservation

Subject: Notice of change to federal rule regarding access to antibiotic drugs and consequences for USFWS hatcheries

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

- All in-feed treatments of FDA approved antibiotics will require a Veterinary Feed Directive (VFD). These will include Aquaflor®, Terramycin® 200 for Fish, Romet® 30, and Romet® TC. The FDA prohibits end-users from top-coating antibiotics on medicated feed[1]. Products that were previously "over the counter" will no longer be able to be used extra-label as prescribed by a veterinarian because such use of a VFD drug is prohibited.

- All immersion treatments with FDA approved antibiotics will require a veterinary prescription. This will include products like Pennox® 343, and Terramycin 343® for marking skeletal tissue of fish.

The rule does not apply to other 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 FAC? Our hatcheries will need to establish a valid veterinarian-client-patient relationship (VCPR) and work with veterinarians and local fish health specialists to obtain prescriptions/VFDs for the affected drugs. Be aware that the definition and requirements of a valid VCPR vary by state.

[1] In-feed treatments applied under a compassionate INAD authorization may still be purchased as a premix and prepared by top-coating.

What should you do? It is anticipated that there will be 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 will help avoid lengthy delays to fish treatment.

If your hatchery does not already work with a veterinarian, consult with your fish health center to identify a qualified veterinarian. Working with your veterinarian and fish health specialist, it is recommended that you 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 drugs/medicated feed onsite 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.

Our goal is to prevent infectious disease, but should a medicated feed treatment or immersion antibiotic treatment become necessary, the Service will follow all laws and regulations with regard to antibiotic use, including the new Veterinary Feed Directive rule change. If you have further questions, please contact your Fish Health Center or the Aquatic Animal Drug Approval Partnership Program.

Thank you for your attention to this matter.