Antibiotic Use in Finfish

In the United States, antibiotics may be used in fish culture for control of bacterial infections, if necessary and under the direction of a U.S. licensed veterinarian.

Note: These recommended steps are provided as general information only and are not intended to represent authoritative positions of NOAA, AFWA, AVMA, or USFWS. Consult with a veterinarian before considering any antibiotic use.

Learn more:
Veterinary Feed Directive (FDA)
Approved Aquaculture Drugs (FDA)
CFR Part 225
CFR Part 530
CPG 615.115

Acronyms and Abbreviations:

CFR: Code of Federal Regulations
CPG: Compliance Policy Guide
FDA: Food and Drug Administration
Rx: Prescription
VCPR: Veterinarian-Client-Patient Relationship
Vet: U.S. Licensed Veterinarian
VFD: Veterinary Feed Directive

WHAT TO DO WHEN CONSIDERING USING APPROVED FINFISH ANTIBIOTICS

Step 1:
Establish a Veterinary-Client-Patient Relationship (VCPR)

Step 2:
Vet makes diagnosis and treatment plan in accordance with VCPR (including use for skeletal marking).

Step 3:
Review whether the antibiotics under consideration have an FDA approved medication.

Yes

VFD (medicated feed):
Obtain VFD order from the vet and proceed with use in accordance with the VFD.

or

Rx (immersion or injection):
Obtain a prescription (immersion, injection) from the vet and proceed with therapy.

No

VFD (medicated feed) Extralabel Use:
Vet determines whether extralabel use of an FDA approved medicated fish can be authorized via VFD order in accordance with CPG 615.115 (see websites below for more info). Therapy requires a VFD order from the vet.

or

Rx (immersion or injection) Extralabel Use:
Vet determines whether extralabel use of an FDA approved drug can be authorized under a prescription in accordance with 21 CFR part 530 (see websites below for more info). Therapy requires a prescription from the vet.
NOTES: Because both Aquaflor© and Romet-30© are Category II Type A medicated articles, manufacturing of medicated feed using them must be in a licensed medicated feed mill. These licensed feed mills must follow cGMPs per 21 CFR 225.10 through 21 CFR 225.115.

Because Romet TC© is a Category II Type B medicated feed and Terramycin© 200 is a Category I Type A medicated article, manufacturing of medicated feed may take place in an unlicensed feed mill. Unlicensed feed mills, including those mixing on farm, must follow cGMPs per 21 CFR sections 225.120 through 225.202.

AUTHORIZATION AND USE OF MEDICATED FEED OR PRESCRIBED ANTIBIOTICS

Medicated Feed:

VFD order signed by a vet in accordance with VCPR. If the medicated feed is being administered for extralabel use, then the VFD order and recommendation are signed by a vet and in accordance with CPG 615.115.

Licensed feed mill

Licensed feed mill

Unlicensed feed mill

Distributor

Distributor

Proceed w/ therapy

Proceed w/ therapy

Prescribed Antibiotics:

Prescription (Rx) signed by a vet and under a valid VCPR. If the drug is to be administered for extralabel use, then the prescription should be used in accordance with 21 CFR part 530.

Terramycin© 343, OXYmarine™, Tetroxy© 343, Pennox 343©, Tetroxy© Aquatic

Proceed w/ therapy

SUMMARY OF USE REQUIREMENTS FOR APPROVED FINFISH ANTIBIOTICS

<table>
<thead>
<tr>
<th>Antibiotic, Authority, and Authorized Actions</th>
<th>Aquaflor©</th>
<th>Romet-30©</th>
<th>Romet-TC©</th>
<th>Terramycin© 200</th>
<th>Terramycin© 343, OXYmarine™, Tetroxy© 343, Pennox 343©, Tetroxy© Aquatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>VFD order signed by a vet in accordance with a VCPR. If this is an extralabel drug use, then the VFD order and recommendation are signed by a vet with a valid VCPR and in accordance with the provisions of CPG 615.115.</td>
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<td>Licensed feed mill +/- distributor (mfg in accordance with cGMP 225.10 through 225.115).</td>
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<td>Rx signed by a vet. If this is an extralabel drug use, then Rx should be signed by a vet with a valid VCPR and in accordance with 21 CFR part 530.</td>
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