



NOAA FISHERIES

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.



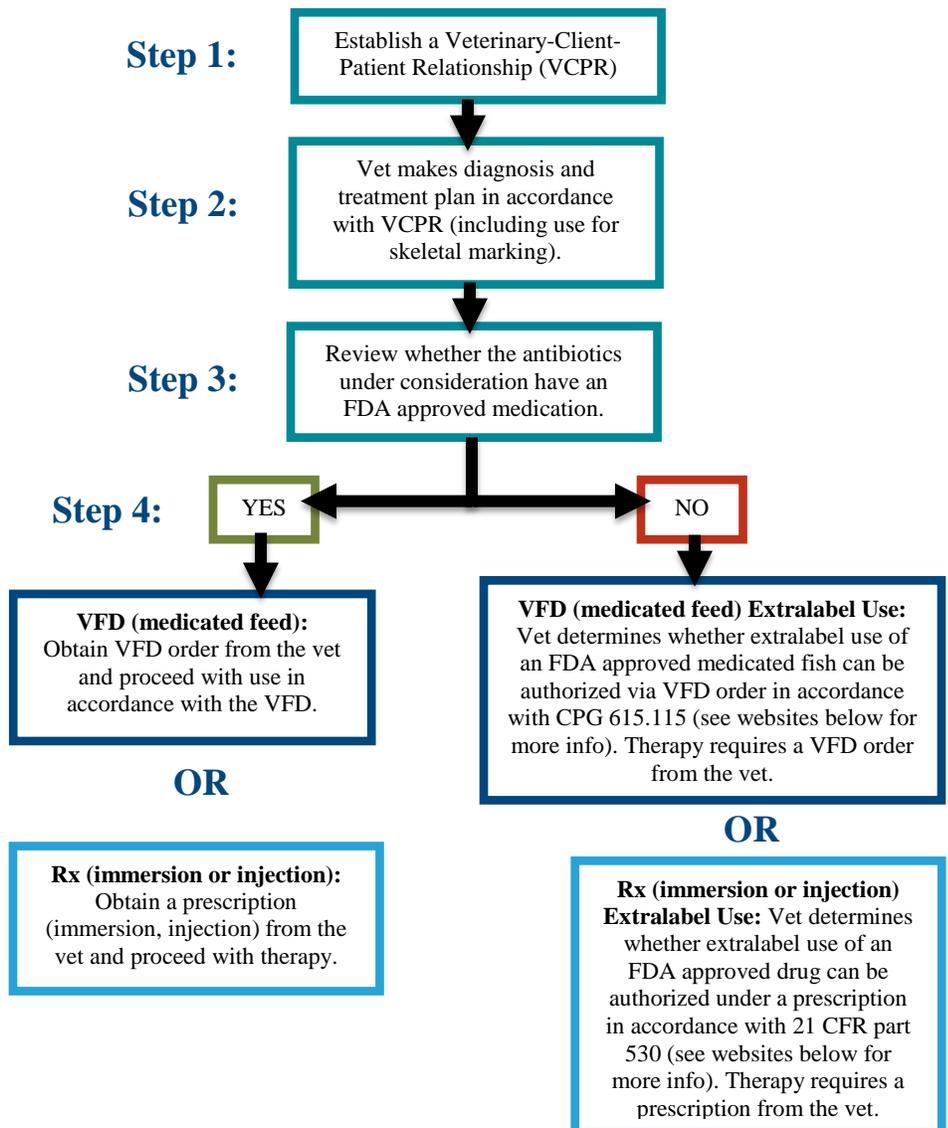
Acronyms and Abbreviations

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

Antibiotic Use in Finfish



What to do when considering using approved finfish antibiotics



NOTE: 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. See websites below for more info.

NOTE: 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. See websites below for more info.



For more information on terms above, please visit:

Veterinary Feed Directive:
www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-vfd

FDA Center for Veterinary Medicine:
www.fda.gov/animal-veterinary/aquaculture/approved-aquaculture-drugs

CFR Part 530: www.ecfr.gov/cgi-bin/text-idx?SID=ac0df7caaaba4721d92aaf3eab31e94f&mc=tru&node=pt21.6.530&rgn=div5

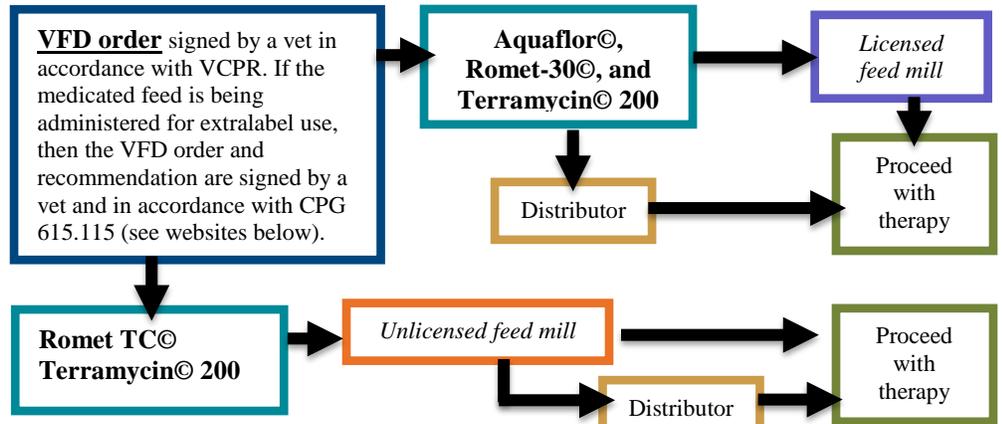
CFR Part 225: www.ecfr.gov/cgi-bin/text-idx?SID=ac0df7caaaba4721d92aaf3eab31e94f&mc=tru&node=pt21.4.225&rgn=div5

CPG 615.115:
www.fda.gov/media/71960/download

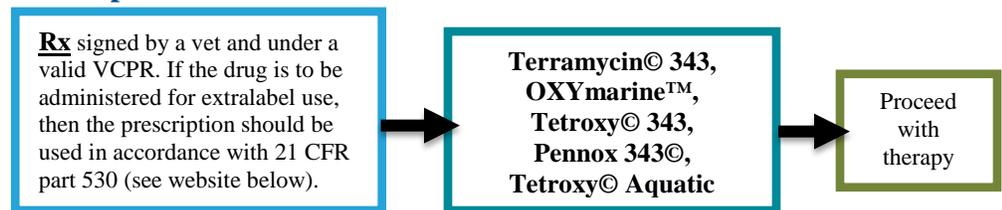


Authorization and Use of Prescribed Antibiotic or Medicated Feed

Medicated feed:



Prescription:



Summary of Use Requirements for Approved Finfish Antibiotics

| Antibiotic, Authority, and Authorized Actions | Aquaflor® | Romet-30® | Romet-TC® | Terramycin® 200 | Terramycin® 343, OXYmarine™, Tetroxy® 343, Pennox 343®, Tetroxy® Aquatic |
|--|-----------|-----------|-----------|-----------------|--|
| 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. | ✓ | ✓ | ✓ | ✓ | |
| Licensed feed mill +/- distributor (manufactured in accordance with cGMP 225.10 through 225.115). | ✓ | ✓ | ✓ | ✓ | |
| Unlicensed feed mill +/- distributor (manufactured in accordance with cGMP 225.120 through 225.202). | | | ✓ | ✓ | |
| Rx signed by a vet. If this is an extralabel drug use, then the Rx should be signed by a vet with a valid VCPR and in accordance with 21 CFR part 530. | | | | | ✓ |