Aquaflor® (florfenicol)

AQUAFLOR® (florfenicol) Type A Medicated Article Veterinary Feed Directive (VFD)

REQUIRED INFORMATION EXPLANATION & COMPLETION GUIDE

1. **Name of VFD Drug:** The registered name of the VFD drug AQUAFLOR® (florfenicol) Type A medicated premix article containing the active ingredient florfenicol.

2. **Client:** The contact information for the client or caretaker of the animals to receive the medicated feed including name, home or business address, and telephone number.

3. **Veterinarian:** The contact information for the veterinarian issuing the VFD, including name, home or business address, and telephone number.

4. **Approximate Number of Animals:** Indicate the approximate number of animals to be fed the VFD drug medicated feed authorized by this VFD at the location(s) specified (#5) by the expiration date of the VFD (# 18).

5. **Animal Location:** Physical location or premises where the animals specified in the VFD to be fed the medicated feed are located.

6. **Species of Animals to be Treated:** Circle one of the four fish species/types listed that will receive the medicated feed authorized by this VFD.

7. **Indication:** Circle the appropriate disease and pathogen indication corresponding to the fish species/type (#6) to be treated with this VFD order.

8. **Florfenicol Dose:** Circle or indicate the dose of florfenicol desired for the treatment specified with this VFD order. The most common florfenicol dosages used in fish species are 10 mg/kg/day for 10 days or 15 mg/kg/day for 10 days. Treatment of freshwater-reared warmwater finfish for *Streptococcus iniae* with florfenicol is only approved at the single dosage rate of 15 mg/kg biomass.

9. **Florfenicol (grams/ton):** This florfenicol (grams/ton) column shows the range of florfenicol concentrations in feed required to treat a group of fish depending on dose and feed rate.

10. **Initials:** The veterinarian issuing the VFD should write their initials in the box corresponding to the fish species and indication being treated.

11. **Mix into Type C Medicated Feed to Provide:** This line of the VFD is to be completed with the number of grams of florfenicol to be added to each ton equivalent of feed that will be fed to the animals specified in this VFD order. Write the grams of florfenicol to include in each ton of feed based on the table listed as #14 showing feeding rates and doses of 10 or 15 mg of florfenicol per kg of biomass.

12. **Feeding Rate:** The feeding rate is determined by calculating the pounds of feed administered to a group of fish daily divided by the total weight of all fish being treated (biomass) X 100. Indicate the feeding rate as a percentage of fish biomass to feed the medicated feed authorized by this VFD.

13. **Feeding Duration:** The feeding duration for a medicated feed containing AQUAFLOR® was established during the drug approval process and is approved for a duration of use of 10 consecutive days. There are no refills allowed with Aquaflor® medicated feed.

14. **Feeding Rate and Medication Amount Table:** Knowing the feed rate (as percentage of biomass) listed in the first column of the table and the dose of florfenicol desired for the treatment (either 10 mg/kg or 15 mg/kg), this table can be used to determine the concentration (grams/ton) of florfenicol per ton of feed and the amount (lbs.) of AQUAFLOR® to be added per ton of feed. The table also shows the total fish biomass that can be medicated for the 10-day treatment period per ton of medicated feed.

15. **Special Instructions:** This area of the AQUAFLOR® VFD can be used to include any additional information or instructions from the veterinarian issuing the VFD to the producer or caretaker, including items such as more detailed instructions to contact the veterinarian if clinical signs of disease or mortality continue past treatment, more specific locations where the fish to be medicated are located, age range, specific pond or raceway, etc.

16. **Cautionary Statements:** This part of the AQUAFLOR® VFD contains a variety of Cautionary Statements regarding the use of AQUAFLOR® that are required by the FDA. You should read these Cautionary Statements.

17. **Withdrawal Time:** The established withdrawal period for AQUAFLOR® medicated feeds is 15 days after the last feeding of medicated feed for all approved dosages in all approved species.

18. **Expiration Date:** The last day that the medicated ration containing the VFD drug can be legally fed to the animals specified in the VFD order. The expiration date for an AQUAFLOR® VFD cannot be longer than six months after the date of issuance of the VFD. The expiration date may be less than six months after the issuance date. The expiration date of the VFD is at the discretion of the veterinarian issuing the VFD.

19. **Veterinarian's Signature:** This is a blank space for the written signature of the veterinarian issuing the VFD order. The veterinarian may also sign a VFD order with an electronic signature if the electronic signature is compliant with 21 CFR Part 11 requirements.

20. **Date of Issuance:** The date the VFD was issued to the client and feed mill/feed distributor in month/day/year format.

21. There is a checkbox below the signature line to indicate drug product substitution is not allowed. ***Please check this box.***

22. **Manufacturer:** Merck Animal Health is the manufacturer of AQUAFLOR®. There is nothing to complete in this section. This is information required by the FDA to be on a valid VFD.

Aquaflor® (Florfenicol) Veterinary Feed Directive

Client: _____ **Veterinarian:** _____

Home or Business Address _____ **Address:** _____

Phone: _____ **Phone:** _____

Approximate Number of Animals:

Animal Location:

Indications: Circle the row with the treated species and indication, and initial the corresponding box.

Fish Species	Indication	Florfenicol (mg/kg body weight/day)	Florfenicol (grams/ton)	Initials
Freshwater-reared salmonids	For the control of mortality due to furunculosis associated with *Aeromonas salmonicida*. For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum*.	10 – 15	182 – 2,724	
Freshwater-reared finfish	For the control of mortality due to columnaris disease associated with *Flavobacterium columnare*.			
Catfish	For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*.			
Freshwater-reared warmwater finfish	For the control of mortality due to streptococcal septicemia associated with *Streptococcus iniae*.	15	273 – 2,724	

Mix into Type C Medicated Feed to Provide: _____ grams florfenicol/ton (See table below.)

Feeding Rate: _____ % Biomass

Feeding Duration: Feed as the sole ration for 10 consecutive days.

Feeding Rate	Florfenicol Concentration in Feed		Amount of Aquaflor® (florfenicol) per Ton of Feed		Biomass of Fish Medicated per Ton of Feed per 10-day Treatment Period
% Biomass	Grams/Ton		lbs		lbs
	Dose 10 mg/kg	Dose 15 mg/kg	Dose 10 mg/kg	Dose 15 mg/kg	
0.5	1,816	2,724	8.00	12.00	40,000
1.0	908	1,362	4.00	6.00	20,000
2.0	454	681	2.00	3.00	10,000
3.0	300	450	1.32	1.98	6,666
5.0	182	273	0.80	1.20	4,000

Special Instructions:

Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.

This VFD only authorizes the use of the VFD drug cited in this order and is not intended to authorize the use of such drug in combination with any other animal drugs.

Caution: Feed containing Aquaflor® (florfenicol) shall not be fed to fish for more than 10 days. Following 10 days administration, fish should be reevaluated by a licensed veterinarian before starting another course of therapy. The expiration date for VFD Aquaflor® (florfenicol) must not exceed 6 months from the date of issuance. VFD for Aquaflor® (florfenicol) shall not be refilled.

Not for use in animals intended for breeding purposes. The effects of florfenicol on reproductive performance have not been determined. Toxicity studies in dogs, rats, and mice have associated the use of florfenicol with testicular degeneration and atrophy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for the hematopoietic/lymphopoietic tissues to regenerate was not evaluated.

Sunburn, skin lesions, and skin sloughing have been reported in salmonids treated with florfenicol. Not all adverse drug events are reported to FDA CVM. It is not always possible to reliably estimate the adverse event incidence or to establish a causal relationship to product exposure using this data alone.

Before using this drug for the first time, you must inform the appropriate National Pollutant Discharge Elimination System (NPDES) permitting authority of your intentions and of the following information. Acute and chronic water quality benchmarks for the protection of freshwater aquatic life have been derived by FDA for florfenicol following EPA guidance for calculating Tier II water quality criteria for the Great Lakes System (40 CFR 132, App. A). The acute benchmark value (Secondary Maximum Concentration) is 20.6 mg/L (equivalent to one-half of the Secondary Acute Value). The chronic benchmark value (Secondary Continuous Concentration) is 0.23 mg/L (equivalent to the Final Plant Value). The NPDES authority may require an NPDES permit before you can discharge Aquaflor®. The water quality benchmark concentrations are not discharge limits, but may be used by the NPDES authority to derive such limits for the permit. Additional environmental information on Aquaflor® and the benchmark values are available in an environmental assessment posted at:
http://animaldrugsatfda.fda.gov/adafda/views/#/environmentalAssessments

RESIDUE WARNING: Feeds containing Aquaflor® (florfenicol) must be withdrawn 15 days prior to slaughter.

Expiration Date: _____ Month/Day/Year (Not to exceed 6 months from date of issuance.)

Veterinarian's Signature: _____ **Date of issuance:** _____ (Month/Day/Year)

☐ DRUG PRODUCT SUBSTITUTION IS NOT ALLOWED.

MERCK Animal Health

TAKE TIME OBSERVE LABEL DIRECTIONS

White Copy - Veterinarian Canary Copy - Client Pink Copy - Feed Mill