

AQUAFLO[®] & VFD Review & Update

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AQUAFLO[®]
(florfenicol) TYPE A MEDICATED ARTICLE



AQUAFLO R Review & Update

CAUTION: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

AQUAFLO R®
(florfenicol) TYPE A MEDICATED ARTICLE

AQUAFLO^R Type A Medicated Article Review

- Type A feed premix containing 50% active ingredient (florfenicol) specifically formulated for use in fish
- Broad spectrum, veterinary-only antimicrobial with the broadest approved range of use in fish species and control of species of pathogenic bacteria
- High bioavailability – assures delivery of antimicrobial to fish
- Well distributed in fish tissue and fluids – gets to where pathogens are

AQUAFLO^R
(florfenicol) TYPE A MEDICATED ARTICLE

- Available in sinking and floating feeds...top-pressed or incorporated

Additional Label Claims Now Approved

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

Now Approved for Use in
Recirculating Systems!

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The New Veterinary Feed Directive (VFD) Rule

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Topics

- **History of VFD Rules and Changes**
- **VFD Rule Changes**
 - **for Producers**
 - **for Veterinarians**
 - **for Feed Mills**

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History of VFD Rules

The VFD changes are important,
but no big deal!

- First VFD drugs created 1996 ADAA
- First VFD Rule published December 2000
- New VFD Final Rules published June 2015
 - GFI 209
 - GFI 213

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Goals of VFD Final Rule

- **Judicious use of Antimicrobials**
 - Avoid unnecessary &/or inappropriate use
 - Use of antimicrobials for therapeutic purposes
 - Veterinary oversight
- **Tracking of Medicated feeds**
 - Manufacturing
 - Distribution
 - Production site
 - Use

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New VFD Rules: Requirements & Changes for Producers

- **Aquafior®: New VFD 1 Oct 2015**
- **Romet®, Terramycin®: OTC so no VFD until January 2017**
- **Still no ELDU allowed**
- **Must be working with a veterinarian: need VCPR**
- **Keep VFD 2 years...a copy**

AQUAFIOR®
(florfenicol) TYPE A MEDICATED ARTICLE

New VFD Rules: Requirements & Changes for Producers

- VFD will list # animals to treat, farm location of animals, dose, & feed rate
- Producer & feed mill will need to make final determination of # pounds of medicated feed required
- No requirement to list # tons medicated feed
- 'Expiration date' definition: time in which medicated feed delivered as a result of a specific VFD must be fed; Aquaflor has up to 6 months

AQUAFLO R[®]
(florfenicol) OPPEL MEDICATED ARTICLE

New VFD Rules: Requirements & Changes for Veterinarians

1. Must be licensed to practice in state the animals reside in
2. Must be operating in the course of the veterinarian's professional practice and in compliance with all applicable requirements
3. Must have valid VCPR to issue valid VFD
4. Valid VCPR Minimum Elements:
 - DVM has engaged with client
 - DVM has sufficient knowledge about patient via exam &/or visit
 - DVM available for follow-up
 - Visit reports/notes, Diagnostic reports, Outcomes May be Important
5. Keep original VFD 2 years; copies to feed mill or distributor & client/producer

New VFD Rules: Requirements & Changes for Veterinarians

8. No ELDU; issued VFD must be in compliance with Approved Use/Indications/dosages
9. VFD must be complete...all blanks completed, signed
10. Can send/distribute electronically...signature issue & requirements; scanned/faxed copy of completed & signed VFD ok
11. Expiration Date is the time the VFD is valid & producer can feed the VFD feed
12. Currently no approved medications allowing refills including AQUAFLO^R
13. VFD may cover animals on multiple locations if meet licensing & VCPR requirements and VFD feed is supplied to multiple locations by a single feed manufacturer

New VFD Rules: Requirements & Changes for Feed Mills

- Will receive a copy of the VFD from veterinarian
- If receive scanned/faxed copy of completed & signed VFD...need to print VFD and file paper version
- Keep VFD copies for 2 years
- Produce VFD's when requested by FDA
- No pounds of feed specified on the VFD
- Will need to calculate amount of medicated feed needed
- VFD from veterinarian must be fully completed to be a valid VFD...mills are allowed to fill a VFD only if the VFD contains all required information

VFD Conclusions

- Encourages veterinary involvement with health program
- Ensures judicious drug usage, which in turn helps to optimize product performance and minimizes development of resistance
- Ensures safety for humans, food and environment

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