# The New Veterinary Feed Directive (VFD) Rule

Timothy S. Kniffen DVM, MS
Merck Animal Health
North American Aquaculture Business Unit

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# AQUAFLOR Fair Balance, All Species

- Feed containing AQUAFLOR (florfenicol) shall not be fed to any approved fish species for more than 10 days
- Following 10 days, fish should be re-evaluated by a licensed veterinarian before instituting further therapy
- All feeds containing AQUAFLOR must be withdrawn 15 days prior to slaughter
- The effects of AQUAFLOR on reproductive performance have not been determined

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# Topics

- History of VFD Rules
- VFD Process
- VFD Rule: Producer Responsibilities
- AQUAFLOR® VFD changes
- Conclusion

# Topics

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

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# 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
- Fluid Situation

Federal Register | Veterinary Feed Directive

# What is a Veterinary Feed Directive Drug?

*- a drug intended for use in or on animal feed which is limited to use under the professional supervision of a licensed veterinarian*

*- use of animal feed containing a VFD drug must be authorized by a lawful Veterinary Feed Directive*

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# What is a Veterinary Feed Directive?

*- a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that authorizes the use of a VFD drug in or on an animal feed.*

*- a VFD authorizes the client (the producer) to obtain and use animal feed containing the VFD drug to treat the client's animals in accordance with the VFD feed label.*

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# History of VFD Drugs

- Veterinary Feed Directive (VFD) is a new FDA drug category
- Federal Animal Drug Availability Act of 1996
- Applies only to in-feed therapeutics
- First rule approved by FDA in 2000
- Type A, Category II
- June 3, 2015- Final rule published by FDA
- October 1, 2015 - Final rule became effective
- January 1, 2017

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# Why VFD Drugs?

- FDA developed new category to control more closely new therapeutics and their use in food animals
- Designed to…
  - *Reduce* potential for antibiotic resistance
  - *Prolong* effectiveness of new therapeutics through judicious use

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# A First for US Aquaculture

- AQUAFLOR is the first antibiotic in aquaculture and second for ALL food animal species to be classified a VFD drug by FDA

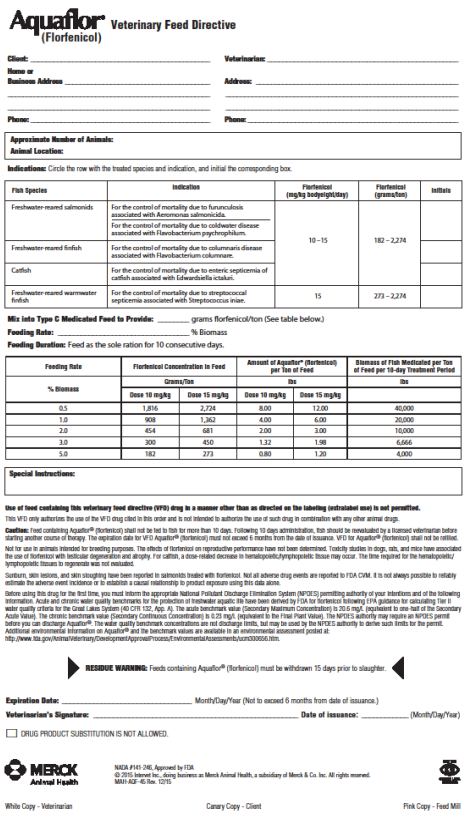
AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# The VFD Process

- Producer contacts veterinarian or lab for diagnosis and treatment
- Vet determines if VFD medication is needed
- Vet issues VFD to producer if drug is required

# The VFD Process

- Producer obtains signed VFD from vet or vet lab and sends/takes to feed distributor
- Copies held by feed distributor and producer
- Original held by Vet
- Feed Distributor may ship VFD feed with a valid VFD order
- Vet ultimately responsible



**Aquaflor** (Florfenicol) **Veterinary Feed Directive**

**Client:** _____ **Veterinarian:** _____

**Name 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 bodyweight/day) | Florfenicol (grams/ton) | Initials |
|---|---|---|---|---|
| Freshwater-reared salmonids | For the control of mortality due to furunculosis associated with Aeromonas salmonicida. | 10 – 15 | 182 – 2,274 | |
| | For the control of mortality due to coldwater disease associated with Flavobacterium psychrophilum. | | | |
| 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 – 2,274 | |

**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 30.6 mg/L (equivalent to one-half of the Secondary Acute Value). The chronic benchmark value (Secondary Continuous Concentration) is 0.25 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://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm330856.htm.

**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

NADA #141-240, Approved by FDA

MAH-AQF-4E-Rev. 12/15

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

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# Veterinary Feed Directive Order

Specific to:

- Drug
- Dose
- Species
- Indication
- Location
- Age class, etc.

Deviations considered violation of Federal Law

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# 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 *Aeromonas salmonicida*.<br>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*. | 10 - 15 | 182-2,724 |
| Catfish | For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*. | 10 - 15 | 182-2,724 |
| Freshwater-reared warmwater finfish | For the control of mortality due to streptococcal septicemia associated with *Streptococcus iniae*. | 15 | 273- 2,724 |

**Now Approved for Use in Recirculating Systems!**

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# Understanding VFD

- Mills may ship VFD-medicated feed with a valid VFD order

- Vets, feed mills/distributors, and producers must keep VFD forms for 2 years

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# Understanding VFD

- No "extra label" or "off label" use permitted with VFD drugs

- There must be a "veterinarian-client-patient" relationship before VFD can be written

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# Federal Government VCPR Definition

A valid veterinarian-client-patient relationship is one in which:

(1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and **the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian**;

(2) There is **sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s)**; and

(3) The practicing **veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.** Such a relationship can exist **only** when the veterinarian has **recently seen and is personally acquainted with the keeping and care of the animal(s)** by virtue of examination of the animal(s), and/or by **medically appropriate and timely visits to the premises where the animal(s) are kept.**

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# VFD Rules: Producer Responsibility

- Contact the Veterinarian to diagnose and treat the animals
- Veterinary Client Patient Relationship required (agree to follow the vet's recommendation)
- Obtain a copy of VFD/Copy is sent to the feed distributor
- Keep a copy of the VFD for 2 years
- Must make VFD available for inspection and copying by FDA
- Feed Distributor can ship the feed upon receiving a valid VFD order
- Administer the VFD feed to the animals
- A VFD feed must not be fed to animals after the expiration date on the VFD. You should contact your vet to request a new VFD order.

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# New VFD Rules: Changes for Producers

- Producer and feed mill will need to make final determination of the amount of medicated feed required for treatment

- No requirement for veterinarian determine the amount of medicated feed required

**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 |

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# New AQUAFLOR VFD Expiration

- The new 6 month Aquaflor VFD expiration provides more flexibility for veterinarians and producers

- **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://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm300656.htm.

**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)

OR®

(florfenicol) TYPE A MEDICATED ARTICLE

# What is the difference between the "expiration date" on a VFD and "duration of use"?

- **Expiration date:** defines the period of time for which the authorization to feed an animal feed containing the VFD drug is lawful

**AQUAFLOR - New Expiration: up to 6 month expiration period**

- **Duration of use:** the length of time that the VFD feed is allowed to be fed to the animals per approved label

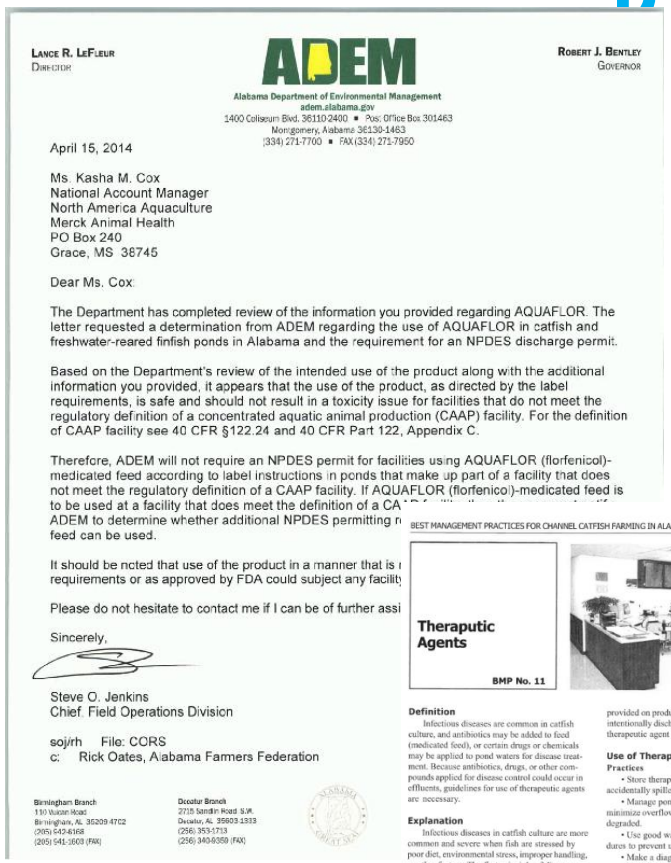
**Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.**

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.

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# AQUAFLOR Veterinary Feed Directive



Lance R. LeFleur
Director

ADEM
Alabama Department of Environmental Management
adem.alabama.gov
1400 Coliseum Blvd. 36110-2400 ▪ Post Office Box 301463
Montgomery, Alabama 36130-1463
(334) 271-7700 ▪ FAX (334) 271-7950

Robert J. Bentley
Governor

April 15, 2014

Ms. Kasha M. Cox
National Account Manager
North America Aquaculture
Merck Animal Health
PO Box 240
Grace, MS 38745

Dear Ms. Cox:

The Department has completed review of the information you provided regarding AQUAFLOR. The letter requested a determination from ADEM regarding the use of AQUAFLOR in catfish and freshwater-reared finfish ponds in Alabama and the requirement for an NPDES discharge permit.

Based on the Department's review of the intended use of the product along with the additional information you provided, it appears that the use of the product, as directed by the label requirements, is safe and should not result in a toxicity issue for facilities that do not meet the regulatory definition of a concentrated aquatic animal production (CAAP) facility. For the definition of CAAP facility see 40 CFR §122.24 and 40 CFR Part 122, Appendix C.

Therefore, ADEM will not require an NPDES permit for facilities using AQUAFLOR (florfenicol)-medicated feed according to label instructions in ponds that make up part of a facility that does not meet the regulatory definition of a CAAP facility. If AQUAFLOR (florfenicol)-medicated feed is to be used at a facility that does meet the definition of a CA
ADEM to determine whether additional NPDES permitting r
feed can be used.

It should be noted that use of the product in a manner that is
requirements or as approved by FDA could subject any facility

Please do not hesitate to contact me if I can be of further assi

Sincerely,

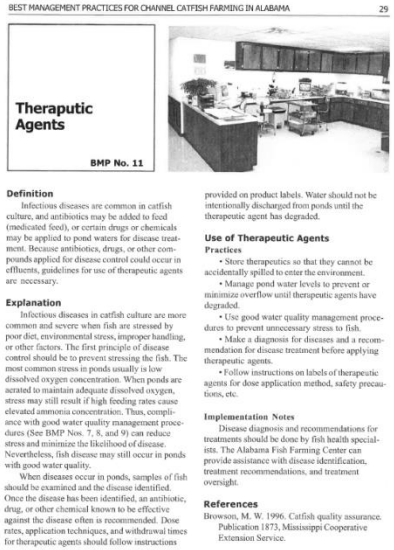
Steve O. Jenkins
Chief, Field Operations Division

sojirh File: CCRS
c: Rick Oates, Alabama Farmers Federation

Birmingham Branch
110 Vulcan Road
Birmingham, AL 35209-4702
(205) 942-6168
(205) 941-1603 (FAX)

Decatur Branch
2715 Sandlin Road, S.W.
Decatur, AL 35603-1333
(256) 353-1713
(256) 340-9359 (FAX)

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://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm300656.htm.



BEST MANAGEMENT PRACTICES FOR CHANNEL CATFISH FARMING IN ALABAMA 29

Theraputic Agents

BMP No. 11

**Definition**

Infectious diseases are common in catfish culture, and antibiotics may be added to feed (medicated feed), or certain drugs or chemicals may be applied to pond waters for disease treatment. Because antibiotics, drugs, or other compounds applied for disease control could occur in effluents, guidelines for use of therapeutic agents are necessary.

**Explanation**

Infectious diseases in catfish culture are more common and severe when fish are stressed by poor diet, environmental stress, improper handling, or other factors. The first principle of disease control should be to prevent stressing the fish. The most common stress in ponds usually is low dissolved oxygen concentration. When ponds are aerated to maintain adequate dissolved oxygen, stress may still result if high feeding rates cause elevated ammonia concentration. Thus, compliance with good water quality management procedures (See BMP Nos. 7, 8, and 9) can reduce stress and minimize the likelihood of disease. Nevertheless, fish disease may still occur in ponds with good water quality.

When diseases occur in ponds, samples of fish should be examined and the disease identified. Once the disease has been identified, an antibiotic, drug, or other chemical known to be effective against the disease often is recommended. Dose rates, application techniques, and withdrawal times for therapeutic agents should follow instructions provided on product labels. Water should not be intentionally discharged from ponds until the therapeutic agent has degraded.

**Use of Therapeutic Agents**

**Practices**

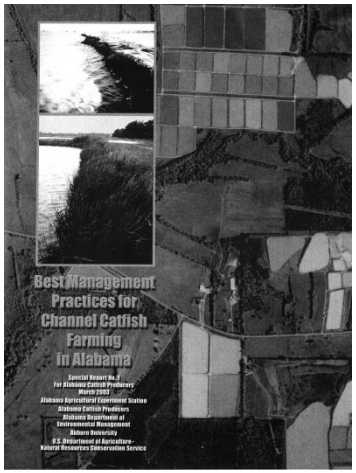
- Store therapeutics so that they cannot be accidentally spilled to enter the environment.
- Manage pond water levels to prevent or minimize overflow until therapeutic agents have degraded.
- Use good water quality management procedures to prevent unnecessary stress to fish.
- Make a diagnosis for diseases and a recommendation for disease treatment before applying therapeutic agents.
- Follow instructions on labels of therapeutic agents for dose application method, safety precautions, etc.

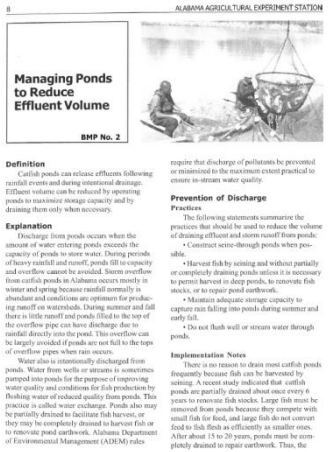
**Implementation Notes**

Disease diagnosis and recommendations for treatments should be done by fish health specialists. The Alabama Fish Farming Center can provide assistance with disease identification, treatment recommendations, and treatment oversight.

**References**

Browson, M. W. 1996. Catfish quality assurance. Publication 1873, Mississippi Cooperative Extension Service.



8 ALABAMA AGRICULTURAL EXPERIMENT STATION

Managing Ponds to Reduce Effluent Volume

BMP No. 2

**Definition**

Catfish ponds can release effluents following rainfall events and during intentional drainage. Effluent volume can be reduced by operating ponds to maximize storage capacity and by draining them only when necessary.

**Explanation**

Discharge from ponds occurs when the amount of water entering ponds exceeds the capacity of ponds to store water. During periods of heavy rainfall and runoff, ponds fill to capacity and overflow cannot be avoided. Storm overflow from catfish ponds in Alabama occurs mostly in winter and spring because rainfall normally is abundant and conditions are optimum for producing runoff on watersheds. During summer and fall there is little runoff and ponds filled to the top of the overflow pipe can have discharge due to rainfall directly into the pond. This overflow can be largely avoided if ponds are not full to the tops of overflow pipes when rain occurs.

Water also is intentionally discharged from ponds. Water from wells or streams is sometimes pumped into ponds for the purpose of improving water quality and conditions for fish production by flushing water of reduced quality from ponds. This practice is called water exchange. Ponds also may be partially drained to facilitate fish harvest, or they may be completely drained to harvest fish or to renovate pond earthwork. Alabama Department of Environmental Management (ADEM) rules require that discharge of pollutants be prevented or minimized to the maximum extent practical to ensure in-stream water quality.

**Prevention of Discharge**

**Practices**

The following statements summarize the practices that should be used to reduce the volume of draining effluent and storm runoff from ponds:

- Construct seine-through ponds when possible.
- Harvest fish by seining and without partially or completely draining ponds unless it is necessary to permit harvest in deep ponds, to renovate fish stocks, or to repair pond earthwork.
- Maintain adequate storage capacity to capture rain falling into ponds during summer and early fall.
- Do not flush well or stream water through ponds.

**Implementation Notes**

There is no reason to drain most catfish ponds frequently because fish can be harvested by seining. A recent study indicated that catfish ponds are partially drained about once every 6 years to renovate fish stocks. Large fish must be removed from ponds because they compete with small fish for feed, and large fish do not convert feed to fish flesh as efficiently as smaller ones. After about 15 to 20 years, ponds must be completely drained to repair earthwork. Thus, the

A ) R ®
(fl ARTICLE

# New VFD Rules: Feed Mill/Distributor Responsibilities

- File a one-time notice with FDA of intent to distribute VFD drugs
- Notify the FDA within 30 days of any change in ownership, business name, or business address
- Obtain a signed acknowledgement letter from downstream distributors (consignee) before the feed is shipped
- The distributor acknowledgement letter affirms:

1) the distributor will not ship such VFD feed to an animal production facility that does not have a VFD

2) the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter

3) the distributor has notified the FDA of their intent to distribute VFD feeds 21 CFR 558.6(c)(5)

- Retain a copy of each consignee distributor's acknowledgement letter for 2 years

# New VFD Rules: Feed Mill/Distributor Responsibilities

- A VFD order may be sent to the feed mill/distributor via hardcopy, fax, or electronically (by emailing a scanned document or by VFD order system compliant with 21 CFR part 11)

- Print a copy the electronic VFD for your files

# New VFD Rules: Feed Mill/Distributor Record Retention

- Keep copies of VFDs for 2 years from the date of issuance
- Produce VFDs for inspection and copying by FDA upon request
- Retain records of the receipt and distribution of all VFD medicated feeds for 2 years
- Retain records of VFD manufacturing for 1 year in accordance with 21 CFR part 225 and make records available for inspection and copying by FDA upon request

# New VFD Rules: Feed Mill/Distributor Responsibilities

- Fill a VFD only if the VFD contains all required information
- The feed mill/distributor, in consultation with the client will determine the amount of feed necessary to treat the approximate number of animals identified by the veterinarian on the VFD
- Ensure that the distributed VFD feed complies with the terms of the VFD and is in manufactured and labeled in conformity with approved label of the VFD drug
- Ensure all labeling and advertising prominently and conspicuously displays the following caution statement: **"Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by on the order of a licensed veterinarian."**

# New VFD Rules: 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

# New VFD Rules: Veterinarians' Responsibilities

- Must be licensed to practice in state the animals reside in
- Must be operating in the course of the veterinarian's professional practice and in compliance with all applicable requirements
- Must have valid VCPR to issue valid VFD
- May enter additional discretionary information to more specifically identify the animals to be treated/fed the VFD feed
- No Extra Label Use
- Must issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug
- Must prepare and sign a VFD and provide providing all required information
- Provide a copy to feed mill/distributor and client/producer
- Keep original VFD 2 years
- Make VFDs available to the FDA for inspection and copying upon request

# New VFD Rules: Changes for Veterinarians

- Must prepare written VFD (21 CRF 558.6(b)(7)) that includes the veterinarian's electronic or written signature (21 CFR 558.6(b)(3)(xv))

- Can send the VFD to the feed distributor by hardcopy, fax, or by electronically (emailing a scanned VFD document) or using a VFD order system to generate the VFD that is 21 CFR Part 11 compliant

- Expiration Date on the VFD specifies the last day that a VFD feed can be fed; the expiration date should be calculated by the calendar date not the number of days

- A single VFD may cover
  - animals on multiple production locations provided he/she can meet licensing and VCPR requirements and provided the VFD feed is supplied to multiple locations by a single feed manufacturer
  - Where the VFD drug is approved for use at multiple drug concentrations, or levels, the veterinarian may issue a singe VFD order covering all those approved levels intended to be used
  - Where a VFD drug is approved for use within a range of drug levels, then the veterinarian may specify a particular drug level within that range, or authorize use at any drug level within the by putting the enter authorized range on the VFD

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# New VFD Rules: Changes for Veterinarians

- VFD will list the number of animals to treat, farm location of animals, dose, and feed rate
- Feed distributor in consultation with the producer determines the amount of feed that is needed to treat

**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 bodyeight/day) | Florfenicol (grams/ton) | Initials |
|---|---|---|---|---|
| Freshwater-reared salmonids | For the control of mortality due to furunculosis associated with *Aeromonas salmonicida.*<br>For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum.* | 10 – 15 | 182 – 2,274 | |
| 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 – 2,274 | |

**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.

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# Optional Information on a VFD

- More specific location of animals to be treated
- Approximate age/weight range of animals to be treated
- Any other info veterinarian wants to include to identify the animals to be treated

# VFD Statement on Label

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

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# AQUAFLOR Veterinary Feed Directive

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://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm300656.htm.

AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE

# VFD Conclusions

- Encourages veterinary involvement with fish health program
- Ensures proper drug usage, which in turn helps to optimize product performance
- Ensures safety for humans, food and environment

CATFISH • TILAPIA • KOI • RAINBOW TROUT • HYBRID STRIPED BASS • BARRAMUNDI • WALLEYE • YELLOW PERCH • LARGEMOUTH BASS • BAITFISH • ORNAMENTALS • BROOK TROUT • ARCTIC CHAR

# Visit our Webpage

## www.aquaflor-usa.com


AQUAFLOR®
(florfenicol) TYPE A MEDICATED ARTICLE