Aquaculture Webinar Series

Introduction: D. Allen Pattillo, USAS Board Member and NCRAC Extension Coordinator
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Use of Veterinary Feed Directive Drugs in Aquaculture

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History of Animal Feed Drugs

• Drugs in animal feed prior to 1996
  ▪ Over the counter
  ▪ Prescription
    • Prescription drugs illegal in animal feeds in some states

• FDA: tighter control over antimicrobials
  ▪ Public concern: environmental contamination, residues in food, antimicrobial resistance
VFD Order and VFD Drug Created by Animal Drug Availability Act of 1996

• Animal Drug Availability Act of 1996
  ▪ Federal Food, Drug, and Cosmetic Act
  ▪ Veterinary Feed Directive (VFD) drug:
    ▪ All animal feed drugs approved after 1996
    ▪ Veterinary Feed Directive Order: a written statement issued by licensed veterinarian that orders the use of a VFD drug in/on animal feed.

• FDA issued First VFD Rule in 2000
Regulations Governing VFD Drugs

• Regulated by FDA with intent to:
  ▪ Reduce bacterial resistance
  ▪ Prolong effectiveness

• Administered under veterinary supervision
Aquaflor® Approved as VFD Drug

- Approved by FDA October 2005
- First aquatic VFD drug
  - Initially for catfish to treat enteric septicemia of catfish (ESC) only
  - Label claim expanded to include many other bacteria and fish species

FDA approves Aquaflor for catfish industry

The U.S. Food and Drug Administration late last month approved Aquaflor for combating ESC in farm-raised catfish, saying the product was safe to use by catfish producers.

It was the first antibiotic approved for use in the catfish industry in 20 years and is the first approved under the FDA’s Minor Use and Minor Species Animal Health Act (MUMS).

Aquaflor is the trade name for the Type A Medicated Article (florfenicol), which was developed for enteric septicaemia in catfish, a bacterial disease which causes millions of dollars in losses to the industry each year.

Aquaflor was developed by Schering-Plough Health Corp. of Union, N.J., a leading human and animal health company. FDA noted that the product is a Veterinary Feed Directive (VFD).
Categories and Types of Animal Drugs

**Category:**

I: No withdrawal period

II: Required withdrawal period

**Type:**

A: Medicated article

B: Medicated Feed

C: Medicated Feed
Classification of Aquaflor® Medicated Feed

- Category II Type C medicated feed

- Manufacture and use requires documentation
Veterinarian

Distributor

Manufacturers

Feed Manufacturer manufactures VFD feed with medicated article; can also be distributor

Producer

Copy of VFD

Copy of VFD*

Original VFD order

* Copy of VFD*
VFD Feed: Veterinarian’s Responsibilities

- Licensed
- Valid Veterinarian-Client-Patient Relationship (VCPR)
  - State vs. Federal
    - Assumes responsibility for fish health
    - Has recent knowledge of patient and/or facility
    - Available for follow-up care
  - Maintain medical records
  - Proper use of medication
    - No extra-label usage
    - Prompt treatment
    - Proper regime
 Veterinarian’s Responsibilities (cont’d)

- Issue VFD order in writing with ALL required information
  - Maintain electronic or original order on file and available for FDA inspection for 2 years
  - Provide electronic or hard copy to client and distributor
VFD Feed: Producer’s (Client’s) Responsibilities

- Cooperate with veterinarian to maintain valid VCPR
  - Follow dose rate, duration, and expiration date
  - Observe withdrawal times
- Maintain electronic or hard copy on file and available for FDA inspection for 2 years
- If in agreement with veterinarian, present copy of VFD order to distributor
VFD Feed: Distributor’s (Dealer’s) Responsibilities

- Notify FDA of intent to distribute VFD medicated feed *prior* to distribution

- Must have signed VFD order prior to delivery of VFD feed to producer’s facility

- Maintain electronic or hard copy on file and available for FDA inspection for 2 years
VFD Feed: Manufacturer’s Responsibilities

• Register with FDA
• Possess medicated feed mill license
  ▪ Can manufacture VFD feeds without signed order
• Maintain VFD feed manufacturing records for 1 year and available for FDA inspection
• If also distributor, maintain electronic or hard copy on file and available for FDA inspection for 2 years
**VFD Form**

(Usually provided by drug sponsor)
1. Name of VFD drug
2. Farmer’s name, address, and phone number
3. Veterinarian’s name, address, phone number
4. Identification of animals to be treated, including species, approximate number, production class and location
5. Condition or disease being treated
6. Feeding directions
7. Amount of drug to be mixed and duration of use
8. The following statement: “Extra-label use is strictly prohibited”

9. Affirmation of intent for combination drugs

10. Any warning or cautionary statements or special instructions (e.g. residue warning)

11. Date of ordering the VFD drug

12. Veterinarian’s signature

13. Expiration date of the VFD order

14. Number of refills (if permitted by the approval)
Optional Information on VFD Order Form

• More specific information on the treated fish location e.g. 10 acre ponds
• Approximate age/weight of fish
• Additional information veterinarian would like to include
Formulation of VFD Medicated Feed (Usually calculated by manufacturer)

\[ \text{[Medication in feed]} = \text{dose rate} \div \% \text{ feeding rate} \]

- Dose rate Aquaflor \( \text{®} \) = 10 mg FFC/kg body weight
- Percentage feeding rate (MS. Delta) = 2%

In this example, florfenicol medicated feed is blended at 500 ppm concentration in catfish feed
Electronic VFD Form Available Through Global VetLink and Rx Express

• Electronic submission of VFD order
  • Compliant with regulations
• Secure email and/or database to feed distributors and producers
  • Only accessible by parties granted access
• Decreases paperwork
• Monthly access fee and account maintenance fee

Link  https://www.globalvetlink.com/products/feedlink/
http://www.dvmrxexpress.com/
What’s New in the New VFD Rule?
(21 CFR 558.6(b))

• Expiration date:
  ▪ 2nd VFD Rule: VFD order expires within 6 months of issuance (veterinarian’s discretion)
    • In effect for Aquaflor® 10/1/2015
    • In effect for Romet® and Terramycin® 1/1/2017

• Duration of use (not new):
  ▪ Part of label claim: Part of approval, conditional approval or index listing
    ▪ e.g. 1x/day for 10 days
  ▪ If VFD order expires prior to completing duration of use, veterinarian must issue a new VFD order
What’s New in the New VFD Rule? (cont’d)

• VFD Second (New) Rule Modified First Rule based on FDA Guidelines #209 and #213
  ▪ #209: Eliminated production use of antibiotics and phased in veterinary oversight for therapy
  ▪ #213: Changed marketing status from over the counter (OTC) to prescription (water) or VFD (feed)

• All medicated feeds VFD feeds by January 2017
  ▪ Includes Romet® and Terramycin®
  ▪ Aquaflor® (always a VFD drug)
What’s New in the New VFD Rule? (cont’d)

• Distributor/producer (not veterinarian) calculate quantity of feed ordered

• Affirmation of Intent: If a combination feed contains ≥ 1 VFD drug, the combination must be ordered with a VFD
  ▪ No currently approved combination VFD or VFD/OTC drugs in aquaculture
  ▪ 21 CFR 558.6(b)
What’s New in the New VFD Rule? (cont’d)

• Transmit orders in person, by FAX, or electronically
  ▪ No telephone orders
  ▪ Electronic orders must be compliant with Part 11
• Maintain VFD orders for FDA inspection for 2 years
  ▪ Original or electronic: veterinarian
  ▪ Hard or electronic copies: distributor and producer
• Refills
  ▪ No refills allowed with VFD aquaculture drugs at this time
Information on VFD Feed Label

- Medicated feed issued by licensed veterinarian
- Complete use information, including feeding directions, refills, cautions, and warnings
- No refills
Example: VFD Orders and Expiration Date

• May 1: Pond 1 is stocked with catfish fingerlings and breaks with enteric septicemia of catfish (ESC)
• Ponds 2, 3, 4, and 5 are adjacent fingerling catfish ponds
• Producer needs VFD drug to treat ESC in Pond 1. He expects fish in ponds 2, 3, 4, and 5 to break with ESC also and requests a VFD order with a 10 week expiration date to cover fish in ponds 1-5
• No refills: If pond 1 breaks with ESC again (after May 1-10, a new VFD order must be issued for it)

May 1-10
May 20 -29
May 21- 30
June 11- 20
June 25 -July 4
Extra-label Use of Medicated Feeds

• No extra-label use of VFD drugs

  ▪ Few drugs available for aquaculture, FDA CVM considering regulatory discretion for extra-label use with New VFD Rule
  ▪ Final decision to be announced when final transition from over the counter (OTC) to VFD drugs take place (01/01/2017)
Highlights of New VFD Rule

• New rule in effect 10/01/2015
• Impacted Aquaflor® 10/01/2015
  ▪ Veterinarian can extend expiration date up to 6 months
  ▪ Production class and approximate number of fish required rather than fish biomass
  ▪ Producer and feed mill calculate the quantity of feed
• Target date for converting OTC medicated feeds to VFD medicated feeds 01/01/2017
• No extra-label use of VFD drugs
  ▪ FDA considering regulatory discretion for extra-label use and will announce with Final Rule 01/01/2017
Thanks for Your Attention!
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Questions about this webinar series should be directed to brentoncontact@iastate.edu
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• United States Aquaculture Society [http://usaquaculture.org/webinars](http://usaquaculture.org/webinars)