

AQUA

frequently asked questions

FAQs

No. 2

VFD Drugs and You: Understanding Your Role

AQUAFLO[®] (florfenicol) Type A Medicated Article is the first antibiotic licensed for U.S. aquaculture in more than 20 years. It is also the second animal health product to be classified by FDA as a Veterinary Feed Directive (VFD) drug, a new category established in 2000 to help the agency more closely control new therapeutic products, primarily antimicrobials, and their use in food animals.

How do VFD feeds differ from other medicated feeds?

Manufacturing of VFD feed is no different than manufacturing other medicated feeds containing Category II animal drugs. All VFD drugs will be Category II drugs, so feed mills will need to have a valid Feed Mill License (FML) to manufacture VFD feeds using the Type A Medicated Article. The major difference is that a VFD form signed by the producer's veterinarian is required to distribute VFD feeds to a producer, and a copy of the VFD form must be kept on file and made available for FDA inspection. Feed mills, their distributors, veterinarians and producers will need to learn about the VFD process and comply with all regulations.

What are the steps in the VFD process?

- The producer contacts a veterinarian for diagnosis and treatment.
- The veterinarian makes a determination that a VFD medicated feed is necessary within the veterinarian-client-patient relationship.
- The veterinarian issues a signed VFD order by including all of the information needed for a valid VFD or by filling out the drug supplier's preprinted form (if available) and giving it to the producer.

- The producer uses the VFD to order the feed from a feed supplier. A VFD feed may not be distributed to a producer without a signed VFD form.
- Licensed feed manufacturers and distributors that ship a VFD feed to a downstream distributor or retailer must receive and retain a copy of written acknowledgement stating that the VFD feed will be further distributed only in accordance with FDA requirements.
- The veterinarian who issues the VFD, the producer and the person or company supplying the VFD feed must retain copies of the signed VFD form for a minimum of 2 years.

What are the responsibilities of the veterinarian, the producer and the feed mill/distributor in the VFD process?

Producers, veterinarians, feed mills and distributors each have specific responsibilities:

THE PRODUCER'S RESPONSIBILITY

- Contact the veterinarian to diagnose and treat animals.
- Agree to follow the veterinarian's recommendations.
- Provide the original VFD order to the feed supplier if the veterinarian has not done so.
- No producer may obtain a VFD-medicated feed or a VFD premix from any source, including a commercial feed company, without a valid VFD unless the producer is also a distributor of VFD medicated feeds or has a FDA Feed Mill License.
- Producers may purchase VFD products in Type B (premix) or Type C (ready-to-feed) form. Producers may purchase Category II Type A premixes if they hold a valid Feed Mill License.

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- Producers can manufacture VFD-medicated feeds if they hold a valid Feed Mill License and comply with current Good Manufacturing Practices (GMPs).
- Keep a copy of the VFD order for a minimum of 2 years.
- Provide VFD orders for review and copying for FDA during inspection.
- Administer the VFD feed to the animal(s).

THE VETERINARIAN'S RESPONSIBILITY

- Be appropriately licensed.
- Write orders for VFDs only under the context of a valid veterinarian-client-patient relationship.
- Prepare and sign a written VFD order, in triplicate, providing all requested information.
- Provide the feed distributor with the original VFD order directly or through the client.
- Give a copy of the VFD order to the producer.
- Retain a copy for your records for a minimum of 2 years.
- Provide VFD orders for review and copying by FDA during inspections.
- Write VFD orders only for drugs approved as VFD drugs.
- Determine how long the VFD will be valid for, within FDA-approved limitations. The expiration date should be included as specified in the regulations.
- If the VFD form cannot be hand-delivered, it can be faxed or e-mailed. Within 5 working days, the veterinarian must assure that the original VFD order is received by the distributor. A veterinarian cannot issue a VFD order over the phone.
- If necessary, the veterinarian can issue another VFD, using a new form, when the previous VFD expires.

THE FEED MILL/DISTRIBUTOR'S RESPONSIBILITY

- Maintain a valid Feed Mill License (FML) Application (Form 3448) and renew registration each year with the FDA using Form 2656 as required by 21 CFR 207.20 and 21 CFR 207.21.
- Retain original VFD order supplied by the veterinarian's or producer for 2 years.
- Provide VFD orders for review and copying by FDA during inspections.
- Possess current approved Type B and/or Type C Medicated Feed labeling for each Type B and/or Type C Medicated Feed to be manufactured prior to receiving the Type A Medicated Article containing the drug.
- Notify FDA only once, by letter, of intent to manufacture and/or distribute feed containing the VFD drug.
- Obtain an acknowledgement letter from all consignees who distribute but are not the ultimate user of the feed.
- Notify the FDA within 30 days of any change in name or business address.
- Ensure that all labeling and advertising prominently and conspicuously displays the following cautionary statement:
"Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful Veterinary Feed Directive used by a licensed veterinarian in the course of the veterinarian's professional practice."

FOR MORE INFORMATION, CALL
1.800.521.5767 OR GO TO
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