

How the VFD Affects You

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A **“veterinary feed directive”** is a...

written (nonverbal) statement...

issued by a licensed veterinarian in the course of the veterinarian’s professional practice tha...

orders the use of a VFD drug or combination VFD drug in or on an animal feed.”

“This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client’s animals **only in accordance with the conditions for use approved, conditionally approved, or indexed by the Food and Drug Administration.”**

“Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a “no-residue” basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required.”

“For the purposes of this part, a **“distributor”** means any person who distributes a medicated feed containing a VFD drug to another person. Such other person may be another distributor or the client-recipient of a VFD”.

“(a) General requirements related to veterinary feed directive (VFD) drugs.

(1) Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.

(2) A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.”

(3) Use and labeling of a VFD drug or a combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. 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.

“(4) All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The distributor and client copies may be kept as an electronic copy or hardcopy.

(5) All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA upon request.”

“(1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:

- (i) Be licensed to practice veterinary medicine; and**
- (ii) Be operating in the course of the veterinarian’s professional practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client- patient relationship (VCPR) as defined by the State. If applicable VCPR requirements as defined by such State do not include the key elements of a valid VCPR as defined in § 530.3(i) of this chapter, the veterinarian must issue the VFD in the context of a valid VCPR as defined in § 530.3(i) of this chapter.”**

“The veterinarian must only issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug.”

“The number of **reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing. In cases where reorders (refills) are not specified on the labeling for an approved, conditionally approved, or index listed VFD drug, reorders (refills) are not permitted; “**

21 CFR Part 530.3(i)

“(i) 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”

21 CFR Part 530.3(i)

“(3) The practicing veterinarian is readily available for followup 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.”

What will be on your
VFD?

- “3) The veterinarian must ensure that the following information is fully and accurately included on the VFD:
- (i) The veterinarian’s name, address, and telephone number;
 - (ii) The client’s name, business or home address, and telephone number;
 - (iii) The premises at which the animals specified in the VFD are located;
 - (iv) The date of VFD issuance;”

“(v) The expiration date of the VFD. This date must not extend beyond the expiration date specified in the approval, conditional approval, or index listing, if such date is specified. In cases where the expiration date is not specified in the approval, conditional approval, or index listing, the expiration date of the VFD must not exceed 6 months after the date of issuance;

(vi) The name of the VFD drug(s);

(vii) The species and production class of animals to be fed the VFD feed;”

“(viii) The approximate number of animals to be fed the VFD feed by the expiration date of the VFD. The approximate number of animals is the potential number of animals of the species and production class identified on the VFD that will be fed the VFD feed or combination VFD feed at the specified premises by the expiration date of the VFD;

(ix) The indication for which the VFD is issued;

(x) The level of VFD drug in the VFD feed and duration of use; “

“(xi) The withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;

(xii) The number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing. In cases where reorders (refills) are not specified on the labeling for an approved, conditionally approved, or index listed VFD drug, reorders (refills) are not permitted; and

(xv) The veterinarian’s electronic or written signature.”

What this means for cattle producers

Your Procedure for a Feed Containing a Medically Important Antibiotic

- Your veterinarian may recommend this in response to a disease challenge identified in your ongoing relationship, or...
- Or, as we transition to VFD drug labels, this may have been a disease control, prevention, or treatment regimen you have used over the years and have now approached your veterinarian for authorization

Your Procedure for a Feed Containing a Medically Important Antibiotic

- Please be prepared that this is not an automatic authorization, but will initiate a conversation
 - **Non-antibiotic alternatives**
 - **Legality** (Does it match the label?)
 - Dose, duration, indication
 - **Need** for the use
 - **Efficacy** of the proposed antibiotic use in relation to your disease challenge
 - Ability to meet the **withdrawal time** prior to slaughter
 - The veterinarian is also tasked with considering issues of **antimicrobial resistance**

Your Procedure for a Feed Containing a Medically Important Antibiotic

- And, please understand that your veterinarian can only legally authorize any VFD or prescription drug within the context of a Veterinary-Client-Patient relationship.
- Your veterinarian will exercise their clinical judgement based on their training and experience within the confines of the law.

Your Procedure for a Feed Containing a Medically Important Antibiotic

- If appropriate, your veterinarian will complete either a written or electronic Veterinary Feed Directive form.
- Your veterinarian will
 - keep the original,
 - provide you with a copy, and
 - provide your designated provider of the medicated feed with a copy

VFD Required?

- Milk replacer with neomycin and oxytetracycline
 - Yes
- Chlortetracycline in the feed for footrot
 - Not allowed, this is illegal extralabel use
- Mineral or feed with chlortetracycline for anaplasmosis prevention
 - Yes, the VFD may only specify label inclusion rates in feed and mineral
- Tylosin for reduction in liver abscesses
 - Yes

VFD Required?

- Monensin (Rumensin[®]) as the only antibiotic in the ration.
 - No, this is not a medically important antibiotic
- Monensin fed concurrently with Tylosin
 - In this case, the VFD for tylosin would need to authorize the concurrent feeding of monensin
- Chlortetracycline or oxytetracycline in the feed for treatment of bovine respiratory disease
 - Yes

Will I need a new VFD for each pen of cattle in a feedlot or each time I pick up a medicated mineral?

- Your veterinarian will determine multiple specifications on the VFD
 - **Regimen** of the antibiotic (dose, duration) within label options (there may be only one or a range)
 - **Number** of cattle to which the VFD drug may be fed
 - **Amount** of the VFD drug which may be purchased
 - The **duration** of use.
 - The length of time the VFD drug is allowed to be fed to the animals.
 - **The Expiration date.**
 - Specifies the last day the VFD feed can be fed

Water vs. Feed, as of December 2016

- **All medically important antibiotics used in the feed will require a VFD**
 - There is no legal use of in-feed drugs other than as provided for on the label
- **All medically important antibiotics used in the water will require a prescription**
 - This prescription may indicate extralabel use of the antibiotic in water if the requirements of the Animal Medicinal Drug Use Clarification Act (AMDUCA) Regulations are met

Your Veterinarians are...

- **Actively engaged with the FDA Center for Veterinary Medicine in initiating the VFD process**
- **Continuing to engage in training on the VFD process as well as all aspects of the approved labels for in-feed use of medically important antibiotics**
- **Committed to working with their clients**

