Veterinary Feed Directive Requirements for Veterinarians

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The animal health products and the U.S. Food and Drug Administration (FDA) approved uses of products discussed in these proceedings are current as of February 2017. Keep in mind that new products may enter the marketplace and current products may change their label directions following an FDA approval process. FDA-approved label directions supersede anything else that you may hear or read about feed medications, including these proceedings. Extra-label use of feed medications has always been and continues to be STRICTLY PROHIBITED. The intent of these proceedings is not to promote any particular product, but to serve as an unbiased resource for proper use of medicated feeds.

Veterinary Feed Directives are not new to the U.S. livestock industry, but they are new to many southeastern livestock producers, veterinarians, feed mills, and feed distributors following implementation of the updated U.S. Food and Drug Administration (FDA) Veterinary Feed Directive (VFD) guidance in January 2017. Prior to the implementation of these new guidelines, the majority of antibiotics used in or on feed for southeastern livestock were available over-the-counter; meaning livestock producers did not need a VFD from a veterinarian to obtain these medications from feed mills and distributors. These proceedings addresses some frequently asked questions to assist veterinarians administering medicated feeds in compliance with FDA VFD regulations.

Veterinary Feed Directives

What is a Veterinary Feed Directive (VFD)?

A VFD is a written 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. 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 by the FDA. A VFD is also referred to as a VFD order.

What is a VFD drug?

A VFD drug is a drug intended for use in or on animal feed, which is limited to use under the professional supervision of a licensed veterinarian.

What is a "combination VFD drug"?

A "combination VFD drug" is an approved combination of animal drugs intended for use in or on animal feed under the professional supervision of a licensed veterinarian, and at least one of the animal drugs in the combination is a VFD drug. However, there are currently only a limited combination of feed additives that are approved to be fed together, so always make sure that any other feed additives are FDA-approved for use with a VFD drug.

What is a VFD feed?

A VFD feed is a feedstuff bearing or containing a VFD drug, and is limited to use under the professional supervision of a licensed veterinarian.

Veterinarian Supervision

What is required for veterinarian supervision?

The veterinarian-client-patient relationship (VCPR) is the basis of professional supervision.

What is a valid veterinarian-client-patient relationship (VCPR)?

The FDA defines a valid veterinarian-client-patient relationship as 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 or manager of the animal or animals) 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 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.

Likewise, the Alabama Veterinary Medical Practice Act defines a valid veterinarian-client-patient relationship as one in which the veterinarian has assumed responsibility for making medical judgments regarding the health of the animal or animals and the need for medical treatment, and is created by actual examination by the veterinarian of the animal or a representative segment of a consignment or herd.

Over-the-Counter, Prescription, and Veterinary Feed Directive Drugs

How do you know if a drug is a VFD drug, rather than an over-the-counter (OTC) drug?

Read the label. All labeling and advertising for VFD drugs and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian." Over-the-counter (OTC) drugs do not have this statement.

What is the difference between a VFD drug and a prescription drug?

FDA approves drugs in these two separate regulatory categories for drugs that require veterinary supervision and oversight for their use. When the drug being approved is for use in or on animal feed, the FDA approves these drugs as a VFD drug. When the drug being approved is NOT for use in or on animal feed, the drug is approved as a prescription drug. For example, prescription drugs require veterinary supervision and oversight for their use and are administered via injections or drinking water.

Why VFD instead of prescription?

When the VFD drug category was created, it was made very clear that VFD drugs are not prescription drugs. The VFD category was created to provide veterinary supervision without invoking state pharmacy laws for prescription drugs that were unworkable for the distribution of medicated feed.

How do you know if a drug is a VFD drug, rather than an over-the-counter (OTC) drug?

Read the label. All labeling and advertising for VFD drugs and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian." Over-the-counter (OTC) drugs do not have this statement.

Is there a slaughter withdrawal time associated with VFD drugs?
Sometimes yes, and sometimes no. It depends on the drug and dosage administered. Refer to the FDA-approved VFD drug label for specific information regarding slaughter withdrawal times.

What is "extra-label use" of a VFD drug and is it allowed?
"Extra-label use" is defined in FDA's regulations as actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. Feeding animals a VFD drug for a duration of time that is different from the duration specified on the label, feeding a VFD drug to control or treat a disease condition not specified on the label, feeding a VFD drug formulated with a drug level that is different from what is specified on the label, or feeding a VFD drug to an animal species different than what is specified on the label are all considered extra-label uses. Extra-label use of medicated feed, including medicated feed containing a VFD drug or a combination VFD drug, is STRICTLY PROHIBITED. For example, feeding chlortetracycline to control or treat pinkeye or foot rot is currently considered an extra-label use and always has been and continues to be illegal. This could change if the manufacturer of a chlortetracycline product sought and was granted FDA-approval for foot rot and/or pinkeye.

Veterinary Feed Directive Transmitting and Record Keeping

How does a livestock producer obtain a VFD feed?
Use of a VFD feed requires the professional supervision of a licensed veterinarian. Producers must have a VFD order from their veterinarian to obtain a VFD feed.

How does a VFD order get from the veterinarian to a VFD feed manufacturer and/or distributor?
A veterinarian may send a copy of the VFD to the manufacturer or distributor via hardcopy, facsimile (fax), or other electronic means. If in hardcopy, the veterinarian is required to send the copy of the VFD to the distributor either directly or through the client.

Who gets the original VFD or a copy of the VFD, and how long must the VFD be kept?
The veterinarian must retain the original VFD in its original form (electronic or hardcopy) for 2 years, and must send a copy of the VFD to the distributor and client. Feed distributors and clients must retain a copy of the VFD for 2 years as well.

Expiration Date versus Duration of Use

What is the "expiration date" for a VFD?
The expiration date on a VFD specifies the last day the VFD feed can be fed. The expiration date cannot exceed 6 months from the date the VFD was issued, and may be less than 6 months in some cases depending on product specifications.

What is the difference between an "expiration date" on the VFD and duration of use?
While the VFD expiration date defines the period of time for which the authorization to feed an animal feed containing a VFD drug is lawful, the duration of use determines the length of time that the animal feed containing the VFD drug is allowed to be fed to the animals. For example, chlortetracycline cannot be fed for more than 5 days for the treatment of bacterial enteritis or bacterial pneumonia, but may have an expiration date of 6 months. That means the client technically has 6 months to obtain the VFD feed and complete the 5-day course of therapy.

Can a VFD feed be used past the VFD expiration date?
A VFD feed must not be fed to animals after the expiration date on the VFD. If a VFD order is set to expire before completing the duration of use on the order, the client should contact their veterinarian to request a new VFD order. This does not mean the client has to necessarily discard the old VFD feed, but they do need a current VFD order to feed it.

Lawful Veterinary Feed Directives

The following information is REQUIRED on a lawful VFD:

- veterinarian's name, address, and telephone number
- client's name, business or home address, and telephone number
- premises at which the animals specified in the VFD are located
- date of VFD issuance
- expiration date of the VFD
- name of the VFD drug(s)
- species and production class of animals to be fed the VFD feed
- approximate number of animals to be fed the VFD feed by the expiration date of the VFD
- indication for which the VFD is issued
- level of VFD drug in the feed and duration of use
- withdrawal time, special instructions (e.g. daily feeding vs free-choice), and cautionary statements necessary for use of the drug
- number of reorders (refills) authorized, if permitted according to the label directions
- the following statement: "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra-label use), is not permitted"
- an affirmation of intent for combination VFD drugs as described in 21 CFR 558.6(b)(6)
- veterinarian's electronic or written signature

The following information is OPTIONAL on a VFD:

- a more specific description of the location of the animals (for example, by site, pen, barn, stall, tank, or other descriptor the veterinarian deems appropriate)
- the approximate age range of the animals
- the approximate weight range of the animals
- any other information the veterinarian deems appropriate to identify the animals at issue

Who is the "client" on the VFD?
The "client" on a VFD is typically the client in the VCPR; the person responsible for the care and feeding of the animals receiving the VFD feed.

Can a VFD authorize a reorder (refill)?
Yes, but only if the FDA drug approval expressly allows a reorder (refill), and only if the veterinarian specifically authorizes a reorder(s). If a drug is silent on reorders (refills), then reorders are not authorized. Most VFD drugs do not allow for reorders (refills).

How do you obtain a blank VFD order?
Many VFD drug sponsors have made VFD orders for their drugs available, or, as a veterinarian you may create your own VFD for a VFD drug using the requirements for a lawful VFD above.

How do you issue a VFD for a combination VFD drug?
You may expand or limit the use of a VFD drug along with OTC animal drug(s) in an approved combination(s), as appropriate, by stating the affirmation of intent on the VFD order.

Major and Minor Animal Species

What are "major and minor animal species" with respect to VFDs?
FDA regulations define cattle, horses, swine, chickens, turkeys, dogs, and cats, as major species. All animal species, other than humans, that are not major species are minor species (e.g. sheep, goats, fish, honeybees, etc.).

When is a VFD needed for a minor species?
The VFD requirements apply to all VFD drugs for use in major or minor species. Some example VFD drugs approved for use in minor species include florfenicol in aquaculture and oxytetracycline in honey bees.

Veterinary Feed Directive Drug Administration

VFD drugs must be administered according to label directions. VFD drugs are either mixed in the daily ration, administered daily as a top-dress, or in unique situations can be fed free-choice. The exact route of administration depends on FDA-approved label directions. Unless specifically allowed per FDA-approved drug guidelines, VFD drugs should be administered on a daily basis.

Veterinarian Responsibilities for Providing Lawful Veterinary Feed Directives

What are your responsibilities as a veterinarian when providing veterinary feed directives?

- must be licensed to practice veterinary medicine
- must be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements
- must write VFD orders in the context of a valid client-patient-relationship (VCPR)
- must 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
- must prepare and sign a written VFD providing all required information
- may enter additional discretionary information to more specifically identify the animals to be treated/fed the VFD feed
- must include required information when a VFD drug is authorized for use in a drug combination that includes more than one VFD drug
- must restrict or allow the use of the VFD drug in combination with one or more OTC drug(s)
- must provide the feed distributor with a copy of the VFD
- must provide the client with a copy of the VFD order
- must retain the original VFD for 2 years
- must provide VFD orders for inspection and copying by FDA upon request

VFD Feed Manufacturing

Does a feed mill need a medicated feed mill license to manufacture VFD feed?
It depends. Feed mills are required to have a license if any of the VFD drugs they use to manufacture medicated feed are Category II, Type A medicated articles (defined at the end of this bulletin). A license is also required in some situations involving certain liquid and free-choice medicated feeds. In other

cases, they may only need to notify the FDA prior to distributing animal feed containing a VFD drug for the first time.

What is the FDA definition of a "distributor" as it relates to VFD feeds?
Under VFD regulation, a "distributor" means any person who distributes a medicated feed containing a VFD drug to another person.

What is required in order to become a VFD distributor?
All distributors of VFD feed must notify the FDA before they distribute for the first time. A distributor must also notify the FDA within 30 days of a change in ownership, business name, or business address.

Are VFD feed distributors allowed to make pioneer/generic drug substitutions?
Yes, distributors may use an approved substitute (e.g., one brand of Type A medicated article instead of another) when manufacturing VFD feeds, unless specifically prohibited on the VFD order. Substitution is allowed when both products are FDA-approved for the same use.

It is important to note that Aureomycin® is the ONLY chlortetracycline product that is currently FDA-approved for use in free-choice feeds or mineral mixes, and it can only be used free-choice when following very specific guidelines. For example, Aureomycin® can only be used in free-choice feeds as an aid in control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline. Aureomycin® cannot be used be used in free-choice feeds to treat or control any other disease conditions. Since Aureomycin® is the only chlortetracycline product that is currently FDA-approved for used in free-choice feeds or mineral mixes, substitution for another chlortetracycline product would not be allowed in this case.

Definitions

Below are some terms you may encounter with respect to classifications for animal drugs as they relate to medicated feeds:

1. Category I drug – These drugs require no withdrawal period in each species for which they are approved.
2. Category II drug – These drugs require a withdrawal period 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.
3. Type A medicated article – a medicated article intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. A Type A medicated article is essentially an undiluted feed medication that must be further mixed and diluted before it can be fed to animals. Examples include, but are not limited to, Aureomycin® 90 Granular, ChlorMax® 50, and PENNCHLOR 90 G®, all of which are designed to be blended with feed to make a complete feed and/or mineral mix. Of those examples, only Aureomycin® 90 Granular could be blended into a free-choice mineral mix.
4. Type B medicated feed – a medicated feed that is intended solely for the manufacture of other medicated feeds (Type B or Type C). It is manufactured by diluting a Type A medicated article or another Type B medicated feed. A Type B medicated feed is essentially a diluted, partially mixed feed medication that must be further mixed and diluted before it can be fed to animals. An example is a mineral mix containing 2800 grams per ton chlortetracycline (CTC) that is intended to be mixed with feed to produce a complete feed containing CTC, but the CTC is delivered in a mineral or supplement mix that goes into the feed.

5. Type C medicated feed – a medicated feed intended as the complete feed for the animal or may be fed "top dressed" (added on top of usual ration) or offered "free-choice" (e.g., supplement) in conjunction with other animal feed. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may also be further diluted to produce another Type C medicated feed. Examples include 1) a bulk or bagged preconditioning feed containing CTC designed to be fed as a complete feed to weaned calves, or 2) a CTC-containing top dress formulation to be added to feed at 1 lb/head/day.

For additional information:

AskCVM@fda.hhs.gov
Guidance for Industry #120
21 CFR 558.6 (VFD)
21 CFR 225 (cGMP)
Website: http://www.fda.gov/safefeed

References:

1. U.S. Food and Drug Administration Veterinary Feed Directive (VFD)
   http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm
2. The Compendium of Veterinary Products
   http://www.bayerlivestock.com/show.aspx/resources/compendium-of-veterinary-products