



Veterinary Feed Directive

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Under the Animal Drug Availability Act (ADAA) of 1996, congress created a new regulatory category for drugs called veterinary feed directive (VFD) drugs. Prior to this new rule, all drugs were classified by the Food and Drug Administration (FDA) as over-the-counter (OTC) or prescription (Rx) drugs. A VFD drug is an animal drug intended for use in or on animal feed requiring the supervision of a licensed veterinarian.

VFD drugs are not prescription drugs. VFD drugs are not governed by state pharmacy laws, unlike prescription drugs. Prescription drugs are not mixed in or on animal feed. Prescription drugs may be used under certain conditions in an extra-label manner, which is strictly prohibited for VFD drugs.

Until now, only a select few drugs have been designated VFD drugs. On June 3, 2015, the Food and Drug Administration (FDA) released the final version of the amended new animal drug regulation for the VFD drugs. The revised rule will change all OTC feed grade antimicrobials that are medically important antimicrobial drugs (drugs that are important for therapeutic use in humans) to VFD drugs. Some of the common OTC beef cattle drugs used in or on feed that will be affected by the change in the rule are chlorotetracycline, neomycin, oxytetracycline, tylosin and sulfas. A few drugs that are not considered important in human medicine such as ionophores, coccidiostats, bacitracins, bambermycin, carbadox and pleuromutilin will continue to be available OTC. The one current VFD drug used in beef cattle, tilmicosin, will switch to the new rule on October 1, 2015. The OTC drugs used in or on feed will change to VFD drugs on January 1, 2017.

In keeping with the FDA's theme of judicious use of medically important antimicrobials, pharmaceutical companies have voluntarily agreed to remove any growth performance claims from the label of VFD drugs. This change means use of these drugs for weight gain or improved feed efficiency is prohibited. Emphasis is placed on using these drugs for prevention, control and treatment of diseases under the oversight of a veterinarian.

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VFD feeds may only be purchased with a VFD order. A VFD order is a written statement issued by a licensed veterinarian after examining and diagnosing an animal(s) condition. When the veterinarian deems it necessary to treat, control or prevent the disease, he or she may order the use of a VFD drug or combination VFD drugs in or on animal feed. A producer may obtain a VFD order from their veterinarian, provided they have a proper Veterinary-Client-Patient-Relationship (VCPR). The definition of a VCPR is defined by federal regulation as:

1. A veterinarian has assumed the responsibility for making the medical judgements 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).
3. The practicing veterinarian is available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can only exist when the veterinarian has recently seen or 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.

A valid VFD should contain the following information:

- Veterinarian's name, address and phone number
- Client's name, address and phone number
- Premises at which the animals specified in the VFD are located
- Date of VFD issuance
- "Expiration date"
- Name of VFD drug
- Species and production class of animals to be fed
- Approximate number of animals
- The indication for which the VFD is issued
- The level of VFD drug in the feed and the "Duration of Use"
- The withdrawal time, special instructions and cautionary statement
- "Reorders or Refills"
- The statement: "Use of feed containing this veterinary feed directive (VFD) in a manner other than directed on the labeling (extra label use) is not permitted."

- An affirmation of intent for combination VFD drugs
- Veterinarian's signature

Premise is a description of where the animals are located. It needs to be specific enough for someone that may not be familiar with the area to find those animals. A producer may include landmarks, GPS information or pen numbers in addition to an address to help better describe the location.

The "expiration date" specifies the last day a VFD feed can be fed, not the date the drug becomes ineffective. In the drug approval process, some, but not all, drugs have this information included on the label. For those drugs without a specified date, the veterinarian will assign an "expiration date" not to exceed 6 months. Producers may not feed the VFD feed beyond the "expiration date." If a producer cannot complete the therapy before the "expiration date," the producer should contact their veterinarian and obtain a new VFD.

The "duration of use" determines the length of time the animal feed containing a VFD drug is allowed to be fed to the animals.

Some producers may question the difference between "expiration date" and "duration of use." The "expiration date" is the last day the feed may be fed. The "duration of use" is number of days of therapy. For instance, if a VFD drug has an "expiration date" of 45 days and a "duration of use" of 14 days, the producer has 45 days to obtain the VFD feed and complete the 14 days of therapy. If the VFD drug label does not specify the "expiration date" or "duration of use," then the veterinarian will specify those dates, which may not exceed 6 months.

During the drug approval process, if a reorder (refill) is approved, then a veterinarian is permitted to authorize a reorder. If label is silent on reorders, a veterinarian may not authorize a reorder.

"Extra-label" use of VFD drugs or OTC drugs in feed is strictly forbidden by the FDA. Neither the producer nor the veterinarian is allowed to use VFD drugs or OTC drugs in a manner not specified by the label. A producer may not feed

the VFD feed in a manner that is different than what the label specifies. Examples of "extra-label" use are feeding to a different species, feeding at a different concentration, feeding longer than the "duration of therapy," or feeding past "expiration date."

A VFD drug may be combined with another VFD drug or OTC drug, if specified by the label of the VFD drug. A veterinarian must specifically allow for a VFD drug to be combined with another VFD drug or OTC drug in the VFD order.

A producer has certain responsibilities when feeding a feed containing a VFD drug. If the veterinarian gives the distributor's copy of the VFD order to the producer, the producer must provide the VFD order to the feed distributor. A producer is responsible for feeding a feed with a VFD drug according to the label written by the veterinarian. He or she must not feed the VFD feed beyond the expiration date. Lastly, a producer must maintain a copy of the VFD order for a minimum of 2 years and provide a copy of the VFD order for inspection and copying if requested by the FDA.

If a producer wishes to obtain more information about veterinary feed directives, he or she may view the document Code of Federal Regulations, Title 21, Chapter I, Subchapter E, Part 558 or go to <http://www.fda.gov/animalveterinary/developmentapprovalprocess/ucm071807.htm>.

References

- Guidance for Industry #120: Veterinary Feed Directive Regulation Questions and Answers.
- Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.
- Guidance for Industry #213: New Animal Drugs and New Animal Generic Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations.
- Code of Federal Regulations, Title 21, Chapter I, Subchapter E, Part 558.
- Code of Federal Regulations, Title 21, Chapter I, Subchapter E, Part 530.

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