

Antibiotic Use and the Veterinary Feed Directive

We enjoy one of the safest and most affordable food supplies in the world thanks to years of hard work by many—farmers, ranchers, veterinarians, processors, packers, distributors, government agencies, and others. To protect the gains made, it is the responsibility of livestock producers to understand and follow the laws and be prepared to meet the new and changing standards set in the years to come.

The U.S. Food and Drug Administration (FDA) is responsible for protecting public health by assuring the safety, efficacy, and security of human and animal drugs, biological products, and the food supply, among other things. The FDA Center for Veterinary Medicine (CVM) specifically regulates animal drugs, animal feeds, and animal devices. All medications (drugs) used in livestock, such as cattle, sheep, goats, pigs, and poultry, are regulated by the FDA because they are used in animals that will enter the human food supply. It's that simple.

Animal drugs are available as over-the-counter (OTC), prescription (Rx), or through a veterinary feed directive (VFD). For prescriptions and VFDs, veterinarians are responsible for authorizing the proper medications, in a legal manner, only to those animals that truly need them. In turn, producers are responsible for the proper use and administration, according to the drug label, and documentation of all prescription and VFD medications used in their animals.

Dispensing, prescribing, or authorizing a prescription or VFD product requires a valid veterinary-client-patient relationship (VCPR). *It is illegal for a veterinarian to dispense or write a prescription or VFD for an animal/herd he/she has not seen or is unfamiliar with.* A VCPR is important for both veterinarians and livestock producers because it communicates a type of “agreement” between parties on the responsibility and care for the animals. Under the guidelines of the FDA Animal Medicinal Drug Use Clarification Act (AMDUCA), a VCPR exists when all of the following conditions are met (Title 21, Code of Federal Regulations, Part 530 or 21 CFR 530):

- ▶ The veterinarian has assumed responsibility for making clinical judgments regarding the health of the animal/herd and the need for medical treatment, AND the client has agreed to follow his/her directions.
- ▶ 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).

- ▶ The 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 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.

Drugs used in food animals must be used according to their labeled directions, unless the veterinarian feels that an extra-label drug use (ELDU) is indicated. The FDA allows ELDU only under the context of an established VCPR, and only with products that are not prohibited for ELDU. Extra-label drug use means the “actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling; use for indications (disease or other conditions) not listed in the labeling; use at dosage levels, frequencies, or routes of administration other than those stated in the labeling; and deviation from the labeled withdrawal time based on these different uses” (21 CFR 530). A current list of drugs prohibited from ELDU can be found at www.fda.gov or www.farad.org.

Rules regarding ELDU apply to both OTC and prescription products. This is an area that is often misunderstood: *both OTC and prescription products require veterinary oversight to be used in an extra-label manner.* In other words, just because you can purchase a product without a prescription doesn't mean you can use it any way you'd like. Withdrawal times for extra-label use of any product, as well as use according to the label, must be provided by the veterinarian. Medication delivered in feed can only be used according to the label. Extra-label use of medication in feed is strictly prohibited and has been for many years. Veterinarians cannot legally prescribe the use of any feed additive other than what is on the label.

Changes in Medicated Feed Laws: The Veterinary Feed Directive

Medicated feeds are currently available either OTC or by VFD. VFDs are a classification of drug defined in 1996 under the Animal Drug Availability Act that allows administration of certain “medically important” drugs in or on animal feeds. A VFD is “a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional

practice that orders the use of a VFD drug or combination VFD drug in or on animal feed.” Tilmicosin used in feed for the treatment and prevention of cattle and swine respiratory disease is one example of a product that currently requires a VFD for use.

Medicated feeds have gained a lot of attention over the past few years over concern of the potential development of antimicrobial resistance in animal and human populations. As a response to these concerns, the use of medications in feed that are considered “medically important” in human medicine will be restricted in the near future to treatment, control, or prevention of bacterial diseases of animals, under the oversight of a veterinarian. This removes the growth promotion, feed efficiency, and milk production uses from the labels of all currently approved medically important drugs used in feed. Furthermore, after January 1, 2017, any listed “medically important” antibiotics currently available in feed for animals will require a VFD (Table 1). In addition, medically important antimicrobials currently available to be used in water will require a veterinary prescription.

How will this work? After a veterinarian has determined that an animal or group of animals requires a medicated feed product, the veterinarian will issue a VFD to the producer and also provide a copy of the VFD to the distributor either directly or through the client. The producer can then obtain the medicated feed from the feed distributor. The feed distributor will be allowed to fill the VFD order as long as they have an “intent to distribute” on file with the FDA and an “acknowledgement letter” on file with the drug supplier or feed manufacturer that states the product will only be dispensed to producers with a valid VFD. The veterinarian will keep the original VFD, and both the producer and the distributor will be required to keep copies of the VFD for 2 years.

The move to VFD regulations will undoubtedly cause some confusion as well as some initial inconvenience to cattle producers, veterinarians, feed distributors, and manufacturers alike. However, these new requirements will help ensure the judicious use of antimicrobials in food animals, while continuing to ensure our safe and wholesome food supply. It’s important that everyone understands the regulations to make the transition to VFD feed products go smoothly. Some of the most frequently asked questions are discussed on the next pages.

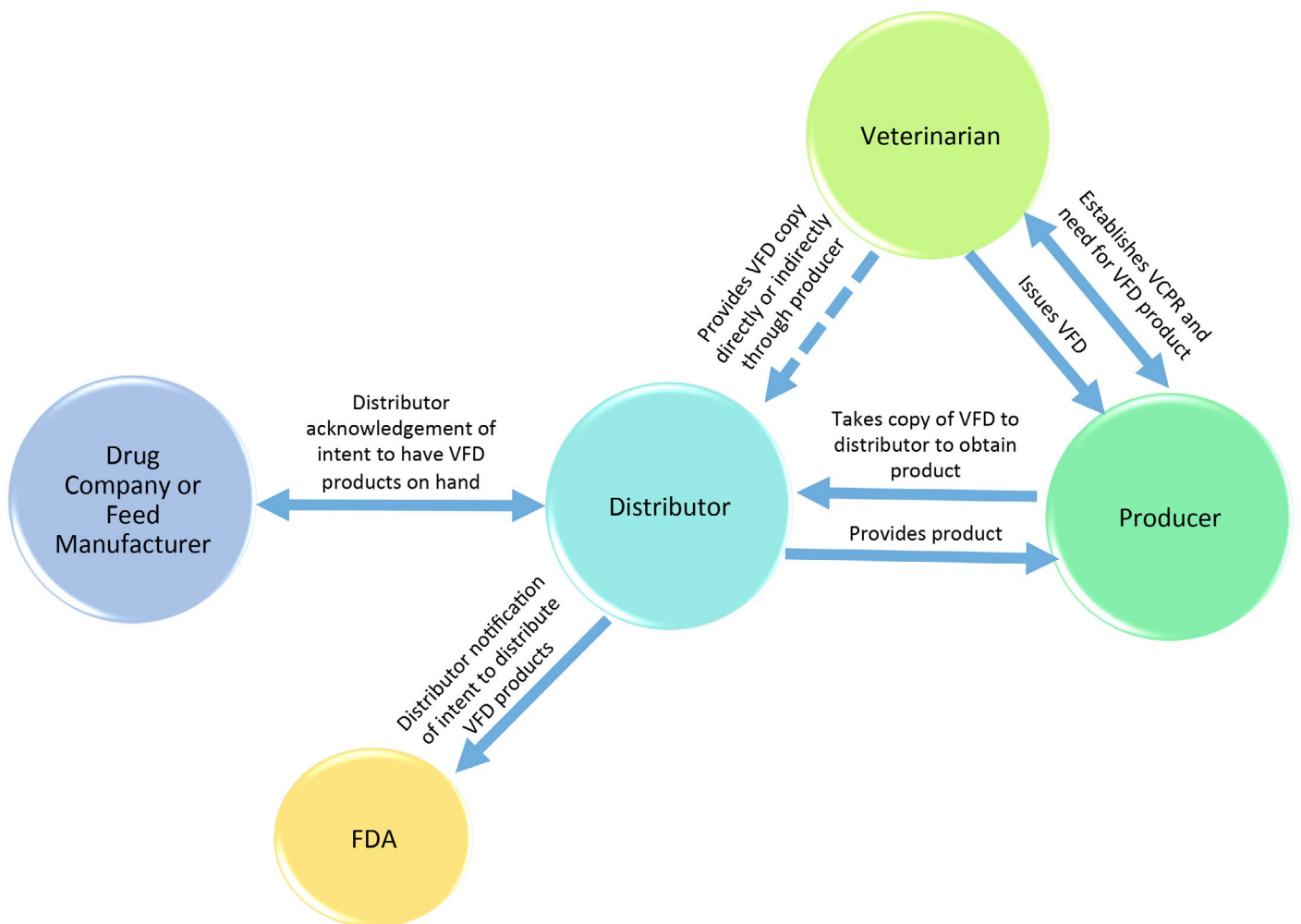


Table 1. Drugs transitioning from OTC to VFD status after January 1, 2017.*

Drug name	Examples of proprietary drug names
chlortetracycline	Aureomycin, CTC, CTC. Cloratet, ChlorMax, Chlortetracycline, Pennchlor, Deracin
chlortetracycline/sulfamethazine	Aureo S, Aureomix S, Pennchlor S
chlortetracycline/sulfamethazine/penicillin	Aureomix 500, Pennchlor SP
hygromycin B	Hygromix
lincomycin	Lincomix
oxytetracycline (OTC)	TM, OXTC, Oxytetracycline, Pennox, Terramycin
oxytetracycline/neomycin	Neo-Oxy, Neo-Terramycin
penicillin	Penicillin, Penicillin G Procaine
sulfadimethoxine/ormetoprim	Rofenaid, Romet
tylosin	Tylan, Tylosin, Tylovet
tylosin/sulfamethazine	Tylan Sulfa G, Tylan Plus Sulfa G
virginiamycin	Stafac, Virginiamycin, V-max

*Additional drugs may be approved but are not currently marketed for livestock.

Adapted from FDA CVM. Most current list of VFD drugs can be found at: <https://www.fda.gov/animal-veterinary/development-approval-process/drugs-veterinary-feed-directive-vfd-marketing-status>

Frequently Asked Questions

What is a VFD?

A VFD (also known as a VFD order) is a written statement issued by a licensed veterinarian that orders the use of a VFD drug or combination VFD drug in or on animal feed.

What type of medications will require a VFD after January 1, 2017?

Medicated feeds containing antibiotics that are important to both human and animal health (also known as “dual use” antibiotics) will require a VFD. These include antibiotics currently used in cattle feeds, such as chlortetracyclines, oxytetracyclines, and tylosin. Anthelmintics (dewormers), coccidiostats, ionophores, and a few other antimicrobials that are not routinely used in humans will not be affected. A complete and updated list of drugs that will be transitioning to VFD status can be found at <http://www.fda.gov/animalveterinary/developmentapprovalprocess/ucm071807.htm>.

How do I know if my current mineral or feed contains a medication that will require a VFD?

Read the feed tag. Many premixes and minerals, such as “fly control” minerals, contain low levels of antibiotics. The product information sheet will contain a list of all medications as well as any related cautionary or withdrawal statements. After January 1, 2017, all VFD products will contain the following statement on the label: “Caution: federal law restricts medicated feed containing this veterinary feed directive drug (VFD) to use by or on the order of a licensed veterinarian.”

If I have a supply of medicated feed left over at the end of 2016, can I still use it?

You will need to obtain a VFD from your veterinarian in order to use any medicated feeds after January 1, 2017, even if you have previously purchased the product and have it in your possession.

Can I still mix my own feed using a VFD drug?

Yes, as long as you have a VFD order to get the medication needed to manufacture your feed.

Will the VFD order allow for generic substitutions of a drug?

Yes, generic substitutions for a pioneer drug are allowable as long as the veterinarian authorizes the use of an approved generic drug. For combination VFD products, the generic drug must also be approved in combination in order to be used.

Can I still obtain injectable over-the-counter (OTC) antibiotics?

Yes, regulations involving the acquisition and use of OTC injectable antibiotics are currently not under revision. Medications administered in the water that are currently available OTC, such as neomycin, sulfas, and tetracyclines, will require a prescription from your veterinarian for use after January 1, 2017.

Can my veterinarian call in a VFD order to my local feed distributor?

No. VFDs can be issued in hard copy/paper form, electronically, or by fax, but they cannot be issued verbally.

Will my local co-op be able to have these medicated feeds on hand when I need them, or will I have to wait a period of time before receiving my feed?

As long as your feed distributor (co-op, feed mill, etc.) has a “letter of intent” on file with the FDA, and an “acknowledgement letter” with the drug supplier or feed manufacturer, they will be able to keep a stock of medicated feeds on hand to distribute to customers with a valid VFD.

I have cattle located in several locations throughout the state. Do I need a VFD for each premise?

No. A VFD can be written for multiple locations owned by the same person as long as the feed is acquired from the same distributor.

Once I obtain a VFD from my veterinarian, how long is it good?

A VFD will have both an expiration period and a duration of use specified on it. The *expiration period* refers to how long the VFD is valid. This will be determined by either the product label or by your veterinarian after evaluating the medical needs of your animal(s) and cannot exceed a period of 6 months. The *duration of use* refers to the amount of time an animal or group of animals should be fed the medicated product. The duration of use will be specified by the labeled directions for that particular drug.

Can a veterinarian distribute VFD products?

Under VFD regulations, a veterinarian can distribute VFD products as long as they notify the FDA that they intend to distribute animal feeds containing a VFD product. This one-time “notification letter” essentially establishes the veterinarian as a VFD distributor and allows them to fill a VFD order. As a recognized distributor, the veterinarian must follow all rules pertaining to VFD distributors.

What species of animals will be affected by the new regulations?

All species of food-producing animals, including cattle, poultry, swine, and even minor food species such as honeybees and food fishes, will be required to follow the new regulations for medicated feed and water products.

This ruling will require a lot of paperwork. How long should I keep copies of VFDs?

The producer, veterinarian, and feed distributor must keep records for 2 years and have them readily available for FDA inspection upon request. VFD manufacturers must keep product-manufacturing records for 1 year.

What can I do to prepare for the new regulations?

Discuss the drug laws as well as the upcoming changes with your herd veterinarian and review medications that you currently use. If you don't have a herd veterinarian, now is the time to establish a veterinary-client-patient relationship. Focus on disease prevention strategies such as fly control and preconditioning programs for calves, which may reduce the need for antimicrobials, rather than worrying about where that next bag of medicated feed is going to come from. Evaluate your herd health record-keeping practices since new rules will require additional record-keeping and documentation. If you use medications in feed, understand the VFD process so that future implementation will be smooth.

Here in the U.S., we want to continue to enjoy one of the safest and most affordable food supplies in the world. It's our job to manage our livestock appropriately to ensure consumer confidence and continue to provide safe and wholesome food products. We can do that by understanding and practicing the judicious use of antimicrobials. For the most current information on drug laws or veterinary feed directives, contact your herd veterinarian or visit the FDA's website at <http://www.fda.gov/animalveterinary/developmentapprovalprocess/ucm071807.htm>.

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