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The Veterinary Feed Directive: The Why, What, and How Guide for Livestock Producers

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Why?

THE FOOD AND DRUG ADMINISTRATION (FDA) has taken regulatory action to ensure drugs used to treat bacterial diseases in both humans and food animal species are used appropriately and safely. This regulation applies to all food-producing animals, even those not intended for actual food production. This regulatory action is designed to address public concerns regarding antibiotic resistance, food safety, and animal health and welfare. Veterinarians now have greater oversight of antibiotic use in feed and water used to treat food-producing animals. In summary, the FDA developed the following judicious-use strategy for antimicrobials:

The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health. The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.

The FDA has deemed antibiotic resistance one of the most serious threats to animal and human health. The Veterinary Feed Directive (VFD) is a regulation driven by the FDA to address public health concerns and food safety, to protect drug efficacy, and to aid in the judicious use of medically important antimicrobial drugs in food-producing animals. Medically important antimicrobials (MIAs) are drugs used to treat disease in both animals and humans. The FDA proposed that addressing these issues by increasing veterinarian oversight and transparency in the use of MIAs will reduce the incidence of antimicrobial resistance. Essentially, this new rule ends performance-enhancement uses of feed-grade antimicrobials and places the use of these products labeled for prevention, control, or treatment of disease in food-producing animals under the control of licensed veterinarians. Currently, the VFD regulations do not affect ionophores, parasite/insect control drugs, reproductive drugs, and injectable antibiotics.

How and When?

The VFD addresses two principles to 1) limit the use of MIAs in food animals to therapeutic applications, and 2) provide veterinary oversight of MIAs. The principles were designed to ensure judicious use and good judgment in using and prescribing antimicrobials and to enforce drug-residue withdrawal times. Table 1 describes the VFD implementation timeline.

What Is a Veterinary Feed Directive?

A VFD is a written statement issued by a licensed veterinarian that authorizes and supervises the purchase and use of an approved VFD drug or a combination VFD drug in animal feeds. A combination VFD drug is an approved combination of new animal drugs intended for use in animal feeds. The VFD expires within six months from the issue date and cannot be used once it has expired. Refills and top dressing on feeds are not permitted with VFD drugs. If additional treatment is needed, the VFD must be reissued by the veterinarian. All parties, including veterinarians, producers, 4-H livestock/poultry participants, and feed mills, must keep records for two years as per federal guidelines. However, states have the authority to increase the length of time records are kept. It is important to understand that this regulation affects everyone who is raising food-producing animals, including those responsible for a single animal or hundreds of animals. Table 2 describes common feed-use antibiotics affected by the VFD regulation.

Five important terms should be understood as they apply to the VFD regulations. These terms include the Veterinary-Client-Patient Relationship (VCPR), expiration date, duration of use, withdrawal period, and extra-label use.

Veterinary-Client-Patient Relationship

A VCPR is critical to navigating the VFD rules and regulations. This is a relationship you must initiate with a licensed veterinarian of your choosing. A veterinarian is qualified and responsible for making medical judgments regarding animal health and treatment needs. The veterinarian must examine and diagnose animal conditions and have sufficient knowledge of the animal(s) being treated within a 12-month time period. The veterinarian must also determine when an animal needs a VFD drug, the

Table 1. VFD timeline.

Date	Action
December 2013	• Drug companies asked to voluntarily revise their product labels to remove claims of growth promotion and increased feed efficiency.
October 1, 2015	• VFD rule activated. • Three Medically Important Antibiotics (MIAs) identified: Avilamycin, Florfenicol, and Tilmicosin.
October 1, 2015 – December 31, 2016	• Pharmaceutical industry allotted time to address label changes on medicated feed products. • Time period established for veterinarians, producers, and feed mills to navigate rule logistics.
December 8–10, 2016	• Growth and/or performance claims ruled for removal from labels.
January 1, 2017	• Full rule went into effect requiring veterinarian oversight on all MIAs used in or on feed to require a VFD and for those used in drinking water to require a prescription (Rx). • VFD list expanded to include all medicated feed additives containing MIAs. • Injectable antibiotics are currently exempt.

Table 2. Common feed-use antibiotics affected by the VFD regulation.*

Species	Drug Name*
Cattle	Tilmicosin, Neomycin, Tylosin, Penicillin, Virginiamycin, Chlortetracycline, Oxytetracycline, Sulfamethazine; and combinations of these antibiotics
Swine	Avilamycin, Florfenicol, Chlortetracycline
Sheep	Tetracycline, Chlortetracycline, Oxytetracycline
Goats	No VFD drugs are currently labeled for use in the treatment of goats
Poultry	Chlortetracycline, Oxytetracycline, Halofuginone, Lincomycin, Neomycin, Penicillin, Hygromycin B, Sulfadimethoxine + Ormetoprim, Virginiamycin
Fish	Aquaflor
Honeybees	Tetracycline, Oxytetracycline, Tylosin, Lincomycin†

* Feeds containing these drugs are no longer available over the counter and require veterinary oversight. This includes protein tubs fortified with insect growth regulators, minerals, starter rations, and milk replacers.

† These drugs are generally administered in a water-based solution and require a prescription.

daily dosage, and the length of treatment, and must be available for a follow-up in case of an adverse reaction or therapy failure. The veterinarian can help ensure the appropriate drug is used to minimize the chance of antibiotic resistance, and to keep antibiotic residues out of the food supply.

Expiration Date

An expiration date is the legal period of time authorized to feed an animal a feed containing a VFD drug. The date of expiration should be calculated by the calendar date, not the number of days. For example, if using a six-month expiration date for a VFD, if the VFD is written on July 10, then the expiration date will be January 10 of the following year. The expiration date of the VFD is also the last date any VFD feed can be fed—do not use the VFD feed after this date. If further treatment is needed, a veterinarian needs to reevaluate the animals. The maximum treatment period for a VFD feed is six months.

Duration of Use

Duration of use is a concept separate from the expiration date. Established by a veterinarian, the duration of use is the length of time that a feed containing a VFD drug can be fed. For example, in swine, the currently approved VFD drug tilmicosin has an expiration date of ninety days with a duration of use of twenty-one days. This means that when the VFD is issued, the client has ninety days to obtain the VFD feed and to complete the twenty-one-day course of therapy. A veterinarian can also write a VFD for less than six months for small producers.

Withdrawal Period

A withdrawal period is the amount of time necessary for an animal to metabolize an administered product and the amount of time necessary for the product concentration level in the tissues to decrease to a safe, acceptable, and legal level. Animals should not be marketed into the food supply during the withdrawal period. Every federally approved drug or animal health product has a withdrawal period printed on the product label or package insert. Products carry meat withdrawal periods ranging from 0 to 60 days. For example, animals treated with a product that has a withdrawal period of forty-five days should be withheld from sale or slaughter for at least forty-five days. Withdrawal times are not the same for all drugs. Withdrawal periods may be extended when combinations of drugs are used or when drugs are used in an extra-label manner.

Extra-Label Use

Extra-label use of a drug occurs when the actual or intended use is not in accordance with the approved labeling. The following are examples: feeding animals a VFD feed for a duration of time that is different from what is specified on the label; feeding VFD feed formulated with a drug level that is different from what is specified on the label; or feeding VFD feed to an animal species different than what is specified on the label. Extra-label use of medicated feed, including medicated feed containing a VFD drug or a combination VFD drug, is not permitted for cattle, swine, and poultry. Some latitude is available for extra-label use in minor species, i.e., sheep and goats.

VFD Drugs Versus Prescriptions

There are differences between a VFD and a written prescription. The two terms are distinguished by the intended use of the drug. When a drug is used in animal feed, it is classified as a VFD drug. If the drug is not used in animal feed but is used in water, it is classified as a prescription. That means all water-soluble antibiotics and sulfa products labeled for use in water require a written prescription. Both classifications require a new prescription or VFD after the expiration date or completion of a treatment period. VFD drugs cannot be used in water and most of them are not soluble in water. The VFD category circumvents state pharmacy laws that do not work for the distribution of medicated feed. Table 3 identifies water-use antibiotics and Table 4 identifies feed-use antibiotics.

The same drug categories are used in both water and feed treatments. However, formulations of these drugs that are used in feed and are not water soluble require a VFD. The drug formulations that are water soluble require a prescription from a veterinarian. Table 5 identifies some products requiring a prescription versus a VFD.

Table 3. Affected water-use antibiotics.

Antimicrobial Class	Drugs Approved for Use in Water	Species Used in	Application
Aminoglycosides	Apramycin, Gentamicin, Neomycin, Spectinomycin, Streptomycin	Cattle, Swine	Bacterial diseases; *Escherichia coli*, *Salmonella*, *Pasteurella*
Lincosamides	Lincomycin	Cattle, Swine, Poultry	A variety of bacterial diseases
Macrolides	Carbomycin, Erythromycin, Tylosin	Cattle, Swine	Respiratory infection, Enteritis, Metritis
Penicillins	Penicillin	Cattle	Local and systemic bacterial infections
Streptogramins	Virginiamycin	Cattle, Swine, Poultry	*Staphylococci* infections
Sulfas	Sulfachloropyrazine, Sulfachlorpyridazine, Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline	Cattle, Swine, Sheep, Goats	Coccidiosis, Mastitis, Metritis, Toxoplasmosis, Respiratory infections
Tetracyclines	Chlortetracycline, Oxytetracycline, Tetracycline	Cattle, Swine, Poultry	Keratoconjunctivitis, Chlamydiosis, Anaplasmosis, Actinobacillosis

Table 4. Affected feed-use antibiotics.

Antimicrobial Class	Drugs Approved for Use in Feed	Species Used in	Application*
Aminoglycosides	Apramycin, Hygromycin B, Neomycin, Streptomycin	Cattle, Swine, Poultry	Bacterial diseases; *E. coli, Salmonella, Pasteurella*
Diaminopyrimidines	Ormetoprim, Trimethoprim	Cattle, Swine	Pneumonia
Lincosamides	Lincomycin	Swine, Poultry	Dysentery, Pneumonia, Enteritis
Macrolides	Erythromycin, Oleandomycin, Tylosin	Cattle, nonlactating Dairy Cattle, Swine, Sheep, Poultry	Pasteurella, Salmonella, Pneumonia, Dysentery, Mastitis, Respiratory infection
Penicillins	Penicillin	Cattle, Swine, Sheep, Poultry	Metritis, Pneumonia, Leptospirosis, Skin infections
Streptogramins	Virginiamycin	Cattle, Swine, Poultry	Common bacterial infections
Sulfas	Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline	Cattle, Swine, Sheep, Poultry	Actinobacillosis, Coccidiosis, Mastitis, Metritis, Toxoplasmosis, Respiratory disease
Tetracyclines†	Chlortetracycline, Oxytetracycline, Aureomycin	Cattle, Swine, Sheep, Poultry	Keratoconjunctivitis, Chlamydiosis, Anaplasmosis, Actinobacillosis, Respiratory disease, Pneumonia, Enteritis, Vibrionic abortions in sheep

* Applications vary by species. Not all applications are listed.

† Labeled uses vary by manufacturer.

Table 5. Examples of products requiring prescriptions (Rx) versus a VFD.

Water-Soluble Drugs Requiring an Rx	Drugs Used in Feed Requiring a VFD
Oxytetracycline HCL Soluble Powder	Aureomycin 4G Crumbles (chlortetracycline)
L-S 50 Soluble Powder (lincomycin and spectinomycin)	Scour-Ease Medicated (neomycin and oxytetracycline)
SulfaMed-G Soluble Powder (sulfadimethoxine)	Sav-a-Caf (neomycin sulfate and oxytetracycline)
Di-Methox Soluble Powder (sulfadimethoxine)	Calf Medic Plus (neomycin and oxytetracycline)

VFD Labels and Forms

All VFD drug labels contain the following 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." The VFD drug labeling must be prominently displayed. Since over-the-counter drugs are not VFD drugs, they do not have to include this statement.

VFD feed cannot be distributed without a signed VFD form. Valid forms must contain

- the veterinarian's and client's contact information
- the date of issuance
- animal identification number, number of animals, production class of animals, and species
- location of the animal(s)
- the name of the VFD drug
- indications and issuance of VFD, i.e., disease and why prescribed
- level of drug in feed and duration of use
- drug-use instructions and withdrawal times
- cautionary statements
- the drug's expiration date
- the veterinarian's license number and the licensing state
- 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)
- the authorizing veterinarian's electronic or written signature

Find a valid VFD Form as prescribed by the FDA at https://www.isvma.org/wp-content/uploads/2016/11/AVMA-VFD-form.pdf

Producers, 4-H Livestock Owners, and VFD

The VFD requires additional work and planning for all involved parties. Without a proactive approach, livestock owners and managers lose quick access to necessary medicated feeds. This could result in increased animal health issues, increased use of therapeutic treatments versus preventive treatments, and increased animal health costs. Over two hundred products have changed from being available over the counter to requiring a VFD. Consult a veterinarian to prevent delays in obtaining antimicrobials used in feed or water; discuss the products you use and when they are needed. Begin these conversations early to prevent treatment delays.

Your basic responsibility as a producer is to provide animal feed containing VFD drugs only to animals identified on a VFD order. Others include using only approved combinations of VFD drugs; not using feed whose drugs have passed their expiration date; and adhering to the entire time period prescribed for treatment.

Regarding any necessary paperwork, you or your veterinarian must provide a copy of the VFD order to the feed distributor and maintain a copy of that order for two years.

Most importantly, work with your veterinarian regarding animal health issues.

In the past, livestock owners/managers had the ability to purchase supplements fortified with chlortetracycline, mineral supplements, range meals, and special-purpose feed blends (starter rations and milk replacers). Producers still have access to nonmedicated feed options, but all medicated formulations of these products now require a VFD. For example, in the past, chlortetracycline was used for weight gain and feed efficiency, control of bacterial pneumonia, treatment of scours and anaplasmosis, and has been used for extra-label purchases for grazing fescue and treatment of pink eye, foot rot, and liver abscesses. Chlortetracycline can no longer be used in feed or water for weight gain and feed efficiency and any extra-label use is not allowed.

Table 6 identifies nonmedically important medicated feed additives approved for weight gain and feed efficiency that are currently available over the counter.

Table 6. Nonmedically important feed additives available over the counter (that do not require a VFD) for livestock.

Common Name	Active Ingredient	Application
Corid Deccox*	Amprolium Decoquinate	Coccidiosis prevention
Bovatec Rumensin*	Lasalocid Monensin	Weight gain Coccidiosis prevention No withdrawal time Available in mineral mix
Gainpro	Bambermycin	Weight gain No withdrawal Available in mineral mix
Bloat Guard	Poloxalene	Bloat prevention
Melengestrol acetate (MGA)	Synthetic progesterone	Synchronization programs
Safe-Guard Rumatel	Fendenbazole Morantel tartrate	Internal worm parasite control

* These products are not approved for combination use. The current exception is Deccox and Rumensin.

Farm, Ranch, and 4-H Livestock Participant Scenarios

Beef

Scenario 1: A group of calves develops scours. Under the VFD regulation, over-the-counter medicated milk replacers are no longer available. Nutrition, colostrum management, and vaccination protocols are now more critical than ever. However, if a producer chooses to use antibiotics in feed as a treatment method, a veterinarian must be consulted to diagnose the disease and provide a VFD to the producer. Once the veterinarian writes the VFD, the veterinarian will either send it to the feed mill electronically or you will be responsible for delivering it to a feed manufacturer of your choosing.

Scenario 2: A group of beef yearlings develops coccidiosis. Coccidiostats such as Corid, Deccox, ionophores, and sulfonamides are still available for treatment. These products can be purchased and used without a VFD to treat coccidiosis.

Table 7. Nonmedically important feed additives available over the counter (that do not require a VFD) for poultry.

Common Name	Active Ingredient	Application
Avatec	Lasolocid	Coccidiosis
Corid	Amprolium	Coccidiosis
Bio-Cox	Salinomycin sodium	Coccidiosis
BMD	Bacitracin methylene disalicylate	Enteritis
Deccox	Decoquinate	Coccidiosis
Histostat	Nitarsone	Blackhead disease
Robenz	Robenidine hydrochloride	Coccidiosis
Zoamix	Zoalene	Coccidiosis

Dairy Cattle

Scenario: A herd of dairy heifers develops pneumonia. Tetracycline products are labeled to treat and control this disease. Because treatment might include tetracycline used in feed, you will need to contact your veterinarian for a diagnosis and a VFD. You must follow the VFD order and product labels for the duration of use, as well as dosage. Also, talk with your veterinarian about any other feed additives in the dairy heifer mix to prevent feeding an illegal combination product.

Swine

Scenario: A group of weaner pigs develops enteric (intestinal) bacterial disease from *Salmonella choleraesuis*. Prior to the VFD regulation, swine producers could use Tylan in water or chlortetracycline in feed to treat this health problem. Tylan now requires a prescription from a veterinarian and chlortetracycline requires a VFD. However, Mecadox (carbadox) is not used in human medicine so it does not fall under the VFD regulation and is labeled, so it can be used to treat enteric disease in swine. In this scenario, you can either purchase Mecadox or consult a veterinarian for a diagnosis and VFD.

Small Ruminants

Scenario 1: A flock of ewes is infected with *Campylobacter fetus* (vibriosis), which causes late-term abortions. This disease is treated with Aureomycin in feed. This product can no longer be purchased over the counter. In order to treat the flock and prevent further infection, a written VFD order from a licensed veterinarian must be obtained. This would be an extra-label use in a minor species which is currently allowed. In addition, developing and utilizing an effective vaccination program will aid substantially in disease prevention.

Scenario 2: A flock of goats becomes infected with coccidiosis, a protozoan that causes an infection of the intestinal tract in livestock and poultry. Currently, there are no feed drugs labeled to treat goats. The producer should consult with their veterinarian about the use of injectables, boluses, or prescription drugs that can be used in water.

Poultry

Scenario: A flock of chickens suffers from bloody diarrhea and a loss of appetite. It is suspected the flock has become infected with coccidiosis. Corid (Amprolium) treats coccidiosis in poultry but it is not a veterinary feed drug. You can purchase this product from a farm and ranch supply store over the counter. However, if the condition persists after three days of treatment, consult a veterinarian for a diagnosis and a possible VFD.

Producer and 4-H Livestock Participant Summary Steps

- Initiate a conversation with a veterinarian about your livestock and/or poultry production situation.
- Obtain a VFD order from this veterinarian if the veterinarian diagnoses a disease that can be treated with a VFD drug. Your veterinarian may charge a fee for their time to research and write a VFD.
- Deliver the VFD order to a feed manufacturer or supplier. This can be done electronically or by hand.
- Follow the directive exactly as written.
- Check for additional requirements if you are a producer that manufactures feeds or serves as a distributor.

Summary

The VFD affects all MIAs used in feed. All feed-grade medications can only be used according to label and dose indications as written on the VFD. No provisions allow for their use to promote growth and efficiency. You must receive a signed and written authorization form from a licensed veterinarian to purchase and use VFD antimicrobials in feed. It is highly recommended that you maintain a good relationship with your veterinarian. This enables you to quickly consult with your him/her to obtain VFD antimicrobials when and if deemed necessary for animal treatment.

Additional Information

Fact Sheet: Veterinary Feed Directive Final Rule and Next Steps (FDA): https://www.fda.gov/animal-veterinary/development-approval-process/fact-sheet-veterinary-feed-directive-final-rule-and-next-steps

Merck Sharp and Dohme. *Merck Veterinary Manual (Pharmacology)*. 11th ed. Online version. 2016. Kenilworth, NJ: Merck. https://www.merckvetmanual.com/pharmacology

Veterinary Feed Directive Information

Drugs with Veterinary Feed Directive (VFD) Marketing Status: https://www.fda.gov/animal-veterinary/development-approval-process/drugs-veterinary-feed-directive-vfd-marketing-status

Veterinary Feed Directive (VFD): https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-vfd

Veterinary Feed Directive Producer Requirements (FDA): https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-producer-requirements

Veterinary Feed Directive Requirements for Distributors (Who Manufacture VFD Feed) (FDA): https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-requirements-distributors-who-manufacture-vfd-feed

Veterinary Feed Directive Requirements for Veterinarians—For Veterinary Students (FDA): https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-requirements-veterinarians-veterinary-students

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