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How the Veterinary Feed Directive Affects Cattle Owners[1]

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The Veterinary Feed Directive (VFD) is a federal regulation from the Food and Drug Administration that will change the additives that can be included in animal feed, the ways in which cattle producers manage their animals and veterinarians interact with cattle owners, and the products available for use on the ranch.

What is the VFD?

The VFD is a regulation that controls the use of animal drugs. When the VFD was originally created in 1996, two classes of drugs were identified: over-the-counter (OTC) and prescription (Federal Register 2015). However, no actual prescriptions were required for medicated feeds as that was determined to be impractical for production purposes. As a result, all medicated feeds were classified as OTC. Due to the new amendments that went into effect in January 2016 and are to be fully implemented in 2017, a new category, VFD drugs, was created. The new rules are meant to regulate the use of antibiotics in the animal feed industry in order to preserve the efficacy of the drugs, ensure the drugs are only used for therapeutic reasons, and require the supervision of a veterinarian.

What does the VFD do?

The new amendments make three significant changes to the original VFD rule.

1. They require drug manufacturers to alter labels for certain drug products, remove the statements regarding production issues (e.g., "increased rate of weight gain"), and only state therapeutic uses for health issues.

2. They change the designation of certain additives from OTC to "medically important," which categorizes them as VFD drugs and increases the regulatory requirements of the additives.

3. A veterinarian must fill out a VFD form before any VFD drug or feed containing a VFD drug is provided to a producer.

Why was the VFD developed?

The VFD was developed to address the potential for antibiotic resistance in human and animal pathogens that could be related to increased chronic exposure to or indiscreet use of antibiotics in animals. The intent of the VFD is to regulate the use and preserve the efficacy of antibiotics. The regulation states that shared use drugs, or drugs used in both humans and animals to treat diseases, deemed important for human medicine should be reserved for the prevention, treatment, or control of diseases. These include antibiotics (Federal Register 2015). This new mandate means that medicated feeds cannot be used to improve growth or feed efficiency for production purposes. The terms "prevention," "treatment," and "control" have

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specific meanings when used in relation to disease as well as guidelines that veterinarians will have to consider in each situation to permit the use of VFD drugs (Griffin 2016b). Prevention means that a disease risk is present, and the use of VFD drugs can prevent infection prior to animals becoming sick/infected. Treatment refers to instances in which animals are exhibiting signs of disease that can be treated by a VFD additive. Control is the term used when a percentage of the animals are already sick and symptomatic, and the use of a VFD drug can limit the spread of the disease.

Whom will the VFD affect?

As implemented, the VFD will affect all animals, particular food animals. The VFD will affect the entire beef cattle production chain and its associated industries. Cow-calf, stocker cattle, and feedlot producers will be affected if or when they want to purchase a medicated feed or supplement with a VFD additive. Feed manufacturers and retailers will be affected by increased amounts of required oversight and regulatory paperwork. Additionally, feed distributors will be required to verify that an animal owner possesses a valid VFD form from a licensed veterinarian prior to the sale of a feed or supplement.

How will this affect the cattle owner?

According to the first regulation, an animal owner must have a valid veterinarian-client-patient (VCP) relationship with a veterinarian. This means that the veterinarian must have worked with the client to ascertain the animal's health status, make clinical judgments about the animal's health status, and provide follow-up care (Lashment 2016a). The second regulation requires the veterinarian to complete a VFD form that identifies the specific drug that will be administered. There is a list of items that the VFD form must contain that includes (but is not limited to): the contact information of the veterinarian and client, the premise ID, the expiration date of the VFD order, the name of the drug, the indications for use, the directions for use, and the kind and number of animals (Federal Register 2015). Collection of this information is intended to ensure that the feed additive is used in an appropriate, safe, and judicious manner and to prevent off-label use of the product. VFD drugs are species-, product-, and purpose-specific and are not designed for production in order to prevent off-label use (Lashment 2016a). Once a valid VFD form has been obtained from the veterinarian, it can be taken to a feed or supplement supplier and used to acquire the feed product for use. Use of the feed product must be in accordance with the directions detailed in the VFD. The last regulation is that copies of all VFD forms must be retained for two years by the producer, veterinarian, and feed supplier.

Which products do or do not fall under the VFD?

Essentially all feed-use antibiotics that the FDA, WHO, and CDC consider medically important to humans fall under VFD regulation. There is currently one VFD antibiotic approved for use in cattle, tilmicosin (Pulmotil) that is used to control bovine respiratory disease (BRD). Injectable antibiotics that are used only for treatment and control are not subject to the VFD because they are not included in feed. Medically important antibiotics used in the cattle industry that will require additional labeling or relabeling to be compliant with the VFD regulations include:

- Chlortetracycline (Aureomycin, CLTC, Pennchlor)
- Chlortetracycline + Sulfamethazine (Aureo S 700)
- Neomycin + Oxytetracycline (Neo-Terramycin, Neo-Oxy)
- Oxytetracycline (Terramycin, Pennox)
- Streptomycin
- Sulfadimethoxine
- Tylosin (Tylan)
- Virginiamycin (V-Max) (Griffin 2016a)

The VFD's intent is ultimately to regulate antibiotics that are important to human medicine. Feed additives that do not pose a threat to medical effectiveness in humans will not require a VFD to keep being used in animal production. These additives include products such as anti-foaming agents, ionophores, parasite- or insect-control agents, and steroid hormones. The list below indicates a few of the products that will not require a VFD (Griffin 2016a).

- Amprolium (Corid)
- Bacitracin (Albac, BMD)
- Bambermycin (Gainpro)
- Decoquinate (Deccox)
- Fenbendazole (Safe-Guard)
- Laidlomycin (Cattlyst)
- Lasalocid (Bovatec)
- Melengestrol Acetate (MGA)
- Methoprene (Altosid)

- Monensin (Rumensin)
- Morantel (Rumatel)
- Poloxalene (Bloat Guard)
- Ractopamine (Optaflexx, Actogain)
- Tetrachlorvinphos (Rabon)

What will be included on a VFD?

Certain information will have to be on a valid VFD (Federal Register 2015). This information includes the names, addresses, and phone numbers of the animal owner and veterinarian. Information about the animals, such as physical location, number of animals to be treated, and approximate body weights, must also be on the record. Animals on different premises will require separate VFDs. Necessary information about the feed additive includes its effective date and expiration date, withdrawal time, notes of the combinations or limitations with other VFD drugs or OTC products, total amount of VFD medication and feed to be manufactured, and specific feeding instructions. The expiration date depends on the product, but it must not exceed 180 days. A VFD feed cannot be given to animals after its expiration date. If the animal needs to receive the product for a longer period of time, then a new VFD is required. The amounts and directions on the VFD are not open to interpretation or alteration by the producer. Failure to follow the instructions on the label or VFD constitutes prohibited off-label and extra-label use of the feed.

What are the legalities of the VFD?

An animal owner must possess a valid VFD to legally feed a VFD-medicated feed to animals. Without a valid VFD, the feed in question would be considered unsafe, adulterated, and misbranded according to the Food, Drug, and Cosmetic Act. Any animal consuming a VFD feed in the absence of a valid VFD form would also be considered adulterated and most likely unmarketable. The penalties are outlined in 21 U.S.C. §§331–334 (Lashmet 2016b) and could include imprisonment, monetary penalty, injunctive relief, and/or seizure of property. A first offense could result in one year in prison and a $1,000 fine. Repeat offenders could face three years in prison and a $10,000 fine. Veterinarians in violation of the VFD could be found liable and face penalties from the state veterinary board.

The new regulations for the relabeling and classification of additives will take effect January 2017. The transition to this new system of regulation is an attempt to maintain the efficacy of antibiotics that are important for human medicine. Members of the beef cattle industry must demonstrate that they can be good stewards of the feed additives at their disposal. With increasing pressure from regulatory agencies and the public to eliminate use of antibiotics in animal production, it is important to protect those that can be used. The VFD may provide the mechanism for the beef cattle industry to keep using antibiotics responsibly to treat animal disease and ensure continued production of a safe and wholesome protein source for a growing global population.

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