

Implications of the New Veterinary Feed Directive for Veterinarians and the Feed Industry

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December 3, 1997

The Animal Drug Availability Act of 1996 established a new classification for drugs administered to livestock in the feed. This classification is the veterinary feed directive (VFD) animal drug. It was developed as an alternative to prescription status for new antimicrobial feed additives. This new process is to enhance animal health and food safety by requiring veterinary diagnosis of animal diseases and the issuance of a veterinary feed directive (VFD) by a veterinarian before the livestock producer can purchase and feed a VFD medicated feed. This process is to provide increased control over the use of new therapeutic antimicrobial drugs to assure that VFD medicated feeds are fed correctly and retain their effectiveness.

The VFD process is basically for new antimicrobial therapeutic feed medications. Drugs that are currently approved will retain their present regulatory status. All drugs (old and new VFD's) fall either into Category I (no pre-slaughter withdrawal time) or Category II (require pre-slaughter withdrawal time). A VFD drug is a Category II drug. Those commercial mills and livestock producers that use Category II Type A premixes (high potency) must be licensed with FDA prior to the purchase and mixing of Type A premixes. Facilities which mix Category I drugs and Category II Type B lower potency medicated feeds are not required to license with FDA. Livestock producers may purchase Type B VFD containing feed to manufacture their own feed or purchase an already prepared complete feed without an FDA license, however, they must have a VFD issued by a veterinarian to purchase VFD medicated feeds.

All commercial and on-farm mills that mix medicated feed are subject to compliance with good manufacturing practice (GMP) regulations. Different GMP regulations apply to FDA licensed and non-licensed mills. GMP's are process controls to assure medicated feeds are manufactured correctly for their safe and effective use.

Currently, tilimicosin phosphate is the only VFD drug approved. Tilimicosin phosphate is approved in swine feeds for control of swine respiratory disease associated with two microorganisms. As a Category II drug, the feed mill must be licensed with FDA to purchase the initial high potency Type A drug component (premix). No FDA license is required to mix lower potency Type B feeds to manufacture a complete medicated feed. However, non-licensed mills and all feed distributors that handle VFD drugs must provide FDA a one time "Acknowledgement of Distribution for VFD Feeds" within 30 days of the date of first distribution.

A veterinarian must issue a VFD form before a feed containing a VFD drug may be sold to the livestock producer. This requirement is for both Type B and C medicated feeds. Type C feeds are intended as the complete feed or a top dressed or free-choice

feed. Type B feeds are for further manufacturing only. The Federal Register notice for tilimicosin phosphate setforth the following information that must be provided in the VFD issued by the veterinarian:

1. The name, address, and phone number of the veterinarian and client.
2. Identification of the animals to be treated, including, identification of the species, number of animals, and the location of the animals.
3. Date of treatment and, if different, date of prescribing the VFD drug.
4. Name of the animal drug.
5. Level of animal drug in the feed and amount of feed.
6. Feeding instructions with withdrawal time.
7. Any special instructions and cautionary statement necessary for use of the drug in conformance with the approval.
8. Expiration date of the VFD,
9. Number of refills, if permitted by the approval.
10. Signature of the veterinarian.
11. The veterinarian's license number and the name of the state issuing the license.

The Veterinary Feed Directive Coalition is an organization representing the animal agriculture, veterinary, and feed industries. This coalition's goal is to educate livestock producers, veterinarians, and feed suppliers about the veterinary feed directive (VFD) process. They have prepared the following information to illustrate the Basis VFD Feed Distribution Schematic, example of Acknowledgement of Distribution for VFD Feeds, and answers to questions for producers and veterinarians which you will find helpful:

Producer Questions and Answers About VFD

- Q. What is the VFD and why do we need it?
- A. The VFD is a new category of medicated feeds created by the Animal Drug Availability Act of 1996. It provides an alternative to prescription status for certain therapeutic animal drugs for use in feed, while assuring the participation of a veterinarian who would issue a directive to enable producers to acquire VFD medicated feeds. The FDA's Center for Veterinary Medicine (CVM) expressed a need for greater control over the use of certain new therapeutic antimicrobial medicated feeds. The purpose of the added professional control is to assure the VFD medicated feeds are fed correctly and are effective for as long as possible. The participation of the veterinarian in the producer's decision to use such medicated feeds was essential to satisfy the FDA's concerns.
- Q. Is a VFD a prescription for feed?
- A. In some ways, a VFD is similar to a prescription. You must get it from a veterinarian after a careful diagnosis is made. However, a VFD allows producers to obtain VFD medicated feeds through normal feed supply channels without involving a pharmacist.

Q. Where do I get a VFD product?

A. VFD products will be available through the distribution system now in place for feed antimicrobial products. This means they could be available for feed supply sources, feed processors, veterinarians, and other sources for which you buy feed antimicrobials.

Q. How do I get a VFD product?

A. The process is relatively simple:

1. Call a veterinarian with whom you have a valid veterinarian-client-patient relationship to obtain a diagnosis of a health problem.
2. The veterinarian will write a VFD identifying the medicated feed and the dosage at which it is to be administered. The veterinarian will keep one copy and provide you with two copies.
3. Take a copy of the VFD form to your feed retailer or supplier and place your order.
4. Keep your copy of the VFD form on file for two years.

Q. Does a veterinarian have to examine my animals for me to get a VFD product?

A. No, as long as a valid veterinarian-client-patient relationship (VCPR) exists.

Q. Why must I keep a copy of the VFD form?

A. The Animal Drug Availability Act of 1996 requires veterinarians, producers, and feed suppliers to retain copies of the VFD form for two years. The FDA may determine a need from time to time to examine or copy VFD records of veterinarians, feed suppliers, or producers to verify that VFD products are being dispensed and administered properly.

Q. Will feed products now available come under the VFD?

A. It is anticipated the VFD will apply to new antimicrobial drugs for use in feed. Feed products now available over-the-counter are not expected to be reclassified as VFD medicated feeds.

Veterinarian Questions and Answers About VFD

Q. What is a Veterinary Feed Directive (VFD)? Why do we need the VFD classification?

A. The VFD category of medicated feeds was created by the Animal Drug Availability Act of 1996 to provide an alternative to prescription status for certain therapeutic animal pharmaceuticals for use in feed. The FDA's Center for Veterinary Medicine (CVM) expressed a need for greater control over the use of certain new, therapeutic

antimicrobial medications for feed. The purpose of the added professional control is to reduce the rate of development of resistance and thereby prolong the period of effectiveness of the medication. The participation of the veterinarian in the producer's decision to use such medicated feeds was essential to satisfy the FDA's concerns in this area. Currently labeled over-the-counter (OTC) medicated feeds will not be affected by the VFD. The VFD applies only to new drugs for therapeutic use in feed that are being approved by the FDA.

Q. Can veterinarians sell VFD medicated feeds?

A. Yes. Veterinarians may act as distributors of VFD feeds by notifying the FDA once, in writing, within 30 calendar days of the date of first distribution of the VFD medicated feed. Preprinted forms for this purpose may be available from the drug sponsors.

Q. Is a VFD a prescription for feed?

A. No. The VFD is an alternative to prescription classification for medicated feeds. A prescription status would lead to major disruptions of existing marketplace practices for drug sponsors, feed manufacturers, and animal producers. Among other problems, the prescription status would have triggered state pharmacy laws and regulations that were intended to apply only to the dispensing of other dosage forms of drugs not to medicated animal feed. Similarly, it would have triggered statutory limitations on labeling and marketing practices that would place covered drugs and feeds at a commercial disadvantage when compared with OTC medicated feeds. The VFD will only apply to those specific drugs that are newly approved as VFD medicated feeds. Extra-label use of medicated feeds including VFD drugs is prohibited.

Q. Am I responsible for ensuring that proper mixing of a VFD medicated feed occurs on the farm?

A. The veterinarian is responsible for providing the producer with adequate instructions for mixing (i.e. – dilution and concentration) and use of the VFD medicated feed. The veterinarian is not responsible for supervising the actual mixing of a VFD medicated feed.

Q. Do I assume liability when issuing a VFD?

A. The appropriate use of VFD medicated feeds requires the participation of a veterinarian who acts responsibly and prudently in issuing a VFD. Directing the use of any medication, including a VFD product, that can result in antibiotic tissue residues or otherwise have adverse effects in animals exposes the veterinarian to liability.