120

Guidance for Industry

Veterinary Feed Directive Regulation

(This version of the guidance replaces the version that was made available in March 1, 2001. This guidance document has been revised to update contact information and the number of drugs currently approved for VFD use, to provide our interpretation of the term "appropriately licensed veterinarian," as the term pertains to use of VFD drugs, and to provide our position on VFD orders distributed via the Internet.)

Comments and suggestions regarding the document should be submitted to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. All comments should be identified with the Docket No. 1999N-1591 (formerly 99n-1591).

For general questions regarding this guidance document, contact Zoe Ann Gill, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6867; email: zoe.gill@fda.hhs.gov.

For scientific questions regarding this guidance document, contact Dragan Momcilovic, Center for Veterinary Medicine (HFV-226) Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-453-6856; email: dragan.momcilovic@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
June 26, 2007

What is a Veterinary Feed Directive?

This final guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

A Veterinary Feed Directive (VFD) Order refers to a written authorization for use.

A Veterinary Feed Directive (VFD) Drug refers to a new and specific category of drugs.

Background
Prior to 1996, FDA had only two options for regulating the distribution of animal drugs: 1) over-the-counter (OTC), and 2) prescription. We determined certain new animal drugs, vital to animal health, should be approved for use in animal feed but only if these medicated feeds were administered under a veterinarian's order and professional supervision. For example, veterinarians are needed to control the use of certain antimicrobials. Control is critical to reducing unnecessary use of such drugs in animals and to slowing or preventing any potential for the development of bacterial resistance to antimicrobial drugs. Safety concerns relating to difficulty of diagnosis of disease conditions, high toxicity, or other reasons may also dictate that the use of a medicated feed is limited to use by order and under the supervision of a licensed veterinarian. The VFD category will maintain public health protection while allowing producers to obtain needed drugs efficiently and cost effectively.

What does the term "appropriately licensed" veterinarian mean?

The term "appropriately licensed" veterinarian, as it pertains to VFD regulation 21 CFR 558.6, means that the veterinarian has a valid license to practice veterinary medicine in the State in which the animals are located that he/she is treating within the confines of a valid veterinarian-client-patient relationship.

Which drugs qualify as VFD drugs?
When a new animal drug application is submitted to the Center for Veterinary Medicine for approval, the appropriate division determines whether a drug will be an OTC (over-the-counter), a prescription, or a VFD drug. A practicing veterinarian may not write a VFD order for an OTC drug nor may he/she write a VFD order to be used contrary to the approved application for that drug. A veterinarian may only write a VFD order for

drugs approved for that category and only under the context of a valid client-patient relationship (VCPR) as defined in Title 21, Code of Federal Regulation 530.3(i).

How many drugs have been approved under this category?
To date, two drugs have been approved under this category. The drug tilmicosin is approved for use in the control of swine respiratory diseases, and the drug florfenicol is approved for use in the control of swine respiratory diseases and for control of certain bacterial diseases in aquaculture.

How does the veterinarian obtain a form for a VFD drug?
While it is not mandatory that the VFD drug sponsors provide copies of a form for use by the veterinary profession, we believe the sponsors will make the forms available in triplicate for the sake of efficiency and completeness of the veterinarian's VFD order transmissions. Nevertheless, we continue to give the veterinarian the option of creating his/her own form for a VFD drug.

What specific information does the VFD form require?
- Client's name, address and telephone and facsimile number;
- Identification and number of animals to be treated/fed the medicated feed, including identification of the species of animals, and the location of the animals;
- Date of treatment, and, if different, date of issuing the VFD order;
- Approved indications for use;
- Name of the animal drug;
- Level of animal drug in the feed, and the amount of feed required to treat the animals;
- Feeding instructions with the withdrawal time;
- Any special instructions and cautionary statements necessary;
- Expiration date of the VFD order;
- Number of refills (reorders) if necessary and permitted by the approval;
- Veterinarian's license number and the name of the state issuing the license; and
- The statement: "Extra-label use, (i.e., use of this VFD feed in a manner other than as provided for in the VFD drug approval) is strictly prohibited".
- Any other information required by the VFD drug approval regulation.

What is the responsibility of the feed distributor if the VFD form is not completely filled out?
The feed distributor should not fill an order that does not have all required information. The responsible veterinarian should be notified that the order may not be filled until all the necessary information on the VFD order is provided.

Is there an alternate method by which a VFD order can be transmitted to the feed distributor?
We believe we must accommodate those situations where prompt hand delivery of a VFD order is not possible, but immediate delivery of a VFD feed is necessary. To accomplish this, transmission by facsimile or other electronic means is permitted provided safeguards are in place to prevent misuse. The industry must provide

assurances these technologies, as appropriate, are in compliance Title 21, Code of Federal Regulations, Part 11. The distributor must receive an original signed VFD order within 5 working days of receipt of the facsimile or electronic document. Telephone orders are not allowed.

Does this mean that a VFD order can be transmitted via the Internet?

We would consider the Internet as an acceptable electronic means of transmitting VFD orders provided that the system is shown to be in compliance with 21 CFR, Part 11, and provided that the feed distributor receives an original signed VFD order within 5 working days of receipt of the VFD order via the Internet.

Who is held responsible, the veterinarian, the client (feeder) or feed distributor if the actual VFD order is not properly distributed?
While all bear responsibility, the veterinarian is most in control. Thus, we believe it is the veterinarian's obligation to assure that the original VFD order is distributed to the feed distributor with the timeliness required.

Is a feed mill or feeder permitted to distribute or feed an unapproved drug product that is requested by a veterinarian in a VFD order?
A feed mill may not fill a VFD order and the client may not feed a VFD feed to his/her animals that is in violation of FDA drug approval.

What mechanisms are in place to discourage the producer from faxing the order to multiple feed mills, thus abusing the drug?
While the possibility exists that a client may submit a copy of the VFD order to several distributors to obtain additional VFD feed, the distributor will become aware of the irregularity when the original VFD order does not arrive within 5 days as required by the regulation.

Does the manufacturer of a medicated feed containing a VFD drug require a feed mill license?
Yes. Classifying a drug as Category II adds additional regulatory controls because feed manufacturing facilities must possess a medicated feed mill license and be registered with FDA in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article. Registered feed mills are required to be inspected at least every 2 years. Such inspections will help the agency ensure that VFD requirements are met.

Explain the Distributor Notification Process.
All distributors must notify the Center for Veterinary Medicine of their intent to distribute medicated feed containing a VFD drug. This is a one-time only occurrence. Distributor, in this case, means any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD. A distributor notification must

include the name, address (both physical and mailing, if different) and be sent to: Center for Veterinary Medicine, HFV-226, 7519 Standish Place, Rockville, MD 20855.

Under what circumstances would I be requested to submit an updated notice to the FDA?
An updated notice is required within 30 days of any change in name or business address.

What is a notification letter and how is it different than an acknowledgement letter?
A notification letter is a one-time notice by an individual or company of its intent to distribute a medicated feed containing a VFD drug. An acknowledgement letter is sent to the distributor by a purchaser, who is not the ultimate user of the feed stating it will sell the VFD feed only to a producer with a valid VFD order, or to another distributor who provides a similar acknowledgment letter.

How does this regulation deal with refills, reorders or the length of time a VFD order is valid?
We believe there are situations when refills and expiration dates, possibly of several months, are appropriate to medicate multiple production groups and provide efficient treatment of sick animals. We further believe allowances of this type will vary considerably. Since we cannot predict what types of drugs and disease situations will be presented in the future, the issue of refills and reorders and the duration of time a VFD order is valid will be considered on a drug-by-drug basis as part of the new animal drug approval process.

If a VFD order is written for refills and the subsequent orders are filled at a different establishment than the first, how do both establishments retain the original order?
It is possible the VFD order may be required by one distributor first and later by another for refill. The regulation requires that a feed establishment retain the original copy of the order for two years, thereby making it impossible to forward the original VFD order to another establishment. In these situations, the client should contact the issuing veterinarian and request a new supplemental VFD order.

Veterinarian's Responsibility

- Be appropriately licensed
- Writes order for VFDs only under the context of a Valid Client Patient Relationship (VCPR) as defined in 21 CFR 530.3
- Prepares and signs a written VFD order in triplicate providing all requested information
- Provides the feed distributor with the original VFD order
- Gives copy to producer
- Retains copy for his/her records for a minimum of two years
- Provides VFD orders for review and copying by FDA during inspection.

Producer's Responsibility

- Contacts the veterinarian to diagnose and treat the animals
- Agrees to follow the veterinarian's recommendations
- Administers the feed to the animals
- Provides the original VFD order to the feed supplier if not previously done
- Maintains copy of the VFD order a minimum of two years
- Provides VFD orders for review and copying by FDA during inspection.

Feed Mill/Distributor Responsibility

- Retains original VFD order supplied by the veterinarian/producer for two years from date of issuance
- Provides VFD order forms for review and copying by FDA during inspection
- Files one-time notice with FDA of intent to distribute VFD drugs
- Requires an acknowledgement letter from all consignees who distribute but are not the ultimate user of the feed
- Assures all labeling and advertising must prominently and conspicuously display the following cautionary statement: ``Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice."