

Distributors of Feeds Containing VFD Drugs...

The distributor and distribution

Who is a "distributor"?

Under VFD regulation, a "distributor" means any person who distributes a medicated feed containing a VFD drug to another person.

What do I need to do in order to become a VFD distributor?

You are required to notify FDA prior to the first time you distribute animal feed containing a VFD drug.

Who can I distribute a VFD feed to?

You can distribute VFD feed to another distributor or to the client-recipient of a VFD.

What do I need to do to distribute a VFD feed to another distributor?

You must get a written (nonverbal) acknowledgement letter from the receiving distributor before distributing the VFD feed.

What do I need to do to distribute a VFD feed to the client-recipient of a VFD?

You must get a copy of a VFD containing all the information required by regulation before distributing a VFD feed to the client-recipient.

VFD statement

What is a VFD?

A VFD is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that authorizes the use of a VFD drug or combination VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client's animals only in accordance with the conditions for use approved, conditionally approved, or indexed by the FDA. A VFD is also referred to as a VFD order.

The "acknowledgement letter"

What is an acknowledgement letter and when does it apply to me?

An "acknowledgement letter" is a written (nonverbal) communication provided to you (consignor) from another distributor (consignee). Such letter, provided either in hardcopy or through electronic media, must affirm: (1) that the distributor will not ship such VFD feed to an animal production facility that does not have a VFD; (2) that the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgement letter; and (3) that the distributor has complied with the distributor notification requirements. If you issue VFD feed *only to a client under a VFD order*, you will not need to have an acknowledgement letter.

VFD drug and combination VFD drug

What is a "VFD drug"?

A "VFD drug" is a drug intended for use in or on animal feed that is limited to use under the professional supervision of a licensed veterinarian.

What is a "combination VFD drug"?

A "combination VFD drug" is an approved combination of new animal drugs intended for use in or on animal feed under the professional supervision of a licensed veterinarian, and at least one of the new animal drugs in the combination is a VFD drug.

How do I know if a drug is a VFD drug, rather than an OTC drug?

The label will say if it is a VFD drug. Only VFD drugs, combination VFD drugs, and feeds containing them will be labeled with: "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 "one-time" distributor notification

What information must the notification include?

It must include the following:

- The distributor's complete name and business address;
- The distributor's signature or the signature of the distributor's authorized agent; and
- The date the notification was signed.

Where should the notification be sent?

The notification should be mailed to:

Food and Drug Administration
Center for Veterinary Medicine
Division of Animal Feeds (HFV-220)
7519 Standish Place
Rockville, MD 20855

or faxed to: 240-453-6882

Distributors' responsibilities

What are my responsibilities as the distributor?

You must do the following:

- file a one-time notice with FDA of intent to distribute VFD drugs;
- notify FDA within 30 days of any change in ownership, business name, or business address;
- fill a VFD order only if the VFD contains all required information;
- ensure that the distributed animal feed containing the VFD drug or combination VFD drug complies with the terms of the VFD and is manufactured and labeled in conformity with the approved, conditionally approved, or indexed conditions of use for such drug;
- ensure all labeling and advertising prominently and conspicuously displays the following cautionary 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.";
- retain VFD orders for two years from date of issuance;
- retain records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years;
- provide VFD orders for inspection and copying by FDA upon request;
- retain records of VFD manufacturing for 1 year in accordance with 21 CFR part 225 and make such records available for inspection and copying by FDA upon request;
- obtain, as the originating distributor (consignor), an acknowledgement letter from the receiving distributor (consignee) before the feed is shipped; and
- retain a copy of each consignee distributor's acknowledgement letter for 2 years.

All distributors of VFD feed must notify FDA before they distribute for the first time. A distributor must also notify FDA within 30 days of a change in ownership, business name, or business address

An "acknowledgement letter" is a written (nonverbal) communication provided to you (consignor) from another distributor (consignee). Such letter, provided either in hardcopy or through electronic media, must affirm: (1) that the distributor will not ship such VFD feed to an animal production facility that does not have a VFD; (2) that the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgement letter; and (3) that the distributor has complied with the distributor notification requirements. If you issue VFD feed *only to a client under a VFD order*, you will not need to have an acknowledgement letter.

What should be on a VFD?

This information is required on a lawful VFD:

- veterinarian's name, address, and telephone number;
- client's name, business or home address, and telephone number;
- premises at which the animals specified in the VFD are located;
- date of VFD issuance;
- expiration date of the VFD;
- name of the VFD drug(s);
- species and production class of animals to be fed the VFD feed;
- approximate number of animals to be fed the VFD feed by the expiration date of the VFD;
- indication for which the VFD is issued;
- level of VFD drug in the feed and duration of use;
- withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;
- number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing;
- statement: "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use), is not permitted";
- an affirmation of intent for combination VFD drugs as described in 21 CFR 558.6(b)(6); and
- veterinarian's electronic or written signature.

You may also see the following optional information on the VFD:

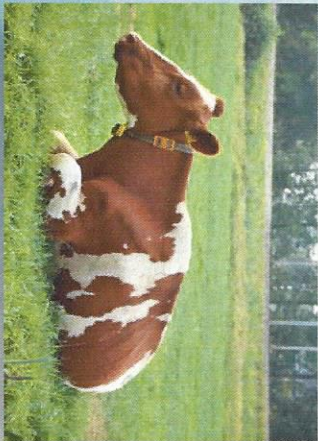
- a more specific description of the location of the animals (for example, by site, pen, barn, stall, tank, or other descriptor the veterinarian deems appropriate);
- the approximate age range of the animals;
- the approximate weight range of the animals; and
- any other information the veterinarian deems appropriate to identify the animals at issue.

VFD drug labeling and advertising must prominently and conspicuously display the VFD caution statement

Record keeping summary

What record(s) am I required to keep and for how long? Depending on whom you distribute VFD feed to, the following applies:

If you ship VFD feed to	Required	Record Retained for
Clients <u>only</u>	VFD (order)	2 years
Other distributors <u>only</u>	Acknowledgement letter(s)	2 years
Both clients and other distributors	VFD (order) and acknowledgement letter(s)	2 years



Requirements for Distributors
(Who Do Not Manufacture VFD Feed)
2015

For more information:

AskCVM@fda.hhs.gov

Guidance for Industry #120

21 CFR 558.6 (VFD)

21 CFR 225 (cGMP)

Website: <http://www.fda.gov/safeFeed>

