Extralabel use

What is an “extralabel use” of a VFD drug and is it allowed?

“Extralabel use” is defined in FDA’s regulations as actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. For example, feeding the animals VFD feed for a duration of time that is different from the duration 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 would all be considered extralabel uses. Extralabel use of medicated feed, including medicated feed containing a VFD drug or a combination VFD drug, is not permitted.

Extra-label use of VFD feed (or any other medicated feed) is not permitted

Client’s responsibilities

What are my responsibilities as the “client”?
As the client, a producer must:

- only feed animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) to animals based on a VFD issued by a licensed veterinarian;
- not feed a VFD feed or combination VFD feed to animals after the expiration date on the VFD;
- provide a copy of the VFD order to the feed distributor if the issuing veterinarian sends the distributor’s copy of the VFD through you, the client;
- maintain a copy of the VFD order for a minimum of 2 years; and
- provide VFD orders for inspection and copying by FDA upon request.

VFD has to be kept for 2 years

For more information:
AskCVM@fda.hhs.gov
Guidance for Industry #120
21 CFR 558.6 (VFD)
http://www.fda.gov/safefeed
A VFD feed can only be used under the professional supervision of a licensed veterinarian

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?  
Read the label. All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display 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.” Over-the-counter (OTC) drugs do not have this statement.

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.

What is an “expiration date” on the VFD?  
The expiration date on the VFD specifies the last day the VFD feed can be fed.

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

Obtaining a VFD feed

How does a producer obtain a VFD feed?  
Use of a VFD feed requires the professional supervision of a licensed veterinarian. Producers must obtain a VFD order from their veterinarian, then send, or take, the VFD order to a feed manufacturer or supplier to get the VFD feed. Producers who manufacture their own feed must have a VFD in order to get the medicated VFD feed to manufacture from. Producers who also manufacture feed for others should be aware that they are acting as a distributor and additional requirements apply. More information on manufacturing and distributing VFD feeds is available at: www.fda.gov/safefeed

“Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.”

What should be on a VFD order?  
This information is required on a lawful VFD order:

- 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.

A lawful VFD has to be complete