#### Use of a VFD feed

#### How do I use a VFD feed?

The VFD feed must be used according to the information specified in the labeling and on the VFD. This means for example that the feed can only be used for the indications and duration of use specified on the label and VFD, and in the animals at premises specified in the VFD. Furthermore, if the VFD authorizes use of a VFD drug in an approved combination, that combination also must be used according to the labeling and VFD.

## What is the difference between an "expiration date" on the VFD and duration of use?

While the VFD expiration date defines the period of time for which the authorization to feed an animal feed containing a VFD drug is lawful, the duration of use determines the length of time, established as part of the approval, conditional approval, or index listing process, that the animal feed containing the VFD drug is allowed to be fed to the animals. For example, in swine the currently approved VFD drug tilmicosin has a duration of use of 21 days and an expiration date of 90 days, which means the client has 90 days to obtain the VFD feed and complete the 21 day course of therapy.

## As a client can I feed a VFD feed past the VFD expiration date?

No. A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.

## My VFD order is set to expire before I can complete the duration of use on the order, what should I do?

A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD. You should contact your veterinarian to request a new VFD order.



#### 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







# Veterinary Feed Directive (VFD)

Producer Requirements 2015



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 does professional supervision mean?

The veterinarian-client-patient relationship (VCPR) is the basis of professional supervision. Veterinarians who issue a VFD order must practice veterinary medicine in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a VCPR as defined by the state. If applicable VCPR requirements as defined by such state do not include the key elements of a valid VCPR as defined by Federal law, the veterinarian must issue the VFD in the context of a valid VCPR as defined by the Federal law.

#### 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