

VFD and VCPR, Client

What is required for veterinarian supervision?

The veterinarian-client-patient relationship (VCPR) is the basis of professional supervision. A VFD must be issued by a licensed veterinarian operating in the course of his/her professional practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR).

What VCPR standard applies?

FDA provides a **list** of states whose VCPR includes the key elements of the federally-defined VCPR and requires a VCPR for the issuance of a VFD. If your state appears on this list you must follow your state VCPR, if your state does not you must follow the federal VCPR as defined in 21 CFR 530.3(i).

Who is the "client" on the VFD?

"Client" is typically the client in the VCPR; the person responsible for the care and feeding of the animals receiving the VFD feed.

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 a VFD for a duration of time that is different from the duration specified on the label, feeding a VFD formulated with a drug level that is different from what is specified on the label, or feeding a VFD 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.

Reorders (refills)

When can I authorize a reorder (refill)?

If the drug approval, conditional approval, or index listing expressly allows a reorder (refill) you can authorize up to the permitted number of reorders. If a drug is silent on reorders (refills), then you may not authorize a reorder (refill).

Use of medicated feed is authorized by a VFD not Rx

A lawful VFD has to be complete

What do I have to include in 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 include 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.

The veterinarian must keep the original VFD for two years



Veterinary Feed Directive (VFD)

Requirements for Veterinarians 2015

For more information:

AskCVM@fda.hhs.gov

Guidance for Industry #120

21 CFR 558.6 (VFD)

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



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 authorize 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.

VFD drug and combination VFD drug

What is a "VFD drug"?

A "VFD drug" is a drug intended for use in or on an animal feed, which 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.

VFD Drugs and Prescription Drugs

What is the difference between a VFD drug and a prescription (Rx) drug?

FDA approves drugs in these two separate regulatory categories for drugs that require veterinary supervision and oversight for their use. When the drug being approved is for use in or on animal feed (a medicated feed), FDA approves these drugs as a VFD drug. When the drug being approved is not for use in or on animal feed, the drug is approved as a prescription drug.

Why VFD instead of prescription?

When the VFD drug category was created, the Act made it clear that VFD drugs are not prescription drugs. This category was created to provide veterinary supervision without invoking state pharmacy laws for prescription drugs that were unworkable for the distribution of medicated feed.



Veterinarians' Responsibilities

- must be licensed to practice veterinary medicine;
- must be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements;
- must write VFD orders in the context of a valid client-patient relationship (VCPR);
- must issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug;
- must prepare and sign a written VFD providing all required information;
- may enter additional discretionary information to more specifically identify the animals to be treated/med the VFD feed;
- must include required information when a VFD drug is authorized for use in a drug combination that includes more than one VFD drug;
- must restrict or allow the use of the VFD drug in combination with one or more OTC drug(s);
- must provide the feed distributor with a copy of the VFD;
- must provide the client with a copy of the VFD order;
- must retain the original VFD for 2 years, and
- must provide VFD orders for inspection and copying by FDA upon request.

Major and Minor Animal Species

What are "major and minor animal species"?

FDA regulations define cattle, horses, swine, chickens, turkeys, dogs, and cats, as major species. All animal species, other than humans, that are not major species are minor species.

When is a VFD needed for a minor species?

The VFD requirements apply to all VFD drugs for use in major or minor species. One VFD drug is already approved for use in minor species (e.g., florfenicol in aquaculture). Other medicated feed drugs for minor species are expected to convert from their present over-the-counter (OTC) status to VFD (e.g., oxytetracycline in honey bees) and at that time a VFD will be required for their use.

ELU of VFD feed is not permitted

VFD transmitting and other topics

How do I send a VFD to the feed distributor?

You must send a copy of the VFD to the distributor via hard-copy, facsimile (fax), or other electronic means. If in hardcopy, you are required to send the copy of the VFD to the distributor either directly or through the client.

Who gets the original or a copy?

You, the veterinarian, must retain the original VFD in its original form (electronic or hardcopy) and must send a copy to the distributor and client.

How do I obtain a VFD order (blank)?

VFD drug sponsors may make the VFD order for their drugs available, or, as a veterinarian you may create your own VFD for a VFD drug.

How do I issue a VFD for a combination VFD drug?

You may expand or limit the use of a VFD drug along with OTC animal drug(s) in an approved combination(s), as appropriate, by stating the affirmation of intent on the 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.

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.

How do I allow pioneer/generic drug substitution on the VFD?

By default, the VFD feed manufacturer may use an approved substitute (e.g., one brand of Type A medicated article instead of another). If you do not want a substitution, you may specify on the VFD that a substitution is not allowed.

The veterinarian must send a VFD copy to the distributor and client