

Veterinary Feed Directive:

FDA Regulation to Help Ensure Judicious Use of Antibiotics in Food-Producing Animals

To write a Veterinary Feed Directive (VFD) for a producer, the veterinarian should follow these **STEPS** (referencing information from the American Veterinary Medical Association)

Select
Terms
Enter
Provide
Save

Select the course of action: Is a VFD drug necessary? Are there alternative therapeutic options?

Legally, any cow, pig, chicken, turkey, duck, pheasant, quail, sheep, or goat, is a food-producing animal (along with lobsters, honeybees, catfish, and salmonids), and must be treated as such when it comes to medications. There are drugs, that cannot, under any circumstances, be administered to them, and the extra-label drug use rules and Minor Use/Minor Species (MUMS) Act do not apply to the VFD. Any use of a VFD drug that deviates from the approved labeling is strictly prohibited.

You will need a Veterinary Feed Directive (VFD) order if the animal:

- 1) is a food-producing animal species, and
- 2) needs an medically important antimicrobial drug administered in feed (e.g. a medicated feed product such as milk replacer)

Other antimicrobial drug products, such as injectables, drugs given orally (not in feed), or in water, may require a prescription, but do not require a VFD order.

Terms: Ensure the following requirements are met:

- The drug chosen to treat the animals is an approved VFD drug, or drug combination, for the intended species and production class, dose, duration, route of administration and indication. Check the drug label.
- The veterinarian has a valid veterinary license in the state where the animal(s) is/are located.
- You have met the Veterinarian-Client-Patient Relationship (VCPR) requirements.
 - In Montana, the veterinary/client/patient relationship (VCPR) is defined in the Administrative Rules of Montana (ARM 24.225.301).

(5) A "veterinarian/client/patient relationship" exists when all of the following conditions have been met:

(a) the veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions;

(b) the veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s) . This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premises where the animal(s) are kept; and

(c) the veterinarian is available for follow-up evaluation in the event of adverse reactions or failure of the treatment regimen.

Typically, a veterinarian has an ongoing relationship with the client and the client's animals being treated such that the veterinarian is familiar with the animal production operation and has made previous visits to their facility(s). This relationship also allows the veterinarian to provide education to the client about appropriate use of medication, including storage, use, and withdrawal times. FDA expects that a veterinarian will only authorize use of a VFD feed in animals for which he or she has such knowledge and familiarity.

Enter the information on the VFD order (paper or electronic). Orders must be written, and cannot be verbal.

1. **Veterinarian information:** Name, business address, phone, and fax or email (fax and email recommended, but optional).
2. **Client information:** The client is the person responsible for feeding the VFD drug. Enter the client's name, home or business address, phone, and fax or email (fax and email recommended, but optional).
3. **Drug(s):** Enter the name of the VFD drug(s) to be used. Either the trade or generic name may be used. You may also specify that no substitutions are allowed by marking the box. Use a separate VFD Order for each VFD drug or approved VFD fixed drug combination.
4. **Drug Level & Duration of Use:** Enter the amount of VFD drug (g/ton or other unit as indicated on the drug label) in feed and the duration of feeding. Refer to the drug label to ensure that the specified level and duration is approved for the indication, species and production class of the animal. The most current and accurate source for label information currently appears to be 21 CFR 558 Subpart B.
5. **Species and Production Class:** This should be as specific as stated in the drug approval. Enter the species and production class of the animal(s) being treated. Refer to the drug label to confirm.
6. **Number of Reorders (Refills) Authorized:** As of now, no VFD drugs are approved for reorders or refills.
7. **Indications for Use (as approved):** Enter the indication verbatim from the product approval. Refer to the drug label to confirm.
8. **Caution:** Enter cautionary statements from the drug label necessary for use of the drug in conformance with the approval. If there is no cautionary statement, required for the use, enter "none" in this field.

9. **Approximate Number of Animals:** Enter the number of animals to be treated by this specific VFD order. To maximize veterinary oversight and promote antimicrobial stewardship, the American Veterinary Medical Association recommends:
- **The number of animals be determined based upon a specific time period or production cycle.** For example, a VFD order is issued for 100 animals in an initial 2-week period. If needed, a new order should be issued for the expected number of animals in the following 2-week period. The VFD order should be written only for the animals treated during a specific time period and should not encompass all animals within the maximum allowed period of 6 months.
 - **Careful attention to label restrictions for specific duration when calculating feed consumption.**
10. **Premises:** Enter the location (e.g. GPS coordinates, street address) of the animals receiving therapy. A list of premises may be attached to the VFD Order. In this case, enter "See attached" and retain a copy of the attachment with the VFD order.
11. **Other identification (e.g., age, weight):** Enter a more specific description of the animals (e.g. age, weight) and/or their location (e.g., by site, pen, barn, stall, tank, etc). Entering this information is recommended, but optional.
12. **Special instructions (if any):** Enter any additional information or instructions necessary for use of the drug in conformance with the approval (e.g. specific treatment, response monitoring, husbandry, or other instructions). For example:
- If a range of drug levels is provided on the label, and you would like the client to use a specific drug level, enter here.
 - You can also add instructions such as: "Monitor animals daily and call if not improved after 72 hours"; "Use in combination feed (if authorized and approved with drug X)"; "Begin feeding at the start of weaning"; "Feed immediately"; or "Feed at onset of clinical signs for labeled duration".
13. **Affirmation of Intent:** You must mark only one of the three statements in this section.
- ***This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.*** Checking this box indicates that only the drug(s) named in the VFD Order can be used. This is the most restrictive option, disallowing any combination of medicated feeds.
 - ***This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.*** Checking this box indicates that the drug(s) in the VFD Order can be used in combination with the drugs specified in the table below the statement, but in no other combinations. The combination(s) must be FDA approved. If this box is checked, you **must** complete the information as described below for combination drugs.
 - ***This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in***

medicated feed that contains the VFD drug(s) as a component. In most cases, this is the default choice. Checking this box indicates that the drug(s) in the VFD order can be used in any approved combination. The combinations must be FDA approved. This will apply to most cases and is the least restrictive allowing use of the VFD with other non-VFD drugs in approved combinations.

14. **Combination Drugs:** Complete this table only if the corresponding Affirmation section box is checked. This is only for specific approved combinations; refer to the label for information to complete the table: drug name, dose, and additional instructions.
15. **Withdrawal Time:** Enter the withdrawal time necessary for use of the drug in conformance with the approval. Find this information on the label of the product or FDA's Blue Bird Label website.
16. **Date of Issuance:** Enter the date the VFD is written.
17. **Expiration Date:** Enter the VFD drug's expiration date. This date must not extend beyond the expiration date specified in the approval, conditional approval, or index listing. If there is no specified date in the approval, the expiration date must not exceed 6 months from the date of issuance. To maintain more stringent oversight, you may indicate a shorter expiration date. For example:
 - You have instructed the client to administer immediately for 14 consecutive days. The expiration date can be approximately 14 days from issuance to ensure compliance.
18. **Veterinarian's Signature:** Complete with your written signature. An electronic signature is acceptable.

Provide copies and relay the information.

Send either a hard or electronic (e.g. email, fax, text) copy of the VFD order to the distributor (e.g., feed mill). Provide a copy to both the distributor and the client; it is the Veterinarian's responsibility, not the client's, to provide the order to the distributor. The order should only be provided to a single distributor. However, multiple locations of the same distributor may operate under the same VFD order.

Save an original copy.

The veterinarian is responsible for keeping the original VFD in its original format (paper or electronic). All parties (veterinarian, client and feed mill) must keep a copy of the VFD Order for at least 2 years. Be prepared to provide the VFD Order for inspection and copying by the FDA upon request.