

## 1. What is a veterinary feed directive (VFD)?

A VFD is a written statement/form completed and issued by a licensed veterinarian that orders the use of a VFD drug or combination VFD drug in or on an animal feed. The form authorizes the client to purchase and use the feed for treatment of the animals under the specific conditions outlined on the VFD form. A VFD drug may also be referred to as a “medically important” drug.

## 2. What are “medically important” antibiotics and which drugs will become VFD drugs?

“Medically important” antibiotics are drug classes that are used in both human and animal medicine. Some examples are listed below.

<b>Class of Antibiotic</b>	<b>Feed-Grade Examples</b>
Aminoglycosides	Neomycin, Streptomycin
Lincosamides	Lincomix®
Macrolides	Pulmotil®, Tylan®
Penicillins	Penicillin, CSP
Streptogramins	Stafac®
Sulfonamides	Sulfamethazine, Aureomix®
Tetracyclines	Aureomycin®, CTC

<b>Established Drug Name</b>	<b>Examples of Proprietary Drug Name(s)</b>
Chlortetracycline (CTC)	Aureomycin, CLTC, CTC, Chloratet
CTC/sulfamethazine	Aureo S, Aureomix S, Pennchlor S Areomix 500, Chlorachel/Pficlor SP,
CTC/sulfamethazine/penicillin	Pennchlor SP, ChlorMax SP
Hygromycin B	Hygromix
Lincomycin	Lincomix
Oxytetracycline (OTC)	TM, OXTC, Pennox, Terramycin
OTC/neomycin	Neo-Oxy, Neo-Terramycin
Penicillin	Penicillin G Procaine
Sulfadimethoxine/ormetoprim	Rofenaid, Romet
Tylosin	Tylan, Tylosin, Tylovet Tylan Sulfa G, Tylan Plus Sulfa G, Tylosin
Tylosin/sulfamethazine	Plus Sulfamethazine
Virginiamycin	Stafac, V-Max



### **3. When will the VFD rule be implemented?**

The VFD rule will be implemented on January 1, 2017. After January 1, 2017, all feeds including VFD drugs or combination VFD drugs can only be purchased with a valid (lawful) VFD form issued by a licensed veterinarian.

### **4. What does a valid (lawful) veterinary-client-patient-relationship (VCPR) entail?**

A valid VCPR has 3 requirements. The veterinarian must: 1) engage with the client and assume responsibility for making clinical judgements about patient health, 2) have sufficient knowledge of the patient(s) via examination and/or visits to the facility where the patient(s) is managed, and 3) provide any necessary follow-up examinations or care.

### **5. Will I have to change my relationship with my vet?**

A valid VCPR must be in place when requesting a VFD form for a feed that includes a VFD drug or combination VFD drug. If a VCPR currently exists, then the relationship with the veterinarian does not need to be changed as long as the VCPR is maintained continuously. If no VCPR exists (see question 3 for requirements), then a relationship must be established with a veterinarian for a VFD form to be issued.

### **6. How will the VFD be enforced?**

The Food and Drug Administration (FDA) is the VFD rule governing body and will ensure the enforcement of the VFD rules and regulations. The FDA will be working with state agencies for statewide enforcement.

The FDA will use a phased enforcement strategy for implementation of the final VFD rule. The first year (2017) will be a transition and educational year as the VFD rule is implemented. When the FDA and state agencies begin to inspect facilities of the rule, they will be monitoring these things:

- 1) Randomly select 3 VFD forms at the feed distributor
- 2) Stop at the indicated producer and veterinarian to confirm VFD copies
- 3) Verify the VFD form has all required information
  - a) Veterinarian contact information
  - b) Client contact information
  - c) Premises specified on the VFD have the indicated VFD animals
  - d) Date of the VFD order
  - e) Affirmation of intent for a VFD combination drug
  - f) Veterinarian's signature



**7. If I buy an extra pallet of medicated feed this fall to feed beyond January 1, 2017, will this exempt me from the VFD rule until I run out of that feed?**

No. Even if feed containing a VFD drug or combination VFD drug is purchased prior to the implementation date, as of January 1, 2017, you must obtain a valid VFD form from a licensed veterinarian, with whom you have a valid VCPR, to continue feeding the previously purchased feed. However, the feed can only be fed if the veterinarian determines that the feed is needed for the prevention, control, and/or treatment of disease for animals listed on the label and the disease the feed is labeled for.

**8. Does the VFD include injectable antibiotics?**

No, the current VFD rule does not include injectable antibiotics.

**9. Can a producer send starter feed with animals to new owners if currently feeding a VFD included antibiotic in the feed?**

No. The VFD was issued to the client indicated in the VFD form. If the feeding of a VFD feed for prevention, control, or treatment of a disease has not been completed at the change of ownership, a new VFD will need to be issued to the new owners by the veterinarian the new owners have a valid VCPR with to finish feeding a VFD feed. The new owners will need to purchase the VFD drug containing feed from a feed distributor and all parties, new and previous, must document the situation.

**10. Can an FFA advisor or 4-H leader be considered “caretaker” or “client” of all of the club’s animals and therefore, maintain the VCPR with the veterinarian?**

The client’s name and information on the issued VFD must reflect the client in the VCPR. The client is the owner of the animal(s) or other caretaker (the person responsible for the oversight of feeding the animals). An FFA advisor or 4-H leader could be considered the caretaker as long as they are assuming responsibility for the care and feeding of the animals.

**11. Who is the “client” if a group of animals with multiple owners are located at the same premises?**

The client indicated on the VFD form will be each individual owner. Therefore, each “client” must be issued a VFD form to feed a VFD drug to their animal(s). Each client would also need a valid VCPR for a VFD form to be issued.

**12. If writing a VFD that is a single owner at multiple locations, do you need a separate VFD for each location?**

The veterinarian may write a VFD that covers animals at multiple locations to be fed the VFD feed by the expiration date on the VFD, provided that the veterinarian can do so in compliance with professional licensing and practice standards and the VFD feed is supplied to locations by a single feed distributor. The veterinarian would also need to be authorizing the same use for all of the animals covered under the VFD (ie. the indications, species, age range, etc.).

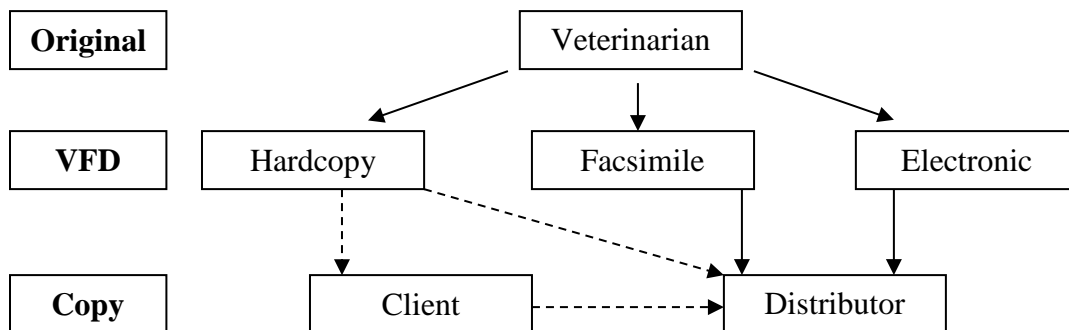
**13. Contracted veterinarians are often out of state or country, how does that impact VFD acquisition or use?**

Veterinarians must be licensed in the state where the animals are located to write a valid VFD.

If one firm represents the veterinarian, feed distributor, and client, it is acceptable for the VFD to be stored in a single location provided that everyone required to have a copy has access and can provide a copy to the FDA investigator upon request.

**14. How long must VFD orders be kept and who must keep them?**

All involved parties (veterinarian, client, feed distributor) are required to maintain a copy of the VFD form for 2 years. The veterinarian is required to maintain the original VFD form in its original format (electronic or paper). The client and feed distributor may keep a copy of the VFD form as either paper or electronic.



**15. In what format can the original VFD be kept?**

The veterinarian must maintain the original VFD form in its original format (electronic or paper). If a hardcopy of the VFD form is completed, the hardcopy must be maintained in this original form. If an electronic VFD form is completed, the original VFD form can be stored electronically. A scanned image of a hardcopy VFD form is not the original form, so the hardcopy must be maintained.



## **16. Can the VFD be electronic?**

Yes. The VFD can be in hardcopy or electronic. The VFD may be sent to the feed distributor as a facsimile, emailing a scanned image of the VFD, or utilizing an electronic VFD generated by a system that is in compliance with FDA regulations.

## **17. What information is required for a valid (lawful) VFD?**

- a. Veterinarian's name, address, and telephone number
- b. Client's name, business or home address, and telephone number
- c. Premises where the animals specified in the VFD are located
- d. Date of VFD issuance
- e. Expiration date of the VFD
- f. Name of the VFD drug
- g. Species and production class of animals being fed
- h. Approximate number of animals to be fed by the expiration date
- i. Why the VFD was issued
- j. Level of VFD drug in feed
- k. Duration of use of feed containing VFD drug
- l. Special instructions including withdrawal time and cautionary statements necessary for use of the drug
- m. Number of reorders (refills) authorized, if permitted by the VFD drug
- n. Statement: "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra-label use), is not permitted"
- o. Affirmation of intent for combination VFD drugs
- p. Veterinarian's signature, electronic or written

## **18. What is an expiration date on the VFD and how is it determined?**

The expiration date is the last day the VFD feed can be fed. The VFD feed must not be fed after the expiration date, even if the duration of use for the prevention, control, or treatment of the disease extends beyond that date. Another VFD must be issued before resuming feeding of the VFD feed.

In some cases, the FDA determines the expiration date of the VFD (number of days the VFD feed can be fed) as part of the approval, conditional approval, or index listing of the VFD drug. The expiration date of the VFD must not extend beyond the expiration date specified in that drug's approval, conditional approval, or index listing.

If an expiration date is not specified, the expiration date of the VFD must not exceed 6 months after the VFD issuance date. The veterinarian, in this case, will use their medical judgement to determine an appropriate expiration date for the VFD.

The expiration date should be calculated by the calendar date, not the number of days. For example, using a 6 month expiration date for a VFD, if the VFD is written on July 10, then the expiration date would be January 10 of the following year. Another example would be a VFD expiration date on the last day of the month, if the VFD is written on August 31, the expiration date would be February 28 on a normal year or February 29 on a leap year.

**19. Can a VFD order be submitted to the distributor via telephone?**

No. The veterinarian is required to issue a written VFD. A VFD cannot be issued verbally via telephone.

**20. Does the state or federal definition of a VCPR apply in Montana?**

In Montana, the federal definition of the VCPR applies. See question 4 for requirements.

**21. Can a VFD authorize the use of an approved generic VFD drug?**

The name of the VFD drug is required on the VFD form. The veterinarian may choose to write the trade name of the approved pioneer or an approved generic (if available) VFD drug or the established name of the drug. The veterinarian may also choose to specify that a substitution by the feed manufacturer of either the pioneer or generic VFD drug on the form is not allowed. If the veterinarian does not specify that a substitution is not allowed, either of the approved VFD drugs may be used. The feed manufacturer may not substitute a generic VFD drug for a pioneer VFD drug in a combination feed if the generic VFD drug is not part of the approved combination.

**22. Are reorders/refills allowed?**

Reorders/refills of the VFD are allowed ONLY if the VFD drug permits them. Where reorders/refills are not specified on the labeling for the VFD drug, reorders/refills are not permitted. Currently, there are no approved VFD drugs that allow reorders/refills.

**23. Is extra-label use allowed?**

No. Extra-label use of feed-grade antibiotics has been illegal since 1996 and remains illegal. The use of the VFD drug is limited to the approved, conditionally approved, or indexed conditions of use.

**24. How will the VFD rule impact minor species?**

The VFD drug products that are labeled for use in minor species (sheep, goats, etc.) will move to VFD status. Extra-label use of medicated feed, including VFD drugs is illegal. Currently, Compliance Policy Guide Section 615.115 discusses extra-label use of over-the-counter medicated feeds for minor species. The FDA is currently reviewing and



developing recommendations for Compliance Policy Guide Section 615.115 to address extra-label use of the VFD feed in minor species.

**25. Can a veterinarian make their own VFD form?**

Yes. The veterinarian may create or use a different VFD form, as long as it contains all of the required information (see question 14).

**26. What should a feed distributor do if the VFD form is not completely filled out?**

The veterinarian is responsible for filling out all of the required information for a VFD form. If the VFD form does not contain all of the required information, the feed distributor must not fulfill the VFD order. The distributor should contact the issuing veterinarian immediately and inform them that the order cannot be filled due to lacking the required information.

**27. Can a producer feed a VFD drug-containing feed past the VFD expiration date?**

No. If the duration of use for feeding a VFD drug extends beyond the VFD expiration date, a new VFD form will need to be issued by the veterinarian. The client must stop feeding the VFD feed until a new VFD form can be issued. If the VFD drug containing feed is not purchased from the feed distributor or is stored without feeding until after the VFD expiration date, a new VFD form must be issued before purchasing the feed from the distributor or feeding the stored VFD feed.

**28. What should a producer do if the VFD will expire prior to completing the duration of use for the feed?**

If the VFD expires prior to finishing the duration of use for the VFD feed, the producer must stop feeding the VFD drug containing feed and request another VFD form from the issuing veterinarian. It is not permitted to feed a VFD feed after the expiration date.

**29. Are ionophores (Bovatec, Rumensin, etc.) or coccidiosis treatments (Corid, Deccox, etc.) included as VFD drugs?**

No. Ionophores and coccidiosis treatments are not “medically important” drugs and are not considered VFD drugs.

**30. Do I need a VFD for feeding a VFD drug in combination with an over-the-counter drug, such as Rumensin/Tylan combination?**

Some VFD drugs are approved for use alone or in a combination with one or more OTC drug. In those circumstances, the issuing veterinarian would specify on the VFD whether he or she authorizes the VFD drug to be used alone or in an approved drug combination

with one or more OTC drug. The veterinarian is required to affirm their intent by including one of the following three statements on the VFD:

- "This VFD only authorizes the use of the VFD drug cited in this order and is not intended to authorize the use of such drug in combination with any other animal drugs."
  - This statement is used if the veterinarian does NOT authorize the VFD drug to be used in combination with any other animal drug in the medicated feed. For those VFD drugs that are only approved as a single ingredient Type A medicated article, there are no approved combinations that contain the VFD drug as a component, this statement is the only one of the three statements that can be used and must be included in the VFD.
- "This VFD authorizes the use of the VFD drug in this order in the following FDA-approved, conditionally approved, or indexed combination in medicated feed that contains the VFD drug as a component." The veterinarian must list specific approved combination medicated feeds following this statement.
  - This statement is used if the veterinarian chooses to authorize the use of the VFD drug only in SPECIFIC combination; the veterinarian may only list approved, conditionally approved, or indexed combination that contain the VFD drug. The producer may use the VFD drug in medicated feed either alone or in those specific combinations that the veterinarian has specified on the VFD.
- "This VFD authorizes the use of the VFD drug cited in this order in any FDA approved, conditionally approved, or indexed combination in medicated feed that contains the VFD drug as a component."
  - This statement is used if the veterinarian authorizes the use of the VFD drug in ANY approved combination that contains the VFD drug. The producer may use the VFD drug either alone or in any approved, conditionally approved, or indexed combination with the OTC drug in the medicated feed.

### **31. Does the veterinarian have to specify the feed distributor on the VFD form?**

The VFD rule requires the veterinarian to send a copy of the VFD form to the feed distributor, but does not require the veterinarian to specify the feed distributor on the VFD. If the VFD form is in hardcopy, the veterinarian must send a copy of the VFD to the feed distributor either directly or through the client. If the veterinarian provides the client with



a hardcopy to take to the feed distributor, the client may go to the feed distributor of their choice.

If the VFD form is being issued directly to the feed distributor by the veterinarian, the client must tell the veterinarian which feed distributor to send the VFD to. If the client is not sure which feed distributor they will use to fill the order, the client should obtain a hardcopy of the VFD form and provide it to the distributor of their choice. If the veterinarian has provided the VFD to a feed distributor and the client decides to fill the order elsewhere, the client must contact the issuing veterinarian to have them revoke the previous VFD from the original feed distributor and reissue a VFD to the new feed distributor.

### **32. Can you purchase a partial order and purchase the remainder at a later date?**

Yes. This may also occur if an insufficient amount of feed containing the VFD drug was available at the time of purchase. However, this would be up to the discretion of the feed distributor and maintaining the proper records as to how much was initially purchased and how much remains on the current VFD.

### **33. Can you change feed distributors mid-order?**

The feed distributor indicated on the VFD form should be the ONLY distributor filling the entire order. In special circumstances (feed distributor runs out of the VFD drug or the mill goes down), there may be a need for two mills to fulfill the order. If that is the case, a new VFD will need to be issued for the remainder of the product needed at the new feed mill. All parties involved, veterinarian, feed distributors, and client should keep all records documenting the situation and it should be made clear that the animals only received the treatment authorized on the VFD form.