

Changes in the Veterinary Feed Directive (VFD)



*What the swine veterinarian
needs to know*



The VFD has changed.



The United States Food and Drug Administration (FDA) has issued a final rule revising the regulation governing the Veterinary Feed Directive (VFD).¹ These changes to the VFD are a key part of FDA's strategy to ensure feed-grade antimicrobials are used judiciously and only when appropriate for specific animal-health purposes.

This brochure has been prepared by the American Association of Swine Veterinarians to highlight the changes to the VFD, the responsibilities of the veterinarian issuing the VFD, and the information that must be supplied on every VFD. A list of important references is provided on the back page for more detailed information.



The new VFD regulation became effective October 1, 2015.

The use of any feed-grade antimicrobial with a VFD label is now subject to the new regulation. This includes tilmicosin, florfenicol, and avilamycin, which are VFD drugs already labeled for use in swine.

Changes in the VFD are designed to enhance veterinary oversight of antimicrobial use in livestock for those products designated as medically important for human health. A list of “medically important” antimicrobials can be found in FDA’s Guidance #152 Appendix A.² Pharmaceutical manufacturers have agreed to voluntarily transition the affected product labels to VFD by December 2016. Essentially all swine antibiotics will be affected, except bacitracin, carbadox, bambarmycin, ionophores, and tiamulin. These antibiotics will remain available for growth promotion or over-the-counter (OTC) distribution, or both.

In order to comply with the new VFD regulation, the veterinarian must:

- Be licensed and operating in the course of normal practice in compliance with all state and federal regulations;
- Write VFD orders in the context of a veterinary-client-patient relationship (VCPR), as discussed on page 5;
- Only issue a VFD that is in compliance with approved use;
- Prepare a written (nonverbal) VFD including the veterinarian’s signature;
- Ensure the VFD includes all required information listed on page 4. There is no FDA-approved standardized VFD form;
- Include certain drug-specific information for each VFD drug when authorizing drug combinations that include more than one VFD drug;
- When issuing a VFD combining VFD and OTC drugs, include on the VFD order an affirmation of intent either to restrict authorized use only to the VFD drug cited on the VFD form or to allow the use of the cited VFD drug in an approved combination with one or more OTC drug(s);
- Provide the distributor and client with a copy of the VFD order either in hardcopy or electronic form or by fax;
- Retain the original VFD for 2 years (the client and distributor must likewise retain their copies for 2 years); and
- Provide the VFD orders for inspection and copying by FDA upon request.

IMPORTANT: Extra-label use of feed-grade antimicrobials remains ILLEGAL for both veterinarians and producers.

Required VFD information

The following information is required on every VFD:

1. The veterinarian's name, address, and telephone number;
2. The client's name, business or home address, and telephone number;
3. The premises at which the animals specified in the VFD are located;
4. The date of VFD issuance;
5. The expiration date of the VFD;
6. The name of the VFD drug(s);
7. The species and production class of animals to be fed the VFD feed;
8. The approximate number of animals to be fed the VFD feed by the expiration date of the VFD;
9. The indication for which the VFD is issued;
10. The concentration of VFD drug in the feed and duration of use;
11. The withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;
12. The number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing;
13. The 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;"
14. An affirmation of intent for combination VFD drugs as described in 21 CFR 558.6(b)(6); and
15. The veterinarian's electronic or written signature.*

*Electronic signatures must be compliant with 21 CFR part 11,³ which involves certification of the electronic signature with FDA prior to use. Signatures that are handwritten on a paper VFD that is subsequently faxed or scanned and emailed, are not subject to 21 CFR part 11.

Veterinary-client-patient relationship

A valid VCPR must exist between the veterinarian, the client, and the animals to be treated in order to issue a VFD.



For the purposes of issuing a VFD, FDA defaults to the VCPR requirements defined in the state veterinary practice act, provided those requirements meet the following minimum standards:

1. The veterinarian has engaged with the client to assume responsibility for making clinical judgments about patient health,
2. The veterinarian has sufficient knowledge of the patient by virtue of patient examination, visits to the facility where the patient is managed, or both, and
3. The veterinarian is available to provide for any necessary follow-up evaluation or care.

If the state practice act either does not include a VCPR requirement or does not meet those minimum standards, the VCPR requirement to issue a VFD defaults to the VCPR as defined in association with the Animal Medicinal Drug Use Clarification Act (21 CFR § 530.3[i]).⁴ The FDA has reviewed state veterinary practice acts to identify those that meet the minimum VCPR requirements, and their state-by-state determination is available online.⁵

Additional items to note

Keep in mind the following:

1. The veterinarian must assign an expiration date to the VFD. This date refers to the length of time during which the VFD is valid and the producer can feed the VFD feed, not the date on which the drug expires. The expiration date must comply with the VFD expiration date indicated on the VFD drug label if the product specifies an expiration date (the veterinarian cannot deviate from this date). If the product label does not indicate a specific date, the veterinarian must assign a date not to exceed 6 months from the date the VFD is issued.
2. If refills are allowed on the product label, the veterinarian must specify the number of refills. As of October 1, 2015, there are no approved medications for which refills are allowed on the label. Thus, refills are illegal unless a future product approval allows refills.
3. The veterinarian issuing the VFD must comply with the veterinary practice act regulations in effect in the state in which the animals receiving the VFD feed reside.
4. In contrast to previous VFD requirements, the new rule requires that the veterinarian estimate the number of animals that will receive the VFD feed, rather than the volume of feed produced.
5. In another change, the VFD may now be transmitted to the feed manufacturer or distributor and to the client electronically (eg, by fax or through a compliant third-party electronic database, but not by telephone) instead of only by hard copy. The veterinarian retains the original copy in whatever format it was generated. The distributor and client copies may be kept either as electronic copies or hard copy. All parties must retain copies of the VFD for a minimum of 2 years.
6. If any drug in an approved combination drug product is a VFD drug, the use of that combination must comply with the VFD rule.

Use of avilamycin, florfenicol, and tilmicosin in swine feed is now subject to the new VFD rules. Manufacturers will transition other medically important, feed-grade antimicrobials to VFD labels by December 2016.

Additional items to note

7. The veterinarian may write a VFD that covers animals in multiple locations (animal-production facilities) to be fed the VFD feed by the expiration date on the VFD, provided he or she can do so in compliance with professional licensing and practice standards and provided the VFD feed is supplied to such multiple locations by a single feed manufacturer (distributor).
8. Signatures on electronic VFD orders issued by veterinarians must be compliant with 21 CFR part 11,³ which involves certification of the electronic signature with FDA prior to use. Distributors and clients who receive and store electronically generated and signed VFD orders must also be compliant with 21 CFR part 11. Hand-signed, paper VFD orders that are, or have been, transmitted by electronic means (such as facsimile, scanned email attachments, etc) are not subject to 21 CFR part 11.
9. There are additional requirements to meet if a veterinarian also distributes VFD feed.



Summary

In summary, effective October 1, 2015, all VFD-labeled products must comply with the new VFD rules.

This brochure highlights the key responsibilities of the veterinarian, but you are urged to familiarize yourself with the regulation as published.¹ The FDA has compiled a fact sheet describing the background and reasons for the changes to the VFD.⁶ The agency has also published an additional draft guidance document, GFI #120,⁷ which answers many of the most frequently asked questions. These documents and additional information are available on the FDA's veterinary feed directive webpage.⁸

Questions about VFDs? Contact AskCVM@fda.hhs.gov.

References

1. Federal Register. Final Rule: Veterinary Feed Directive. Available at: <https://www.federalregister.gov/articles/2015/06/03/2015-13393/veterinary-feed-directive>. Accessed 1 October 2015.
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7. US Food and Drug Administration. Guidance #120 VFD Frequently Asked Questions. Available at: <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>. Accessed 1 October 2015.
8. US Food and Drug Administration. Veterinary Feed Directive (VFD). Available at: <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>. Accessed 1 October 2015.

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