

Guidance for Industry
Veterinary Feed Directive Regulation
Questions and Answers
Final Guidance

(This version of the guidance replaces the version that was made available in June 26, 2007. This guidance document has been revised to include information on transmitting electronic veterinary feed directive (VFD) orders via the Internet.)

This guidance document is intended to provide information concerning veterinary feed directive (VFD) orders.

Comments may be submitted anytime (see 21 CFR 10.115(g)(5)) on a guidance document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-1999-N-1591 (formerly 99n-1591) listed in the notice of availability that publishes in the *Federal Register*. Submit electronic comments to <http://www.regulations.gov>.

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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE**

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Contains Nonbinding Recommendations

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Guidance for Industry

Veterinary Feed Directive Regulation Questions and Answers

This guidance represents the Food and Drug Administration's (FDA) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the number listed on the title page of this guidance.

I. Introduction

Before 1996, there were only two options for dispensing new animal drugs: 1) over-the-counter (OTC), and 2) prescription. Congress determined certain new animal drugs, should be approved for use in animal feed but only if these medicated feeds were administered under a veterinarian's order and professional supervision. For example, veterinarians are needed to control the use of certain antimicrobials. Control is critical to reducing unnecessary use of such drugs in animals and to slowing or preventing any potential for the development of bacterial resistance to antimicrobial drugs. Safety concerns relating to difficulty of diagnosis of disease conditions, high toxicity, or other reasons may also dictate that the use of a medicated feed is limited to use by order and under the supervision of a licensed veterinarian. The VFD category will maintain public health protection while allowing producers to obtain needed drugs.

FDA guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances mean that something is suggested or recommended, but not required.

II. Veterinary Feed Directive Drugs

A. General Questions and Answers

1. What is a Veterinary Feed Directive?

FDA regulations at Title 21 Code of Federal Regulations (CFR), Part 558.3(b)(7) defines "veterinary feed directive" as a written statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a VFD drug in or on an animal feed. This written statement authorizes the client to obtain and use the VFD drug in or on animal feed to treat the client's animals only in accordance with the directions for use approved or indexed by FDA. A veterinary feed directive is also referred to as a VFD order.

2. What is a Veterinary Feed Directive Drug?

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FDA regulations at 21 CFR 558.3(b)(6) defines “veterinary feed directive drug” as an approved new animal drug (or one listed on the index under section 572 of the Federal Food, Drug and Cosmetic Act (the act)) for use in or on animal feed. Use of a VFD drug must be under the professional supervision of a licensed veterinarian.

3. Who determines whether a drug is VFD drug?

When a new animal drug application is submitted to FDA’s Center for Veterinary Medicine (CVM) for approval, the appropriate review division determines whether a drug will be an OTC (over-the-counter) drug, a prescription drug, or a VFD drug.

4. Can a practicing veterinarian write a VFD order for an OTC drug?

No. A practicing veterinarian may not write a VFD order for an OTC drug nor may he/she write a VFD order to be used contrary to the FDA regulation for that drug. A veterinarian may only write a VFD order for drugs approved, conditionally approved, or indexed for that category by the FDA (21 U.S.C. 354) and only under the context of a valid veterinarian-client-patient relationship (VCPR) as defined in 21 CFR 530.3(i).

5. How many drugs have been approved as VFD?

As of the date this guidance was published, two drugs have been approved or conditionally approved under this category and codified in 21 CFR 500. The drug tilmicosin (21 CFR 558.618) is approved for use in the control of swine respiratory diseases, and the drug florfenicol (21 CFR 558.261) is approved for use in the control of swine respiratory diseases and for control of certain bacterial diseases in aquaculture. The drug florfenicol is also conditionally approved for control of mortality in catfish due to columnaris disease (21 CFR 516.1215). Because the list of VFD drugs changes over time with new approvals, which may or may not be reflected in this document, we recommend that you check the FDA website at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm> for more current information.

6. What does the term “appropriately licensed” veterinarian mean?

The term “appropriately licensed” veterinarian, as it pertains to 21 CFR 558.6, means that the veterinarian has a valid license to practice veterinary medicine in the State in which the animals being treated are located.

7. Does the manufacturer of a medicated feed containing a VFD drug from a Type A medicated article require a feed mill license?

Yes, all VFD drugs are Category II drugs and a medicated feed mill license is required to manufacture a Type B or Type C medicated feed from a VFD drug Type A medicated article (21 CFR 558.3(b)(1)(ii) and 558.4(a)).

B. Questions and Answers about VFD orders

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8. What specific information does the VFD order require?

As defined in 21 CFR 558.6(a)(4) the following information is required in the VFD order for the order to be valid:

- Veterinarian's name and address, telephone number and if the VFD is faxed, facsimile number.
- Client's name, address, telephone number and if the VFD is faxed, facsimile number;
- Identification and number of animals to be treated/fed the medicated feed, including identification of the species of animals, and the location of the animals;
- Date of treatment, and, if different, date of issuing the VFD drug;
- Approved or index listed indications for use;
- Name of the animal drug;
- Level of animal drug in the feed, and the amount of feed required to treat the animals;
- Feeding instructions with the withdrawal time;
- Any special instructions and cautionary statements necessary for the use of the drug in conformance with the approval;
- Expiration date of the VFD;
- Number of refills (reorders) if necessary and permitted by the approval;
- Veterinarian's license number and the name of the state issuing the license;
- The statement: "Extra-label use, (i.e., use of this VFD feed in a manner other than as provided for in the VFD drug approval) is strictly prohibited."
- Any other information required by the VFD drug approval regulation.

9. What are the methods by which a VFD order can be transmitted to the feed distributor?

You may transmit a paper copy, or as specified in 21 CFR 558.6(b)(4), a VFD order can be transmitted by facsimile or other electronic means provided you assure that the distributor receives the original signed VFD within 5 working days of receiving the facsimile or other electronic order.

When the order is both generated and transmitted electronically to the distributor using technologies that are in compliance with 21 CFR, Part 11, such an order is referred to in this document as eVFD or eVFD order.

10. Can a VFD order be transmitted by telephone?

No. As specified in 21 CFR 558.6(b)(5) telephone orders are not allowed.

11. Can a VFD order be transmitted via the Internet?

Yes. According to 21 CFR 558.6(b)(4), a VFD order can be transmitted "...by facsimile or other electronic means." The phrase "...other electronic means" includes the Internet. For example, transmitting the VFD by "other electronic means" includes using the Internet to transmit the image of a paper VFD order (e.g., e-mailing a scanned VFD document), or using the Internet to transmit an eVFD order generated in a system that is shown to be in compliance with 21 CFR, Part 11.

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12. What constitutes the “original signed VFD” order?

For purposes of a paper VFD order, the term “original signed VFD” in 21 CFR 558.6(b)(4) means the original paper VFD order hand signed by the issuing veterinarian. When an electronic VFD order is used, the term means the eVFD order electronically signed by the issuing veterinarian with the veterinarian’s authorized electronic signature (see in section C below).

13. Does the requirement to assure the distributor receives the original signed VFD within 5 working days of receipt of a facsimile or other electronic order apply when using the Internet?

When a paper VFD order is transmitted using the Internet (such as the case where a paper copy is scanned and e-mailed), it is required to be followed up by the original hand signed VFD within 5 working days of receipt of the VFD order via the Internet. However, if an eVFD order is generated and transmitted using a Part 11 compliant system, it already bears an authorized electronic signature of the issuing veterinarian and is the “original signed VFD.”

14. Could the third-party server companies require testing of their clients’ computers before starting to transmit eVFD orders?

Whether or not the third-party server companies require testing of their clients’ computers for compatibility with their systems before starting to provide the clients with their service, is a business decision between third-party server companies and their clients and not a FDA requirement.

15. I am a veterinarian and my server company compiles eVFD orders during the day and transmits them all at the same time, e.g., at midnight. What should I do if I want the eVFD order to be delivered immediately to the feed distributor?

For an immediate delivery of an eVFD order, we recommend that you print a copy of the eVFD and have it hand delivered or transmitted by facsimile or other electronic means to the distributor. Because the original eVFD order will be transmitted subsequently through the server, there is no need to follow-up with the paper VFD order hand signed by the issuing veterinarian.

16. I am a veterinarian and would like to cancel my paper VFD order. What should I do?

To cancel a paper VFD order we recommend that you promptly contact the party in possession of the order, who may be either the client if you had issued the order through the client, or feed distributor if you had issued the order directly to the distributor, and request the paper VFD order be cancelled. We recommend that the involved parties document the situation and make the record available at an inspection. In the situation

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where cancellation was requested with a feed distributor, we recommend that the feed distributor document the final outcome of the cancellation request (e.g., feed neither prepared nor issued).

17. I am a veterinarian and would like to cancel my eVFD order. What should I do?

If you request cancellation before the eVFD order leaves the third-party server, we recommend that you contact the server and request that the order not be transmitted. If you request cancellation after the eVFD order has left the server, we recommend that you contact the feed distributor who has the order and request that the order be cancelled.

In either situation we recommend that the involved parties document the situation and make the record available at an inspection. In the situation where cancellation was requested with a feed distributor, we recommend that the feed distributor document the final outcome of the cancellation request (e.g., feed neither prepared nor issued).

18. In the past I issued only paper VFD orders. Do I now have to switch to issuing eVFD orders?

No. Transmitting VFD orders as eVFDs is entirely optional. Paper VFD orders continue to be an acceptable means of authorizing the use of a VFD drug.

19. How do I, a veterinarian, obtain a form for a VFD drug?

Although it is not mandatory that the VFD drug sponsors provide copies of a form for use by the veterinarian, most sponsors will make the forms available to you in triplicate to ensure efficiency and completeness of the veterinarian's VFD order transmissions. Nevertheless, you may create your own form for a VFD drug. Any form, whether provided by the drug sponsor, or created by you, must include the information specified in 21 CFR 558.6(a)(4).

20. Who is held responsible if the VFD or eVFD order is not properly distributed?

Under 21 CFR 558.6(b)(1), the veterinarian is required to give the original VFD order to the feed distributor (directly or through the client), and under 21 CFR 558.6(b)(3), the veterinarian is required to give a copy of the VFD to the client. Thus, it is the veterinarian's obligation to assure that the original VFD order is distributed to the feed distributor within the timeframe required.

21. What should the feed distributor do if the VFD or eVFD form is not completely filled out?

Under 21 CFR 558.6(a)(3), the VFD must be complete or it will be invalid. Hence, the feed distributor should not fill the incomplete order. Instead, we recommend that the distributor notify the veterinarian that the order cannot be filled until all the necessary information on the VFD order is provided.

22. Who is responsible for incorrect calculations on a VFD or eVFD order?

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Under 21 CFR 558.6(a)(4), a VFD order is required to include the level of the drug in feed and the amount of feed required to treat the animals. The issuing veterinarian is responsible for the accuracy of all information required in a VFD order (e.g., species, numbers of treated animals, amounts of feed...).

23. When a VFD drug is approved for use at different drug levels, would one or multiple VFD or eVFD orders have to be issued to cover such drug uses?

Where variable drug levels are approved by regulation, a single VFD or eVFD order may be issued covering all those approved variable drug levels intended to be used, the respective amounts of feed to be fed, and durations of feeding of the feed containing a VFD drug at an approved drug level.

24. Is a feed mill or feeder permitted to distribute or feed drugs not approved as VFD if that is requested by a veterinarian in a VFD or eVFD order?

No.

25. What mechanisms are in place to prevent transmitting the order to multiple feed mills?

Although the possibility exists that a client may submit a copy of the VFD order to several distributors to obtain additional VFD feed, the distributor will become aware of the irregularity when the original VFD order does not arrive within 5 days as required by the regulation. To reduce the potential for having one eVFD distributed by mistake to more than one feed distributor, we recommend that the third-party server's system be set to prevent sending the same VFD to multiple feed distributors.

26. How long must VFD and eVFD orders be retained?

Under 21 CFR 558.6(c), all parties are required to keep VFD orders for a period of two years from the date of issuance.

C. Questions about 21 C.F.R. Part 11

27. What is Part 11?

21 CFR Part 11 sets out the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be generally equivalent to paper records and handwritten signatures executed on paper.

28. What must be done before someone can use electronic signatures, consistent with Part 11?

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Part 11 requires a one-time certification that the electronic signatures in their system, used after August 20, 1997, are intended to be the legally binding equivalent of the signer's handwritten signature.

29. With respect to issuance and receipt of eVFDs, what is required for compliance with Part 11?

Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any FDA records requirements. Therefore, eVFD orders issued by veterinarians must be compliant with Part 11, and eVFD orders received and electronically stored by feed distributors and clients must be compliant with Part 11. Part 11 does not apply to paper records that are, or have been, transmitted by electronic means (such as facsimile, e-mail attachments, etc.).

D. Questions and Answers about the Distributor Notification Process

30. What is the Distributor Notification Process?

As specified in 21 CFR 558.6(d), all distributors must submit a one-time notification letter to FDA of their intent to distribute medicated feed containing a VFD drug. Under 21 CFR 558.3(9), the term "distributor" means any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD. A distributor notification must include the name and address of each business site from which distribution will occur.

31. Under what circumstances would the distributor be requested to submit an updated notice to the FDA?

As specified in 21 CFR 558.6(d)(iv), an updated notice is required within 30 days of any change in name or business address.

32. What is a notification letter and how is it different than an acknowledgement letter?

As specified in 21 CFR 558.6(d), a notification letter is a one-time notice by a distributor of its intent to distribute a medicated feed containing a VFD drug. An acknowledgement letter is a letter that a distributor obtains from a consignee-distributor when the distributor ships an animal feed containing a VFD drug in the absence of a valid VFD. 21 CFR 558.3(b)(ii) defines the term "acknowledgement letter" to mean a written communication provided to a distributor by a consignee who is not the ultimate user of medicated feed containing a VFD drug. It affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another distributor without receiving a similar acknowledgment letter.

E. Questions and Answers about Reorders and Refills

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33. How does this regulation deal with refills, reorders or the length of time a VFD order is valid?

The regulation requires the veterinarian to include the expiration date of the VFD and number of refills (reorders) if necessary and permitted by the approval in the VFD order for it to be valid.

34. If a VFD order is written for refills and the subsequent orders are filled at a different establishment than the first, how do both establishments retain the original order?

It is possible the VFD order may be required by one distributor first and later by another for refill. The regulation requires that a feed establishment retain the original copy of the order for two years, thereby making it impossible to forward the original VFD order to another establishment (21 CFR 558.6(e)). In these situations, the client should contact the issuing veterinarian and request a new VFD order.

F. Questions and Answers about Roles and Responsibilities

What are the veterinarian's responsibilities?

- Is appropriately licensed (21 CFR 558.6(a)(1))
- Writes VFD orders only under the context of a Valid Client Patient Relationship (VCPR) as defined in 21 CFR 530.3 (21 CFR 558.6(a)(2))
- Prepares and signs a written VFD order in triplicate providing all requested information (21 CFR 558.6(a)(5))
- Signs electronically eVFD orders (21 CFR 558.6(a)(3))
- Provides the feed distributor with the original VFD order (21 CFR 558.6(b)(1))
- Gives copy of a VFD or eVFD to the producer (21 CFR 558.6(b)(3))
- Retains copy for his/her records for a minimum of two years (21 CFR 558.6(b)(2))
- Provides VFD orders for review and copying by FDA during inspection (21 CFR 558.6(c)(2))

What are the client's responsibilities?

- Agrees to follow the veterinarian's recommendations (21 CFR 530.3(i)(1))
- Administers the feed to the animals (21 CFR 530.3(i)(1))
- Provides the original VFD order to the feed supplier if not previously done (21 CFR 558.6(b)(1))
- Maintains copy of the VFD orders for a minimum of two years (21 CFR 558.6(c)(1))
- Provides VFD orders for review and copying by FDA during inspection (21 CFR 558.6(c)(2))

What are the feed distributor's responsibilities?

- Retains original VFD order supplied by the veterinarian/producer for two years from date of issuance (21 CFR 558.6(c)(3))

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- Provides VFD order forms for review and copying by FDA during inspection (21 CFR 558.6(c)(2))
- Files one-time notice with FDA of intent to distribute VFD drugs (21 CFR 558.6(d)(1))
- Requires an acknowledgement letter from all consignees who distribute but are not the ultimate user of the feed (21 CFR 558.6(d)(2))
- Assures all labeling and advertising must prominently and conspicuously display the following cautionary statement: ``Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice." (21 CFR 558.6(f))

What are the third-party computer server provider's responsibilities?

- Provides eVFD orders for review and copying by FDA during inspection (21 CFR 558.6(c)(2))