

VFD Information for Distributors

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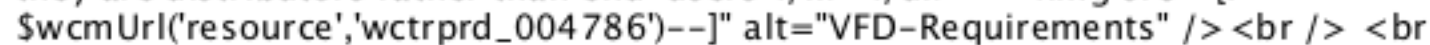
What does a VFD distributor need to know?
You are required to notify the FDA in writing of your "intent to distribute" prior to the first time you distribute VFD drugs or VFD-medicated feeds. By notifying the FDA, you will be added to their list of VFD Distributors and may be visited by an FDA inspector for a compliance check. Visit the [FDA's Distributor VFD page](http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455415.htm) for more information about the one-time notification
You will also need to give your suppliers an acknowledgment letter, sometimes called an AOD, in order to purchase VFD drugs or VFD-medicated feeds. *What's an AOD? See below for more information.*
What documentation does a distributor need to have for each VFD-medicated feed sale?
You must have the correct documentation from your customers when you sell them a VFD drug or VFD-medicated feed.

- If you're selling to anyone other than the producer, you need to have an acknowledgment letter, sometimes called an AOD, from your customer before the product ships
- If you're selling to the producer, you are required to have a lawful VFD that corresponds with the product you're selling
- In addition to the other information required to be on the VFD form, the claim, the species and production class on the product label must also match the information on the VFD form
- You must also make sure that the product is shipped to the customer before the VFD expires

What is an "AOD"?
AOD stands for "Acknowledgement of Distribution Limitations for VFD Feeds"

- The AOD must include specific language that addresses the VFD requirements in the regulations.
- To find the specific language that must be on the AOD, visit the [FDA's Distributor VFD page](http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455415.htm)
- An AOD is the only

documentation that one VFD distributor must give another VFD distributor in order to purchase VFD drugs or VFD-medicated feedsYou will also get an AOD from your customers if they are distributors rather than end-users



What if the VFD form is incomplete or written incorrectly?
While it's the veterinarian's responsibility to complete the VFD form in its entirety and only write the VFD according to the FDA's approval for the VFD drug, it is the distributor's responsibility to ensure that the order is not filled if the VFD is not lawful. The veterinarian needs to be notified that the order cannot be filled until all necessary information on the VFD is provided.

What records is a distributor required to keep?
A distributor is required to keep receiving and distribution records for VFD drugs and VFD-medicated feeds for 2 years.

If you ship VFD feed to:			
	Records Required:	Records Retained for:	
Client-recipients	<u>only</u>	VFD form	2 years
Other distributors	<u>only</u>	Acknowledgment letter(s)	2 years
Both client-recipients	<u>and</u> other distributors	VFD form from clients and acknowledgment letter(s) from other distributors	2 years

A distributor that manufactures VFD feeds is also required to keep VFD-medicated feed production records for 1 year.

FDA's List of Distributors' Responsibilities The FDA's VFD Requirements for Distributors <u>page</u> says that distributors must do the

following:File a one-time notice with FDA of intent to distribute VFD drugs or VFD-medicated feeds before the first product shipmentNotify FDA within 30 days of any change in ownership, business name, or business addressFill a VFD order only if the VFD contains all required informationEnsure that the distributed animal feed containing a VFD drug or combination VFD drug complies with the terms of the VFD and is manufactured and labeled in conformity with the approved, conditionally approved, or indexed conditions of use for such drugEnsure that all labeling and advertising prominently and conspicuously displays the following cautionary statement: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian."Retain VFD forms and corresponding distribution documentation for 2 years from the date of issuanceRetain records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 yearsProvide VFD orders for inspection and copying by FDA upon requestRetain records of VFD manufacturing for 1 year in accordance with 21 CFR §225 and make such records available for inspection and copying by FDA upon requestObtain, as the originating distributor (consignor), an acknowledgement letter from the receiving distributor (consignee) before the feed is shippedRetain a copy of each consignee distributor's acknowledgement letter for 2 years For more information:

<u>FDA's VFD Requirements for Distributors Who Do Not Manufacture Feed page</u>

FDA's VFD Requirements for Distributors Who Manufacture Feed page