

## FDA Begins VFD Inspections “Pilot Project”

The Food and Drug Administration’s (FDA) Center for Veterinary Medicine (CVM) announced a strategy to begin measuring compliance with the VFD rule this year, in preparation for January 2017 when the new changes go into effect.

Part of that strategy is a VFD Inspection Tool that helps guide investigators through the necessary parts of the VFD form as they work with the parties involved in the VFD process (veterinarians, distributors, producers).

According to William T. Flynn, D.V.M., M.S., Deputy Director for Science Policy, CVM, USDA, while the field assignment is meant to address compliance with the VFD rule, the focus is education, not enforcement.

As inspectors talk with the parties involved, they’ll assess whether further education about the new rule is needed and, if so, who needs more education (feed mills, retailers, vets, producers).

It is anticipated that this tool will eventually be routine for the feed manufacturing compliance program, the program that has provided VFD inspections since VFDs were first established in 1996.

### How will the inspection process work?

Using the database of distributor notifications, field staff will begin inspections at VFD distributors with additional follow-up at veterinarians and producers. Dr. Flynn says the Districts have been asked to make appointments when conducting on-farm inspections.

At the VFD distributor, an investigator will examine three randomly selected VFD forms. From these, they will pick one form to follow back to the vet and to the producer.

The investigators will be looking for the following required items on the VFD order:

- Veterinarian’s name, address, and telephone number
- Client’s name, business or home address, and telephone number
- Premises where the animals specified in the VFD order are located
- Date the VFD order was issued
- Expiration date of the VFD order
- Is the name of the VFD drug or drugs identified on the form?
- Species and production class of animals to be fed the VFD feed
- Approximate number of animals to be fed the VFD feed by the expiration date of the VFD order
- Reason the VFD order was issued (the indication)
- Level of VFD drug in the feed and duration of use
- Withdrawal time, special instructions, and cautionary statements necessary to use the drug according to its approved labeling.
- The number of reorders (refills) authorized, if permitted by the drug’s approval, conditional approval, or index listing
- This required statement: “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use), is not permitted”
- Affirmation of intent for combination VFD drugs (see instructions)
- Veterinarian’s electronic or written signature

Specific questions for each party will also be asked.

**Distributor Questions:**

1. Did the distributor notify FDA of the intent to distribute VFD feeds? (Verify VFD Distributor Notification Listing on [www.fda.gov](http://www.fda.gov))
2. Does the distributor keep copies of VFD orders for at least 2 years, if distributing VFD feed to the end user?
3. If the operation being inspected distributes VFD feed to other distributors and not to the end user, does this operation keep copies of acknowledgement letters for at least 2 years from the date of last shipment under the acknowledgement letter?

**VFD Distributor Questions:**

1. Does the feed label contain the VFD Caution statement?
2. Do the drug inventory or production records show the correct amount of drug added?
3. Do the labels and formulas match the VFD orders?

**Veterinarian Questions:**

1. Does the veterinarian have a valid license in those states where VFD feed is being fed?
  - a. If No, can the veterinarian provide any evidence that he or she is complying with applicable state veterinary licensing and practice requirements in the states in which the veterinarian does not have a license?
2. Does the veterinarian know that either the state or federal requirements for veterinary client patient relationship (VCPR) apply in each state?
  - a. Can the veterinarian show any medical record(s) for the client's animals named on the VFD?
3. Does the veterinarian keep copies of VFD orders for at least 2 years?

**Producer (Client) Questions:**

1. Does the client keep copies of VFD orders for at least 2 years?
2. Did the client feed the VFD feed to the authorized number of animals on the VFD order?
3. Did the client feed the VFD feed for the identified duration on the VFD order?
4. Did the client stop feeding the VFD feed prior to the expiration date on the VFD order?
5. Did the client follow the withdrawal period for the VFD feed, if any?
6. Did the client follow any special instructions or caution statements on the VFD order, if any?
7. If a combination VFD feed was fed, was its use consistent with the affirmation statement on the VFD order?
8. Does the client have labels for VFD feeds? If Yes,
  - a. Does the feed label contain the VFD Caution statement?
  - b. Did the drug level on the label match the drug level on the VFD form?
  - c. Is the drug level and indication on the VFD form consistent with the approval?

Questions about the VFD field assignment or Inspection Tool should be directed to Dr. David Edwards, Director, Division of Animal Feeds, Office of Surveillance and Compliance, Center for Veterinary Medicine, FDA ([AskCVM@FDA.HHS.GOV](mailto:AskCVM@FDA.HHS.GOV), or [David.Edwards@FDA.HHS.GOV](mailto:David.Edwards@FDA.HHS.GOV)).

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