See instructions at the end of this document for information on how to complete this form.
Space is provided at the end of the tool for narrative. Please use the narrative space to elaborate on responses and to note any unique situations.

VFD Operation Name			Dates of Inspection Start: End:
FEI Number (if available/applicable)			DUNS Number (if available/applicable)
(**Physical**) Address of the VFD Operation			Lead Investigator
City			
State	Zip Code	Telephone Number	FDA District Office
Name and title of person(s) interviewed			Name and title of most responsible person at this operation

❑ Information above includes changes to operation's name and/or address	Status of the VFD Operation (*Check only one*) [**If firm is Out of Business, Skip ALL Sections]** ❍ Operational ❍ Operational but not manufacturing, holding or distributing VFD feeds ❍ Completely Out of Business

Section 1 – Complete for ALL operations

1. Who are you inspecting? (Select **ALL** that apply)

   - ❑ Distributor who does not manufacture VFD feed (If checked, complete **Section 2**)
   - ❑ Distributor who manufactures VFD feed (If checked, complete **Section 2 and Section 3**)
   - ❑ Veterinarian (If checked, complete **Section 4**)
   - ❑ Client (if checked, complete **Section 5**)
   - ❑ Other (Specify): _____

2. Is this inspection a trace-forward or trace-back step from the VFD Order at the distributor or client (if conducted in the course of a violative drug residue inspection)?

   ❍ No

   If 'No', see instructions.

   ❍ Yes

   If 'Yes', enter the name and location of the distributor/client:

Name:
Physical Address (*Street, City, State, Zip Code)*
Date originating inspection ended

Reset Form

3. If the location has VFD orders on hand, please review up to three random VFD orders.

   a. The following items are required for a VFD order to be lawful. Are these items present in the VFD orders?
      i. For trace forward/back inspections, please use the VFD order that led to the trace as VFD Order #1.

	VFD Order #1	VFD Order #2	VFD Order #3
a. Veterinarian's name, address, and telephone number	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
b. Client's name, business or home address, and telephone number	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
c. Premises where the animals specified in the VFD order are located	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
d. Date the VFD order was issued	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
e. Expiration date of the VFD order	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
f. Is the name of the VFD drug or drugs identified on the form?	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
• What is the name of the VFD drug or drugs?			
g. Species and production class of animals to be fed the VFD feed	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
• What is the species and/or production class?			
h. Approximate number of animals to be fed the VFD feed by the expiration date of the VFD order	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
i. Reason the VFD order was issued (the indication)	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
j. Level of VFD drug in the feed and duration of use	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
k. Withdrawal time, special instructions, and cautionary statements necessary to use the drug according to its approved labeling.	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
l. The number of reorders (refills) authorized, if permitted by the drug's approval, conditional approval, or index listing	❍ Yes ❍ N/A ❍ No	❍ Yes ❍ N/A ❍ No	❍ Yes ❍ N/A ❍ No
m. This 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"	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
n. Affirmation of intent for combination VFD drugs (*see instructions*)	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
o. Veterinarian's electronic or written signature	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No

Section 2 – Complete for ALL distributors

1. Did the distributor notify FDA of the intent to distribute VFD feeds? (Verify VFD Distributor Notification Listing on www.fda.gov, *see instructions*)	❍ Yes ❍ No
2. Did the distributor distribute a VFD feed that complies with the terms of the VFD?	❍ Yes ❍ No
3. Does the distributor keep copies of VFD orders for at least 2 years, if distributing VFD feed to the end user?	❍ Yes ❍ No ❍ N/A
4. Does the distributor keep receipt and distribution records of the VFD feed they distribute under the VFD for 2 years	❍ Yes ❍ No
5. 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?	❍ Yes ❍ No ❍ N/A

Reset Form

Section 3 – Complete ONLY for distributors who manufacture VFD feed

1. Compare the formulas, drug inventory records and labels for three feeds from the VFD orders with regard to:

	VFD Order #1	VFD Order #2	VFD Order #3
a. Does the feed label contain the VFD Caution statement?	❍ Yes ❍ No ❍ N/A	❍ Yes ❍ No ❍ N/A	❍ Yes ❍ No ❍ N/A
b. Do the drug inventory or production records show the correct amount of drug added?	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No
c. Do the labels and formulas match the VFD orders?	❍ Yes ❍ No	❍ Yes ❍ No	❍ Yes ❍ No

Section 4 – Complete ONLY for veterinarians

1.	Does the veterinarian have an active license in those states where the VFD feed authorized by the VFD order(s) is being fed?	❍ Yes ❍ No
a.	If No, can the veterinarian demonstrate 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?	❍ Yes ❍ No
2.	Is the veterinarian aware of the state or federal veterinarian client patient relationship (VCPR) requirements that apply to the state where they are issuing VFD order(s)?	❍ Yes ❍ No
a.	Does the veterinarian have any medical record(s) for the client named on the VFD?	❍ Yes ❍ No
3.	Does the veterinarian keep a copy of the VFD order(s) for at least 2 years?	❍ Yes ❍ No

Section 5 – Complete ONLY for clients

1.	Does the client keep copies of VFD orders for at least 2 years?	❍ Yes ❍ No
2.	Did the client feed the VFD feed to the authorized number of animals on the VFD order (number, species, production class)?	❍ Yes ❍ No ❍ N/A
3.	Did the client feed the VFD feed for the identified duration on the VFD order?	❍ Yes ❍ No ❍ N/A
4.	Did the client stop feeding the VFD feed prior to the expiration date on the VFD order?	❍ Yes ❍ No ❍ N/A
5.	Did the client follow the withdrawal period for the VFD feed, if any?	❍ Yes ❍ No ❍ N/A
6.	Did the client follow special instructions or caution statements on the VFD order, if any?	❍ Yes ❍ No ❍ N/A
7.	If a combination VFD feed was fed, was its use consistent with the affirmation statement on the VFD order?	❍ Yes ❍ No ❍ N/A
8.	Does the client have labels for VFD feeds?	❍ Yes ❍ No
	If Yes,	
a.	Does the feed label contain the VFD Caution statement?	❍ Yes ❍ No ❍ N/A
b.	Does the drug level and indication for use on the feed label match the drug level and indication for use on the VFD form?	❍ Yes ❍ No ❍ N/A
c.	Does the drug level and indication for use on the feed label match the drug's regulatory approval?	❍ Yes ❍ No ❍ N/A

Reset Form

NARRATIVE

Instructions on the next page →

Reset Form

INSTRUCTIONS – For the Lead Investigator

Completing Sections. Sections should be fully completed for each of the individuals or operation types indicated in the header of each Section. Failure to do so may cause this tool to be incomplete. Incomplete VFD Inspection Tools may require follow-up with the investigator and follow-up inspection at the operation.

Completing Questions. The VFD Inspection Tool instructions and flow of questions must be followed.

Narrative. Space is provided at the end of the form for narrative. During the investigation you may encounter issues which could require further explanation. For example, if a facility is no longer distributing VFD feeds, but they still maintain records, you may wish to explain this in this section.

INSPECTION TOOL QUESTIONS

VFD Operation information – Complete for ALL firms, regardless of the firm type.

VFD Operation Name. A VFD Operation is an individual or business involved in the manufacture, distribution, or use of VFD feeds. This includes veterinarians, distributors, and clients. Use the operation's accurate legal name. If the operation is run by a single individual and there is no business name, use the individual's full legal name. Do not use "Doing Business As" (DBA) operation names if at all possible.

Telephone Number. Enter the telephone number for the individual or business.

Physical Address of VFD Operation. The address should reflect the physical location of the firm's activities. Post Office Box numbers are unacceptable. If the firm's mailing address is different than their physical address, please make a note of this information.

Dates of Inspection. Enter the date for the start and end of the inspection specified on the inspection tool.

FEI Number. Enter the operation's Firm Establishment Identification number, if available.

DUNS Number. Enter the operation's Dun and Bradstreet (DUNS) number, if available.

Lead Investigator. Enter the name of the lead investigator.

FDA District Office. Enter the name of the FDA District in which the inspected VFD operation is located.

Name and Title of the Person(s) Interviewed. Record the name and title of the person(s) interviewed during the inspection.

Name and Title of Most Responsible Person at the Operation. Record the name and title of the most responsible person at the facility, for example the operation's President or Manager. This may or may not be the person interviewed during the inspection.

Operational Status. Mark the business's operational status. Inspection reports should be completed for Operational VFD operations. If not manufacturing/holding/distributing VFD feeds, please note their status in the **Narrative** section of this tool, but you do not need to fill the remainder of the tool. If Completely Out of Business, no more information gathering is required. Please follow reporting guidance identified in IOM 5.11- Reporting

Changes to Firm Name and Address. If the facility/site has a new name and/or address, please check the box indicating this and make sure the address recorded on the inspection tool is correct. Please record the VFD operation's former name and/or address somewhere in your inspection tool.

Section 1 - Complete for ALL firms, regardless of the firm type (with the exception of firms which are Out of Business).

Question 1. Who are you inspecting? Please understand the firm type categories provided and use these categories whenever applicable. A ***single VFD operation*** can be categorized as ***one or more VFD operation types***. If a veterinarian is also a VFD distributor, a trace-back inspection to the VFD feed manufacturer may not be necessary. Similarly, if a VFD distributor is also the client, a trace-forward inspection may not be necessary.

Question 2. Is this inspection a trace-forward or trace-back step from the VFD Order at the distributor or client (if conducted in the course of a violative drug residue inspection)? In the current work-plan most VFD inspections will have three parts – consisting of the inspection at the distributor, the client, and the veterinarian. We want to be able to relate the three parts to each other, and this is the primary purpose of the question. For example, if you identify a VFD order for trace-forward/trace-back inspection at a distributor, and then go out to the farm, or the veterinarian's office to conduct the inspection, please mark 'Yes' and identify the distributor to which the client and veterinarian relate. There are three roles in every VFD order – client, veterinarian and distributor, although in some cases a single party may play more than one role (for example, if the client also manufactures the feed, they may also be the distributor), but there will always be a distributor. Please copy the VFD operation's information exactly as it appears on the Veterinary Feed Directive Inspection Tool for the VFD operation where the inspection started.

Not every VFD inspection will involve the trace-forward/trace-back inspection. In these cases, simply mark 'No' and leave the space blank.

Definitions

Distributor who does not manufacture VFD feed: Any person who distributes a medicated feed containing a VFD drug to another person, but does not manufacture such feed. Such other person may be another distributor or the client-recipient of a VFD.

Distributor who manufactures VFD feed: Any person who manufactures and distributes a medicated feed containing a VFD drug to another person. Such other person may be another distributor or the client-recipient of a VFD.

Veterinarian: A person licensed to practice veterinary medicine in the state in which the VFD is being issued.

Client: The person responsible for the care and feeding of the animals receiving the VFD feed. This person may be the owner of the animals or other caretaker.

Question 3. If the location has VFD orders on hand, please review up to three random VFD orders. For each of the items listed in **Question 3 and** for each VFD order collected, answer **Yes** or **No.** As described in 21 CFR 558.6(b)(3), VFD orders must include certain information in order to be lawful. When performing a trace-forward or trace-back inspection, use the VFD order that led to the trace as VFD Order #1.

Question 3.f.● What is the name of the VFD drug or drugs? Enter the name of the drug or drugs on each VFD order in the spaces provided.

Question 3.g. ● What is the species and/or production class? Enter the species and/or production class on each VFD order in the spaces provided. Examples include: dairy cows, nursery pigs, broiler chickens. For more examples and definitions, see GFI #191, Appendix III.

Definition for part n.

Affirmation of intent for combination VFD drugs: The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or may expand such authorization to allow the use of the cited VFD drug(s) along with one or more over-the-counter (OTC) animal drugs in an approved, conditionally approved, or indexed combination VFD drug. The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

1. "This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs."
2. "This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component." [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]
3. "This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component."

Section 2 – Complete for ALL distributors of VFD feeds

Question 1. Did the distributor notify FDA of the intent to distribute VFD feeds? Mark **"Yes"** or **"No"**. A distributor of VFD feeds is required to submit to FDA a one-time notification of its intent to distribute VFD feeds. VFD distributors must also submit to FDA an updated notification within 30 days of any change in ownership, business name, or business address. A current listing of VFD distributors that have notified FDA of their intent to distribute VFD Feeds can be found at: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm. Please verify that the operation is listed and that all information is correct and up-to-date.

Question 2. Did the distributor distribute a VFD feed that complies with the terms of the VFD? Mark **"Yes"** or **"No"**. Distributors of VFD feeds are permitted to distribute an animal feed containing a VFD drug or combination VFD drug only if it 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 drug.

Question 3. Does the distributor keep copies of VFD orders for at least 2 years, if distributing VFD feed to the end user? Mark **"Yes"**, **"No",** or **"N/A"**. Distributors of VFD feeds are required to keep copies of VFD orders for 2 years, if distributing VFD feed to the end user. If the distributor has not distributed VFD feeds older than 2 years, but has maintained all copies of VFD orders at the time of the inspection, this should be classified as a "Yes".

Question 4. Does the distributor keep receipt and distribution records of the VFD feed they distribute under the VFD for 2 years. Mark **"Yes"** or **"No"**. The distributor must keep records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years. If the distributor has not distributed VFD feeds older than 2 years, but has maintained all receipt and distribution records of VFD feeds at the time of the inspection this should be classified as a "Yes".

Question 5. 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? Mark **"Yes"**, **"No"**, or **"N/A"**. When a distributor ships an animal feed containing a VFD drug to another distributor in the absence of a valid VFD order, the original distributor must provide an "acknowledgement letter". Acknowledgement letters are a written (nonverbal) communication and must affirm the following:

1. That the distributor will not ship such VFD Feed to an animal production facility that does not have a VFD.
2. That the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgement letter
3. That the distributor has complied with the distributor notification requirements in 21 CFR 558.6(c)(5)

If the distributor has not distributed VFD feeds older than 2 years, but has maintained all copies of acknowledgement letters at the time of the inspection, this should be classified as a "Yes".

Section 3 – Complete **ONLY** for VFD distributors who manufacture VFD feed

Question 1. Compare the formulas, drug inventory records and labels for three feeds from the VFD orders with regard to:

Question 1a. Does the VFD feed label contain the VFD Caution Statement? Mark **"Yes"**, **"No"**, or **"N/A"** for each VFD Order sampled above. Verify that VFD feed labels contain the following 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."

Question 1b. Do the drug inventory or production records show the correct amount of drug added? Mark **"Yes"** or **"No"** for each VFD Order sampled above. Verify that the amount of drug used shown in the drug inventory corresponds with the amount of drug for the VFD order.

Question 1c. Do the labels and formulas match the VFD orders? Mark **"Yes"** or **"No"** for each VFD Order sampled above. Verify that information on the feed labels and in the manufacturing formulas correspond with the VFD orders.

Section 4 – Complete **ONLY** for veterinarians. In addition to completing VFD orders fully and accurately, the veterinarian has additional responsibilities that must be fulfilled in order for a VFD to be lawful.

Question 1. Does the veterinarian have an active license in those states where the VFD feed authorized by the VFD order(s) is being fed? Mark **"Yes"** or **"No"**. Verify active licensure in the state in which the VFD order is being fed. You may verify licensure by an online search of the State's Licensing Board for Veterinary Medicine, where available. If you are unable to determine licensure, please elaborate why in the narrative section.

Question 1a. If No, can the veterinarian demonstrate 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? Mark **"Yes"** or **"No"**. Some states allow veterinarians licensed in other states to provide certain services across state lines. Ask the veterinarian to show documentation of reciprocity agreements between the states' licensing boards or other documentation demonstrating compliance with licensing and practice requirements in the states in which a license is not required. This is uncommon. If you believe this applies, and you have questions, please contact CVM.

Question 2. Is the veterinarian aware of the state and federal veterinarian client patient relationship (VCPR) requirements that apply to the state where they are issuing VFD order(s)? Mark **"Yes"** or **"No"**. The veterinarian must issue the VFD within the context of a VCPR as defined by the State. If applicable VCPR requirements as defined by such State do not include the key elements of a valid VCPR as defined in FDA's regulations at 21 CFR 530.3(i), the veterinarian must issue the VFD in the context of a valid VCPR as defined in 21 CFR 530.3(i). FDA will consider states with VCPR definitions that at least address the following concepts:

1. The veterinarian engages 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 and/or visits to the facility where the patient is managed,
3. The veterinarian provides for any necessary follow-up evaluation or care to include the key elements of the federally-defined VCPR as set forth in 21 CFR 530.3(i)

Question 2a. Does the veterinarian have any medical record(s) for the client named on the VFD? Mark **"Yes"** or **"No"**. Medical records serve as evidence of a VCPR. Verify that medical records are established for the client feeding VFD feed.

Question 3. Does the veterinarian keep a copy of the VFD order(s) for at least 2 years? Mark **"Yes"** or **"No"**. The veterinarian must retain the original VFD in its original format for 2 years. If the veterinarian has not issued VFD orders older than 2 years, but has maintained all copies of VFD orders at the time of the inspection, this should be classified as a "Yes".

Section 5 – Complete **ONLY** for clients.

Question 1. Does the client keep copies of VFD orders for at least 2 years? Mark **"Yes"** or **"No"**. The client is required to keep copies of VFD order for 2 years and provide such copies for inspection by FDA upon request. If the client has not received VFD orders older than 2 years, but has maintained all copies of VFD orders at the time of the inspection, this should be classified as a "Yes".

Question 2. Did the client feed the VFD feed to the authorized number of animals on the VFD order? Mark **"Yes"**, **"No"**, or **"N/A"**. Client recipients of an animal feed containing a VFD drug must only feed the VFD feed to the authorized number of animals on the VFD order.

Question 3. Did the client feed the VFD feed for the identified duration on the VFD order? Mark **"Yes"**, **"No"**, or **"N/A"**. Client recipients of an animal feed containing a VFD drug must only feed the VFD feed for the identified duration on the VFD order.

Question 4. Did the client stop feeding the VFD feed prior to the expiration date on the VFD order? Mark **"Yes"**, **"No"**, or **"N/A"**. Client recipients of an animal feed containing a VFD drug must only feed the VFD feed prior to the expiration date on the VFD order.

Question 5. Did the client follow the withdrawal period for the VFD feed, if any? Mark **"Yes"**, **"No"**, or **"N/A"**. The withdrawal period before slaughter must be followed.

Question 6. Did the client follow special instructions or caution statements on the VFD order, if any? Mark **"Yes"**, **"No"**, or **"N/A"**. Client recipients of an animal feed containing a VFD drug must only feed the VFD feed in accordance with the VFD order.

Question 7. If a combination VFD feed was fed, was its use consistent with the affirmation statement on the VFD order? Mark **"Yes"**, **"No"**, or **"N/A"**. The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the affirmation statements as described in the instructions for Section 1, Question 3, Part n. Client recipients of an animal feed containing a VFD drug must only feed the VFD feed in accordance with this affirmation statement.

Question 8. Does the client have labels for VFD feeds. Mark **"Yes"** or **"No"**. If the client has labels for VFD feeds on hand, answer the questions below for one of the labels.

Question 8a. Does the feed label contain the VFD Caution statement? Mark **"Yes"**, **"No"**, or **"N/A"**. Verify that VFD feed label contains the following 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."

Question 8b. Does the drug level and indication for use on the feed label match the drug level and indication for use on the VFD form? Mark **"Yes"**, **"No"**, or **"N/A"**. Verify that the drug concentrations and indication for use on the VFD order correspond with the label drug concentration.

Question 8c. Does the drug level and indication for use on the feed label match the drug's regulatory approval? Mark **"Yes"**, **"No"**, or **"N/A"**. Use and labeling of a VFD drug or combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. 21 CFR 558 Subpart B lists the specific new animal drugs for use in animal feeds along with the approved concentration ranges, indications for use, and limitations, and combinations.