Veterinary Feed Directive Questions and Answers

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Photo courtesy of Troy Walz.

KEY POINTS: **When the VFD regulations go into effect, they will ONLY apply to antibiotics used in the feed!** They will not affect other feed-use medications such as ionophores, coccidia, other parasite and insect control drugs, or reproductive control medications. VFD regulations will not apply to antibiotics used by injection, tablet, bolus, or water.

Why has the FDA developed the Veterinary Feed Directive (VFD)?

The driving force is the concern for antibiotic resistance associated with daily antibiotic use in animal feeds. Over a decade ago the decision was made to move toward removing all antibiotic use in livestock that was associated with growth and/or feed efficiency or long-term use (over 21 consecutive days that allowed extended time for bacteria to develop resistance). The VFD concept became the option for allowing vital feed antibiotic use in livestock for protection of their health and well-being. Antibiotics approved for use under the VFD regulations will be for "prevention", "treatment", and/or "control" of specific bacterial diseases.

What is the VFD regulation target?

Antibiotics used in livestock feed and minerals will be the ONLY drugs affected, ***and then*** only the antibiotics considered "Medically Important to Humans". Ionophores are antibiotics NOT important to humans and will not be affected. Additionally no other drugs such as parasite control, insect control, or reproduction control feed additives will be affected.

What exactly is meant by drug use for "prevention", "treatment", or "control" in the VFD regulation?

- "Prevention of Disease" with a VFD can be approved when a known disease risk is present and the VFD antibiotic can be administered to prevent animal infections. None of the animals in the group are exhibiting clinical signs of disease but where the disease is likely to occur if the drug is not administered.
- "Treatment of Disease" with a VFD antibiotic can be approved when animals are exhibiting disease signs.
- "Control of Disease" with a VFD antibiotic can be approved to decrease the spread of disease when a percentage of the animals in the group have exhibited disease signs and the clinically sick are being individually treated.

What is a Veterinary Feed Directive?

A Veterinary Feed Directive (VFD) is a written order (paper or electronic) by a licensed veterinarian in the course of their practice approving the use of a VFD medication. The difference between a VFD and a Veterinary Prescription is a VFD isn't governed by a state's "Board of Pharmacy" which simplifies the inventory control, dispensing, and required records. VFD regulations do not apply to injectable antibiotics.

What does it mean for veterinarians?

Veterinarians will become responsible for all feed use of antibiotics considered by the FDA as medically important to humans. The following bullet list outlines many of the specific tasks that will be required of licensed veterinarians to issue a VFD for a cattle farm or ranch client.

- Veterinarians must be licensed in the state in which the cattle reside.
- Must have a proper VCPR (Veterinary Client Patient Relationship) with the cattle operation.
- Must prepare and sign the VFD supplying all the required information.
- The VFD they authorize must comply with all conditions of approved use.

- Must include required information if the VFD drug is to be used in combination with other VFD drugs.
- Must restrict or allow the VFD drug in combination with one or more approved Over-The-Counter (OTC) feed medication.
- Must assign the approved VFD expiration date and the "drug withdrawal time" following approved duration of the VFD use.
- Can indicate if a "generic" VFD drug can be substituted for the "pioneer" VFD drug.
- Must develop a mixer "flushing" or "clean-out" protocol to prevent a VFD drug from contaminating subsequent mixed feeds.
- Must provide the feed distributor or mill (if other than "on-farm" mixing) a copy of the VFD, which can be transmitted by fax, email, or electronic; however, the distributor must receive a hard copy of the "VFD order" from the vet within 5 working days.
- Must provide the client (cattle operation) a copy of the VFD. If the "client" is also the "mill" they also receive the "mill" copy.
- Must keep original VFD for two years (Two-year retention is also required for the client and feed distributor copies).
- Must provide VFD orders for inspection and copying by the FDA upon request.
- Some VFD medication will allow disease diagnosing by trained non-veterinary cattle care takers.
    - For VFD medications that allow this, the veterinarian must develop training for the non-veterinary care takers, provide documented training, and have a copy of the training outline or materials on file in the cattle operations office.

What does it mean for cattle producers?

Cattle producers must have a relationship with a licensed veterinarian. The FDA and the state's agency regulating "Veterinary Licensure" specifically define this relationship in their regulations as a "Veterinary Client Patient Relationship" (VCPR). It requires the licensed veterinarian writing the VFD to:

1. be familiar with the care and management cattle receive by a client including being able to make a preliminary diagnosis of the targeted concern,
2. be willing to assume responsibility for making clinical judgements and the client agrees to follow the veterinarian's instructions,
3. be willing to provide treatment oversight and will be readily available for follow-up evaluation and case management, and
4. be willing to maintain and evaluate case and treatment records.

Cattle producers will find obtaining VFD antibiotics simpler and less frustrating if they will visit with their veterinarian ahead of the need for the feed antibiotic.

- Let your vet know about upcoming cattle management issues that may require a feed use antibiotic. Examples might include weaning, anticipated cattle purchases, or a seasonal endemic disease such as Anaplasmosis.
- Visit with your vet about how a VFD medication will be obtained on a timely basis through your feed distributor.
- In your conversation be sure to discuss other feed additives you typically use and ask about specific limitations that will have to be considered when a VFD medication is used.

Cattle producers considering a VFD medication might find it useful to visit with their feed distributor about the details to be considered when obtaining the VFD medication from their distributorship.

What information will the cattle owner or manager be required to provide on the VFD form?

The VFD form requires the veterinarian's client's name, address, phone number, location of the cattle, the approximate weight of the cattle, and the number of cattle that will be covered under the VFD.

What records will cattle owners and managers be required to keep?

- A copy of the signed VFD received from your veterinarian must be kept for two years.

- VFD medication use records, which includes feed mixing records, must be kept and be made available to the FDA if requested.
- No FDA inspectors will come to the cattle operation using a VFD unless they are using the most concentrated VFD product available and the VFD requires a withdrawal time. The most concentrated FDA approved feed additive is known as a "Type A Article" drug and it is classified as a "Category 2" drug if a withdrawal time is required.

Will a cattle owner or manager have to see a veterinarian to get a VFD?

Not necessarily. If the cattle owner or manager has a VCPR with a veterinarian, together they can develop outlines for situations when VFD medication use would be appropriate. Using these outlines VFD usage can be anticipated and in many situations the VFD medication can be available as required to address the health and well-being of the cattle without the veterinarian personally evaluating the cattle. For example, a veterinarian can develop guidelines and training for tentatively diagnosing a disease listed on the approved VFD medication and documentation of the trained personnel will allow the use of the VFD medication without the cattle being personally evaluated by their veterinarian.

Will one VFD cover cattle owned by one person in different pastures?

Yes, a VFD can be written to cover the same health condition in cattle owned or managed by the same operation if the cattle are in multiple locations, including across county lines. However, some VFD antibiotics will have labeling inclusions similar to "Use only in cattle fed in confinement for slaughter" and/or "fed in a complete feed" and/or "included in the sole ration". If these types of statements are included on the label, use in pasture situations would not be allowed by the FDA.

Will a VFD antibiotic be allowed to be used in breeding cattle?

It will depend on the approved label. Some VFD antibiotics will have not been studied in breeding cattle or replacement heifers/bulls and will not be labeled to feed breeding cattle. There currently is a feed-grade antibiotic approved for controlling anaplasmosis. The current labeling allows its use in breeding beef cattle. If the company that controls this antibiotic applies for VFD approval there is no reason to think restrictions on its use in breeding cattle would be added.

Will one VFD cover cattle owned by one person in different states?

No, a separate VFD will be required. Additionally, the veterinarian that writes the VFD is required to be licensed to practice in the state where the cattle are being kept when the VFD antibiotic is being used on those cattle.

What flexibility will cattle producers have in how they dose a VFD medication?

Simple answer is NONE! Regulations governing feed medications have NEVER allowed usage other than as labeled! "Off label Use" or "Extra Label" has never been allowed and this legal requirement will continue with the use of VFD medications. For cattle producers that also have sheep and/or goats, the FDA will not allow a VFD written for cattle to be used for sheep and/or goats.

Will a VFD antibiotic be allowed for pink-eye or foot-rot?

Pink-Eye and/or Foot-Rot "prevention", "treatment", and/or "control" are not listed on the labels of any of the feed-grade antibiotics currently approved and therefore use for these diseases is not allowed by the FDA. Use for these diseases may or may not be allowed in the future depending on the approval requests by companies applying for VFD approval for their feed grade antibiotic and the FDA's ruling on those requests.

What flexibility will be available for mixing a VFD medication?

The cattle operation will have the same flexibility for how the VFD is mixed in a complete feed as has been available previously for use of FDA-approved feed additives. Restrictions on which FDA additives can be used together and how much of an additive

can be added per ton of feed have long existed and these restrictions will continue with VFD regulation implementation in December 2016.

Will special procedures or mixers be required to use a VFD medication?

An issue often overlooked by producers that practice on-farm feed mixing is cross contamination of feeds with FDA-approved feed additives. A procedure to "flush-out" a feed mixer after using a VFD will need to be developed. Their veterinarian, nutritionist, or extension educator can assist with developing a flush-out procedure. Typically this involves running a small amount of a coarse feedstuff through the feed mixer after a VFD medication has been mixed. The feedstuff used to clean or "flush-out" the feed mixer can be used in the ration for the cattle receiving the VFD on the following day.

Will VFD antibiotics have a marketing withdrawal time?

It will depend on the specific VFD antibiotic being considered. The VFD tilmicosin (Pulmotil) currently approved by the FDA has a 28-day withdrawal time. There are a number of antibiotics the FDA currently approves for disease prevention, treatment, or control that do not require a withdrawal time and there is no reason to think the FDA will add withdrawal times to medications for which a withdrawal is not currently required.

How long does a VFD remain in effect after it is written by my veterinarian?

VFD orders will have both an "Effective Date" and an "Expiration Date". The "Effective Date" is not necessarily the date your veterinarian signs the VFD order. On the VFD order a veterinarian is required to indicate an "Effective Date" and the VFD antibiotic for which the order is written will have a "VFD order Expiration Date" requirement. The VFD antibiotic cannot be fed after the end of the "Expiration Date".

Will the length of time from the "VFD order Effective Date" to the "VFD order Expiration Date" be the same for all VFD antibiotics?

The FDA has indicated the expiration date could vary between the different VFD antibiotics approved. If the VFD antibiotic does not explicitly indicate the length of time for an order to expire, the VFD regulations require the veterinarian to limit the VFD order expiration date to 180 days or less. Pulmotil, the only VFD the FDA has currently approved, expires 45 days after the date the veterinarian indicates as the "effective date". The effective date will be the last day the use of a VFD antibiotic can be used. For example, if the VFD antibiotic intended for use has a 45-day expiration time and the course of therapy is 14 days, the last day a course therapy can begin is day 31 of the 45-day window between the 'Effective Date" and the "Expiration Date".

When does this regulation take effect?

It went into effect June 3, 2015. Currently, feed manufactures are revising medicated feed labels to remove all feeding performance statements. These labels will read for use to treat, control, or prevent a disease. The first of these revised labels will be available January 1, 2016. Labeling transition will continue to January 1, 2017 when all feed-grade antibiotic will require a valid VFD.

What products require a VFD?

All feed-use antibiotics that the FDA, World Health Organization, and Center for Disease Control (CDC) consider "medically important to humans". Currently, the FDA has approved one VFD antibiotic, tilmicosin (Pulmotil), for use in cattle feed to control Bovine Respiratory Disease (BRD).

Medically important antibiotics currently being used in cattle feeds that have label indications for prevention, treatment, and/or control of specific bacterial disease as required by the VFD regulations, but that will require new approvals by the FDA to continue the feed antibiotic use when the VFD regulation becomes effective in December 2016 include the following.

- Chlortetracycline (Aureomycin, CLTC, Pennchlor)
- Chlortetracycline + Sulfamethazine (Aureo S 700)
- Neomycin + Oxytetracycline (Neo-Terramycin, Neo-Oxy)
- Oxytetracycline (Terramycin, Pennox)
- Tylosin (Tylan)
- Virginiamycin (V-Max)

What products don't require a VFD?

VFD regulations focus on "Medically Important Antibiotics" as these represent the only medication type that has been identified that the use in livestock feed could potentially jeopardize the drug's effectiveness in humans. Therefore medications used to control parasites, reproduction, bloat, etc. will not require a VFD. These include:

- amprolium (Corid),
- bacitracin (Albac, BMD),
- bambermycin (Gainpro),
- decoquinate (Deccox),
- fenbendazole (Safe-Guard),
- laidlomycin (Cattlyst),
- lasalocid (Bovatec),
- melengestrol acetate (MGA),
- methoprene (Altosid),
- monensin (Rumensin),
- morantel (Rumatel),
- poloxalene (Bloat Guard),
- ractopamine (Optaflexx, Actogain), and
- tetraclovinphos (Rabon).

Can a VFD medication be used in a feed that contains other FDA-approved feed additives?

Yes, provided the FDA has approved the medications to be used together in the same feed. For decades the FDA has approved combination use of monensin (Rumensin), tylosin (Tylan), and melegestrol (MGA) in the same feed. Tilmicosin (Pulmotil), the only VFD antibiotic currently approved by the FDA, is approved for combination use with monensin. There is no reason to think the FDA will not continue to approve combination use of VFD medications approved in the future with other FDA-approved feed medications.

Examples

Below are two examples for the use of the currently approved VFD, which we will refer to as "T-antibiotic"

EXAMPLE: Newly weaned calves

Cattle producer contacts their vet about newly weaned calves that are developing pneumonia and indicates that at least 10% are showing the DART signs (depression, loss of appetite, respiratory movement changes, and an elevated temperature). These were signs they and their vet had previously discussed as keys to early diagnosis of pneumonia.

Vet writes a VFD using the form provided for "T-antibiotic".

- The form includes the name, address, and phone number of both the cattle owner and the veterinarian.
- The location of the cattle is noted on the form.

- The form also indicates how many cattle are to be covered by the VFD and their approximate weights.
- The amount of VFD medication that will be needed is calculated and recorded on the form (not required in the final rule).
- A note is included if the VFD drug is to be used in combination with another drug as approved by the FDA.
- The "effective date" of the VFD and the "expiration date" as calculated from the effective (start) date is listed.
- The required withdrawal time is recorded on the VFD form.
- The veterinarian signs the form and provides a copy for both the cattle producer and for the feed distributor that will provide the VFD medication.

For this example the VFD for "T-antibiotic" has a 45-day "expiration date" calculated from the "VFD effective date" listed on the VFD form by the veterinarian. This means that the VFD therapy must be initiated within the 45-day window from the "VFD effective date" to the "VFD expiration date" … BUT that allows for a complete therapeutic cycle to be completed.

- The VFD approved "T-antibiotic" will be fed to 100 calves that average 500 lbs.
- The VFD for "T-antibiotic" requires that at least 10% of the cattle in the group are exhibiting signs of pneumonia.
- The VFD "T-antibiotic" is fed for 14 continuous days and a 28-day withdrawal is assigned at the end of the 14-day treatment.
- To meet the 45-day VFD expiration window, the "T-antibiotic" must be started no later than 31 days from the VFD effective date. (45-day window – 14 therapy cycle = 31-day window to start a therapy cycle).

Three concentrations of "T-antibiotic" are available for on-farm mixing. For this example a "Type B Article" 5.68 gm/lb product will be used. This is especially convenient for this example as the dose is 5.68 mg/lb of calf. Therefore, each pound of 5.68 gm/lb Type B product will medicate two 500lb calves each day during the 14-day treatment. The total amount of Type B product to be used for the 100 calves weighing 500 lbs for the entire 14-day treatment will be 700 lbs.

- The ration being fed to the calves is 75% dry matter (DM).
- "T-antibiotic" has a few use restrictions that must be followed. They are:
  - Cattle in the group that are exhibiting clinical signs of pneumonia should be removed for individual treatment.
  - An injectable antibiotic in the same macrolide class cannot be used in conjunction with or prior to the use of the "T-antibiotic".
  - The "T-antibiotic" must be used in a complete feed which means no other feed or feedstuff can be offered.
  - Cattle must receive between 1.5% and 2.0% of their body weight of the complete feed on a dry matter basis (DMB).
  - No other feed can be offered while feeding the VFD medicated feed (no extra hay or lick tubes).
  - The feed mixer used to prepare the complete feed should be "flushed-out" before being used to mix feed not containing the tilmicosin.
- Between 1000 As-Fed lbs to 1333 As-Fed lbs of the 75% DM complete ration will meet the 1.5% to 2.0% daily intake restriction for the 100, 5 CWT calves required by the VFD for "T-antibiotic".
- The amount of the "T-antibiotic" 5.68 gm/lb of the Type B product used daily for the 100, 5 CWT calves will be 50 lbs. This amount will be added to the 1000 to 1333 lbs of As-Fed daily feed delivery.

EXAMPLE: Feeder planning on purchasing several loads of high-risk calves in the next month

A vet's client, John Doe is planning to buy 10, 100-head loads of 5 CWT high-risk calves starting the first of next month (e.g., Aug 1) with the last load coming in during the next four weeks.

Vet needs to contact the VFD medication supplier (e.g., feed store) to let them know John Doe will be using a VFD medication and what concentration of the medication they want to use. It may take the supplier 1 to 2 weeks to get the medication in stock.

John Doe's vet (licensed in the state where the cattle will reside AND as a VCPR) can write a VFD for "T-antibiotic" and as a "Special Instruction" indicate the "VFD to begin Aug 1, 2015".

- The expiration date for "T-antibiotic" is labeled as 45 days. Therefore in this example the VFD usage window will be from Aug 1st to Sep 14th. WHICH MEANS, all feeding of "T-antibiotic" on this VFD must stop at midnight Sep 14th.
- "T-antibiotic" has a 14-day feeding cycle. Therefore all groups for cattle identified to receive "T-antibiotic" must be started on a treatment cycle by Aug 31st.
- If there is any delay in receiving the anticipated 10 loads of cattle, a second VFD will need to be written to extend the potential treatment past the expiration of the original VFD (Sep 14th).
- The dose of "T-antibiotic" is 5.68 mg/lb per day. "T-antibiotic" is available in a 5.68 gm/lb pellet. Therefore the dose would be 1 lb of these pellets per 1,000 lbs of cattle being treated.
- "T-antibiotic" has a couple of important feeding restrictions:
  - Must be fed to cattle consuming feed between 1.5% and 2.0% of the body wt. on a DMB.
  - No other feedstuff can be offered … not extra hay, lick tubes, etc.
- The total amount of "T-antibiotic" that will be needed for a group of 100, 5 CWT calves will be:
  - 1 pound of pellets to treat 1,000 lbs of cattle per day.
  - 5 CWT x 100 head = 50,000 lbs. … 50,000 lbs / 1000 lbs = 50 lbs of pellets / day.
  - 50 lbs of pellets x 14 days in therapy cycle = 700 lbs of "T-antibiotic" pellet (5.68g/lb).
- The total amount of feed that is 65% dry matter (DM) fed to a group of 100 cattle weighing 5 CWT would be calculated as follows.
  - Feed intake can range between 1.5% to 2.0% of BW on a DMB.
    - At 1.5% BW (DMB) = 500 x 1.5% = 7.5 lbs (DMB) daily feed.
      - 7.5 lbs / 65% = 11.5 lbs As Fed (AF) feed per day
      - 11.5 lbs daily x 14 days = 161 lbs AF / head x 100 head = 16,100 lbs AF feed
    - At 2.0% BW (DMB) = 500 x 2.0% = 10 lbs (DMB) daily feed.
      - 10 lbs / 65% = 15.4 lbs As Fed (AF) feed per day
      - 15.4 lbs daily x 14 days = 216 lbs AF / head x 100 head = 21,600 lb AF feed

Both the total amount of VFD medication to be used and the total amount of feed it will be mixed with must be recorded on the VFD form.

All parties (vet, VFD medication suppler, and producer) must have a copy of the completed VFD form. These copies must be retained for two years.

The VFD medication supplier (feed mill) must have a copy before the medication can leave their premise. It can be a fax or email copy, BUT, a hard copy must be provided to the VFD medication supplier within 5 working days!

- Note: if the VFD supplier is new to working with VFD medications, they must notify the FDA of their intent to distribute VFD medications. This is a "one-time" notification. Once the notification has been submitted the supplier will not have to repeat the process, even if a new VFD product becomes available for them to distribute.

Example of a form for notifying the FDA

- Notice to FDA of Distribution of VFD Feeds

I/We hereby notify the Food & Drug Administration the I/we have begun distributing VFD feeds.

Please Print or Type the following information:	
Name of Responsible Party	
Name of Firm or Individual	
Business Address"	
Site Address if different than the Business Address"	
City/State/Zip	
Signature of Responsible Party	
Date	

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http://beef.unl.edu/veterinary-feed-directive-questions-and-answers