# FAQ: FDA Veterinary Feed Directive Regulation

#### Rev. 1-26-2016

# In this document, you will find a list of potential questions you will receive from producers. Standard answers have been given to create consistent and factual messaging. This list is not static, we intend to add questions and answers with your input.

#### Q: What is a VFD drug?

A: A VFD drug is a drug intended for use in or on animal feed that is limited to use under the supervision of a licensed veterinarian.

### Q: What is a VFD Order?

**A:** A Veterinary Feed Directive Order (VFD) is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that authorizes the use of a VFD drug in or on an animal feed. The VFD authorizes the client-recipient (producer) to obtain and use animal feed containing a VFD drug.

### Q: Can you provide a quick overview?

**A:** The FDA has taken important steps toward fundamental change in how medically important antibiotics can be legally used in feed or water for food-producing animals. The agency is moving to eliminate the use of such drugs for production purposes (i.e., growth promotion & feed efficiency) and bring their remaining therapeutic uses in feed & water under the supervision of licensed veterinarians – changes that are critical to ensure these drugs are used judiciously and only when appropriate for specific animal health purposes. This rule is an important part of the agency's overall strategy to ensure the judicious use of medically important antimicrobials in food-producing animals.

### Q: What does judicious use mean?

**A:** The dictionary definition of judicious is: Having, showing, or done with good judgment or sense. As it pertains to this regulation, the FDA believes it is important that these medically important drugs (important for treating human disease) to be used under the guidance of a licensed veterinarian for appropriately targeted animals at risk for a specific disease and that they be used for a limited duration.

### Q: When will I need a VFD to order these medicated feeds?

**A:** VFD's are currently required for Tilmicosin and Florfenicol. A Veterinary Feed Directive will be required for the expanded list of antimicrobial drugs included in animal feed beginning 1/1/17.

### Q: What is the objective?

**A:** To include veterinarians in decision-making process. Two key principles: Limit use of medically important antimicrobial drugs to those uses considered necessary for assuring animal health (i.e., therapeutic purposes) and to increase veterinary involvement/consultation.

# Q: What are the responsibilities of the producers?

A: There are three important facts that producers should be concerned with:

- 1. Animal feed containing a VFD drug must be fed according to a VFD issued by a licensed veterinarian
- 2. Do not feed a VFD feed after the expiration date on the VFD
- 3. Provide a copy of the VFD order to the distributor of the VFD animal feed
- 4. Maintain all VFD records for 2 years

# Q: As a producer, what should I be doing right now?

A: You should make it a top priority to develop a relationship with your local veterinarian.

# Q: What is the definition of a vet/client relationship?

**A:** According to the AVMA, a Veterinarian-Client Relationship, or VCR for short, exists when your veterinarian knows your animal well enough to be able to diagnose and treat any medical conditions it develops. In other words, there won't be a 1-800-VFD-LINE.

#### Q: What is a distributor?

A: Anyone who distributes a feed containing a VFD drug to another person—may be another distributor or the client-recipient of the VFD.

#### Q: How are distributors defined?

A:

- On-farm mixers that only manufacture medicated feeds for use in their own animals are not distributors
- On-farm mixers must only be manufacturing VFD feed for their use in their own animals on their own farm, meaning that the
  ownership of the feed mill, the animals and the animal production facility must be the same and the on-farm mixer must be the
  person using the VFD feed
- If an on-farm mixer distributes to another producer, that mixer will be considered a distributor
- If a producer wishes to receive a VFD feed without a VFD in hand, they must follow the notifications required for a distributor and they may not feed the VFD feed without a valid VFD in hand

# Q: How does this affect water meds?

A: Medically important water soluble/concentrates will be converted to RX prescription by Dec. 2016. This is different than a VFD.

#### Q: What is the handling process for a VFD?

**A:** VFD orders may be handwritten or sent electronically. . While electronic formats are allowed, the 21 CRF Part 11 storage requirements must be met. The process of electronic or paper submission is still being determined and will be communicated to you.

#### Q: How about label claims, will they be eliminated?

A: Yes. Production label claims (Growth promotion/feed efficiency) will no longer be allowed beginning January 1, 2017.

Q: Can you show me an example of a VFD so I can see what information is needed?

VFD example	Veterinary Feed Directive					
	Veterinarian:	Client:				
	Address:	Address:				
		Phone:				
	Fax or email (optional):	Fax or email (optional):				
	Drug(s)Name:	Drug(s) Level: g/ton Duration of use:				
	Species and Production class: Number of reorders (refills) authorized (if permitted by the drug approval):					
	Indications for use (as approved):					
	Caution (related to this medicated feed, if any):					
	<u>USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS</u> DIRECTED ON THE LABELING (EXTRALABEL USE) IS NOT PERMITTED					
	VFD Date of Issuance:	(Month/Day/Year) VFD Expiration Date:(Month/Day/Year) (As specified in the approval: sannot exceed 6 months after (ssannor)				
	Approximate Number of Animals:					
	Premises:					
				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.		
				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:		
				Drug(s)	Drug Level(s) and any Special Instructions	
	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.					
		Withdrawal Time (r any: This VFD Feed must - be withdrawndays prior to slaughter				
	Veterinarian's Signature					

#### Q: What are the affected drugs?

Apramycin (not marketed)	Oleandomycin (not marketed)		
Avilamycin (new)	Oxytetracycline		
Chlortetracycline	Penicillin (approval withdrawn)		
Erythromycin (not marketed)	Sulfamethazine (not marketed alone)		
Florfenicol (already VFD)	Sulfadimethoxine/Ormetoprim		
Hygromycin B	Sulfamerazine (not marketed)		
Lincomycin	Tilmicosin (already VFD)		
Neomycin (not marketed alone) Tylosin			
	Virginiamycin		

A: List of the affected drugs in which Purina handles today:

The combinations below will no longer be manufactured/marketed:

- Chlortetracycline/Penicillin/Sulfathiazole
- Chlortetracycline/Penicillin/Sulfamethazine
- Penicillin(expect drug sponsor to discontinue)
- Any other drug in combination with a VFD drug will require a VFD order

#### Q: Why these drugs?

**A:** These drugs have been deemed medically-important for human use. All uses of antimicrobial drugs, in both humans and animals, contribute to the development of antimicrobial resistance, it is important to use these drugs only when medically necessary.

#### Q: Will a VFD cost me money?

**A:** Early indication from veterinarians is that for a "call" to write a VFD, many will charge. A range of \$25-\$50 per call has been discussed, though not confirmed.

More information regarding the VFD Regulation will be posted on the Purina® Business Link Portal in the near future.