

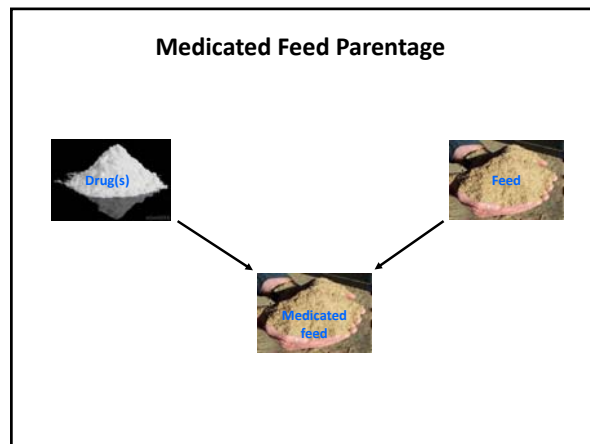
FDA U.S. Food and Drug Administration  
 CENTER FOR VETERINARY MEDICINE

## Veterinary Feed Directive (Introduction)

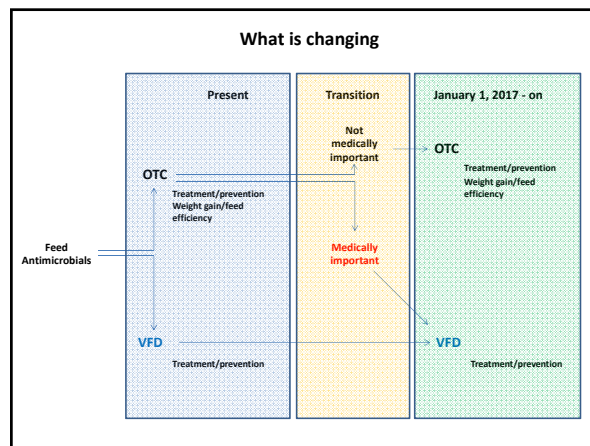
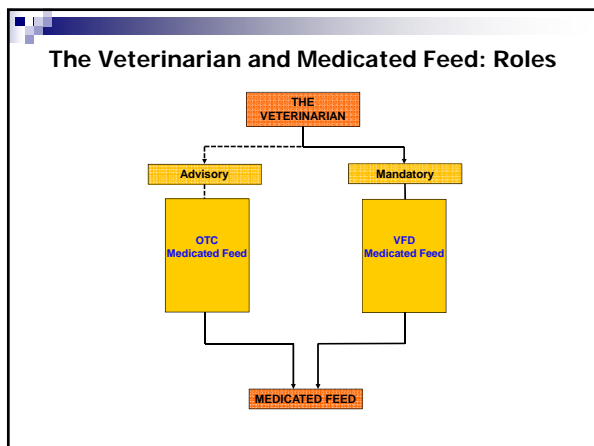
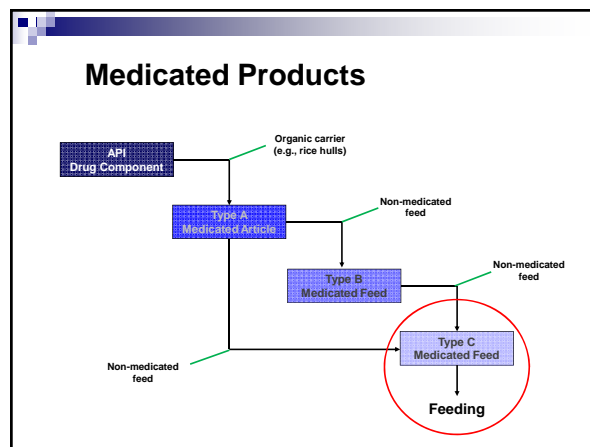


Dragan Momcilovic DVM, PhD, DACT  
 Veterinary Medical Officer  
 Center for Veterinary Medicine (CVM)  
 U.S. Food and Drug Administration (FDA)

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- ### Medicated Products
- Type A medicated article
  - Type B medicated feed
  - Type C medicated feed



FDA U.S. Food and Drug Administration  
 CENTER FOR VETERINARY MEDICINE

# Veterinary Feed Directive (regulation)

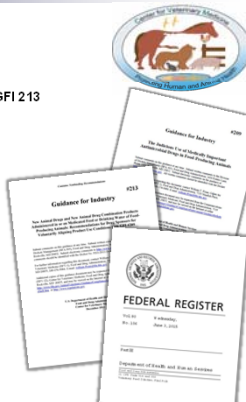
Center for Veterinary Medicine  
 Dragan Momcilovic DVM, PhD, DACT  
 Veterinary Medical Officer  
 Center for Veterinary Medicine (CVM)  
 U.S. Food and Drug Administration (FDA)



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## Agenda

- Introduction
  - Medicated Feeds, Water, GFI 209 and GFI 213
- Overview of the New Rule
  - Background
  - Definitions
  - Major Provisions
    - General Requirements
    - Veterinarian Requirements
- Important dates
  - October 1, 2015
  - January 1, 2017
- Conclusions




## Introduction



New Rule  
 FEDERAL REGISTER

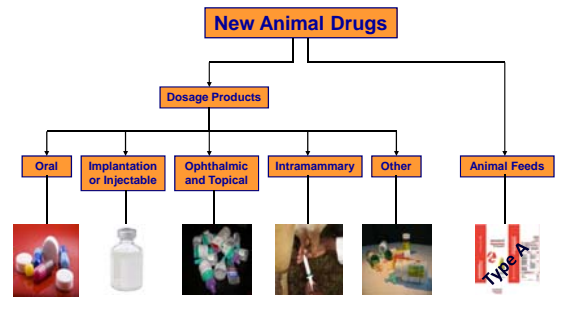
## FDA Organization Overview



<http://www.fda.gov/AboutFDA/CentersOffices/Organization/Charts/ucm393155.htm>

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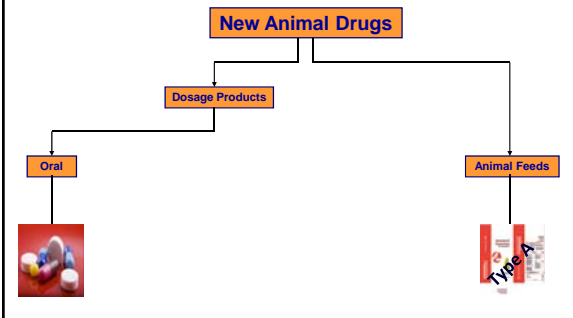
## Approved New Animal Drugs and Their Uses



New Animal Drugs

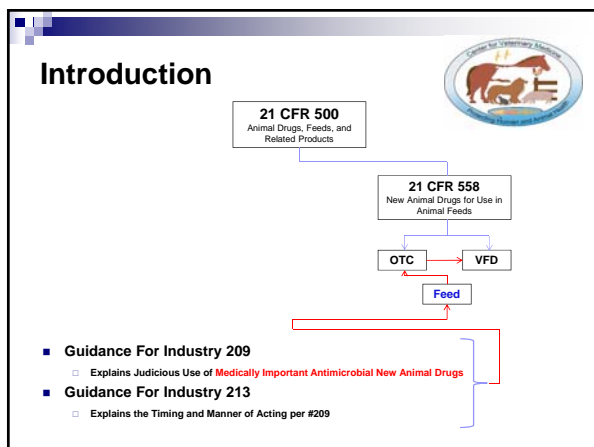
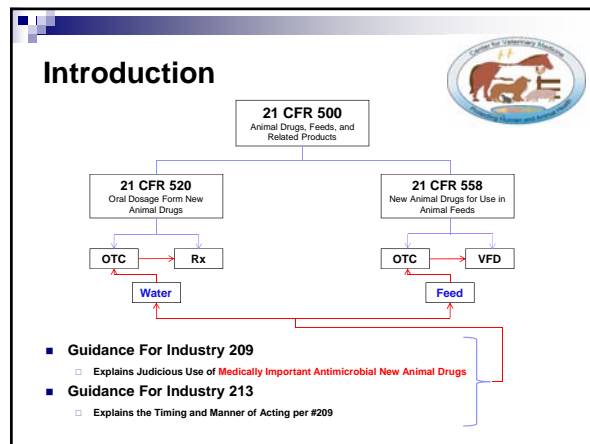
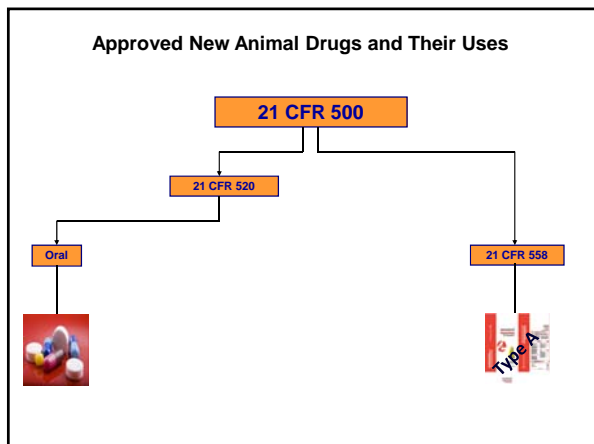
- Dosage Products
  - Oral
  - Implantation or Injectable
  - Ophthalmic and Topical
  - Intramammary
  - Other
- Animal Feeds
  - Type A

## Approved New Animal Drugs and Their Uses



New Animal Drugs

- Oral
- Animal Feeds
  - Type A





### Background

- With passing the ADAA in 1996, Congress created a new regulatory category for certain animal drugs used in animal feed called veterinary feed directive drugs or VFD drugs
- FDA has determined that some new animal drugs, vital to animal health, should be approved for use in animal feed but only if such medicated feeds are used under the professional supervision of a licensed veterinarian in the course of the veterinarian's practice

### What is VFD?

- VFD is a drug
  - A "veterinary feed directive (VFD) drug" is a new animal drug intended for use in or on animal feed which is limited by an approved, conditionally approved application, or index and
  - for use only under the professional supervision of a licensed veterinarian who authorizes such use by a lawful veterinary feed directive.
- VFD is a document
  - A "veterinary feed directive" is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a VFD drug or combination VFD drug in or on an animal feed, and
  - this written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client's animals only in accordance with the approved, conditionally approved application, or index.

### What is VFD?

- VFD is a drug
 
- VFD is a document
 

### Other Relevant Definitions

- A “distributor”
  - A “distributor” means any person who distributes a medicated feed containing a VFD drug to:
    - another distributor, or
    - the client-recipient of a VFD.

### Other Relevant Definitions

- A “distributor”
  - A “distributor” means any person who distributes a medicated feed containing a VFD drug to:
    - another distributor, or
    - the client-recipient of a VFD.
- A “combination VFD drug”
  - A “combination veterinary feed directive (VFD) drug” means a combination new animal drug intended for use in or on animal feed which is limited by an approved application
  - at least one of the new animal drugs in the combination is a VFD drug, and
  - it can be used only under the professional supervision of a licensed veterinarian when authorized by a lawful VFD.

### A “combination VFD drug” (examples)

### New Rule – “Veterinary feed directive drugs” (21 CFR 558.6)

- (a) General requirements related to veterinary feed directive (VFD) drugs
- (b) Responsibilities of the veterinarian issuing the VFD
- (c) Responsibilities of any person who distributes an animal feed containing a VFD drug or a combination VFD drug

### New Rule - General Requirements (21 CFR 558.6(a))

- Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.

### VFD Rule - General Requirements (21 CFR 558.6(a))

- Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.
- A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.

### New Rule - General Requirements (21 CFR 558.6(a))

- Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.
- A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.

Legend: Blue line = VFD, Red bar = Feeding

### New Rule - General Requirements (21 CFR 558.6(a))

- Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.
- A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.
- Use and labeling of a VFD drug or a combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. 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.

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- Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.
- A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD.
- Use and labeling of a VFD drug or a combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. 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.
- All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The distributor and client copies may be kept as an electronic copy or hardcopy.

### New Rule - General Requirements (21 CFR 558.6(a))

- All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA upon request.
- All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement:

**VFD Feed**

“Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.”

Repository of Blue Bird labels at: <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm>

### New Rule – Veterinarian Responsibilities (21 CFR 558.6(b))

- (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
  - be licensed to practice veterinary medicine
  - be operating in the course of the veterinarian’s professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)

**State VCPR applies**

- if VCPR defined by such State includes the key elements of a valid VCPR defined in § 530.3(i)

**Federal VCPR applies**


- if VCPR defined by such State does not include the key elements of a valid VCPR defined in § 530.3(i)

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm>

### New Rule – Veterinarian Responsibilities (21 CFR 558.6(b))

- (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
  - be licensed to practice veterinary medicine
  - be operating in the course of the veterinarian’s professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)
- (2) Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug

### New Rule – Veterinarian Responsibilities (21 CFR 558.6(b))




- (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
  - be licensed to practice veterinary medicine
  - be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)
- (2) Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug
- (3) Includes fully and accurately all required information

### Information Required on VFD

1. Vet's and client's names/addresses/telephone
2. The premises at which the animals specified in the VFD are located
3. Date of VFD issuance
4. VFD expiration date
5. The name of the VFD drug(s)
6. Species and production class of the animals to be fed the VFD feed
7. The approximate number of animals to be fed by the expiration date of the VFD
8. The indication for which the VFD is issued
9. Drug level and duration of use
10. Withdrawal time/any special instructions/cautions by the drug approval
11. Number of reorders (refills) authorized - if permitted by the drug approval
12. The 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"
13. An affirmation of intent for combination VFD drugs
14. Veterinarian's electronic or written signature

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### VFD Rule – Veterinarian Responsibilities (21 CFR 558.6(b))



- (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
  - be licensed to practice veterinary medicine
  - be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)
- (2) Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug
- (3) Includes fully and accurately all required information
- (4) Includes the following optional information

### Information Optional on VFD

1. More specific description of the location of treated animals (e.g., pen...)
2. The approximate age/weight range of the animals
3. Any other information the veterinarian deems appropriate to identify the animals specified in the VFD

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### VFD example

**Veterinary Feed Directive**

Veterinarian: \_\_\_\_\_ Client: \_\_\_\_\_  
 Address: \_\_\_\_\_ Address: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Phone: \_\_\_\_\_  
 Fax or email (optional): \_\_\_\_\_ Fax or email (optional): \_\_\_\_\_

Drug(s) Name(s): \_\_\_\_\_ Drug(s) Level(s): \_\_\_\_\_ g/lb(s) Quantity of feed: \_\_\_\_\_  
 Species and Production Class: \_\_\_\_\_ Number of animals (total) authorized to receive this feed: \_\_\_\_\_  
 Indications for use (as approved): \_\_\_\_\_  
 Caution (insert in the indicated text field): \_\_\_\_\_

**USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG BY A PERSON OTHER THAN AN INDIVIDUAL ON THE PREMISES IS PROHIBITED (21 CFR 558.6(b))**

VFD Date of Issuance: \_\_\_\_\_ Withdrawal Time: \_\_\_\_\_ VFD Expiration Date: \_\_\_\_\_ (Withdrawal time is not intended to authorize the use of the VFD drug(s) in combination with any other animal drug.)

Appropriate Number of Animals: \_\_\_\_\_  
 Premises: \_\_\_\_\_  
 Other information (e.g., tag, weight, color): \_\_\_\_\_

Special instructions (if any): \_\_\_\_\_

**Affirmation of intent for combination VFD Drugs (check one box):**  
 The VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drugs in combination with any other animal drug.  
 The 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:  
 \_\_\_\_\_  
 The 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 (see 21 CFR 558.6(b)) must be withdrawn \_\_\_\_\_ days prior to slaughter ◀

Veterinarian's Signature: \_\_\_\_\_  
 Date: \_\_\_\_\_

Animals must receive a copy of this VFD for 3 years from the date of issuance.


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### VFD Rule – Veterinarian Responsibilities (21 CFR 558.6(b))



- (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
  - be licensed to practice veterinary medicine
  - be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)
- (2) Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug
- (3) Includes fully and accurately all required information
- (4) Includes the following optional information
- (5) Includes the drug-specific information for each VFD drug used in the combination

### VFD Rule – Veterinarian Responsibilities (21 CFR 558.6(b))



- (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
  - be licensed to practice veterinary medicine
  - be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)
- (2) Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug
- (3) Includes fully and accurately all required information
- (4) Includes the following optional information
- (5) Includes the drug-specific information for each VFD drug used in the combination
- (6) Affirms whether the VFD drug(s) may be used alone or in an approved combination with over-the-counter drug(s)

### Affirms his/her intent on VFD

(i) "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."

(ii) "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.]

(iii) "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."

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### Affirms his/her intent on VFD


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(iii) "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."

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### VFD example



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### Affirms his/her intent on VFD


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(iii) "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."

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### VFD example



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**VFD example**

**Veterinary Feed Directive**

Veterinarian: \_\_\_\_\_ Client: \_\_\_\_\_  
 Address: \_\_\_\_\_ Address: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Phone: \_\_\_\_\_  
 Fax or email (optional): \_\_\_\_\_ Fax or email (optional): \_\_\_\_\_

Drugs/Name(s): \_\_\_\_\_ Strength Level: \_\_\_\_\_ g/lb. Duration of use: \_\_\_\_\_  
 Species and Production Class: \_\_\_\_\_ Number of animals (public) authorized to receive this feed: \_\_\_\_\_  
 Indications for use (as approved): \_\_\_\_\_  
 Caution (describe the indicated feed form): \_\_\_\_\_

**USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE OVER FEEDS IN A MANNER OTHER THAN AS DIRECTED ON THE LABEL IS UNLAWFUL AND IS NOT PERMITTED**

VFD Date of Issuance: \_\_\_\_\_ Month/Day/Year VFD Expiration Date: \_\_\_\_\_ Month/Day/Year (do not extend beyond 600 days)  
 Appropriate Number of Animals: \_\_\_\_\_  
 Position: \_\_\_\_\_  
 Other identification (e.g., tag, weight) Label: \_\_\_\_\_  
 Special Instructions (if any): \_\_\_\_\_

**Authorization of Issuance (for combination VFD Drugs) (check one box):**  
 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 drug.  
 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 \_\_\_\_\_  
 Example: Drug X + Drug Y 40 g/ton + 100 g/ton

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 if any. This VFD Feed must be withdrawn \_\_\_\_\_ days prior to slaughter ◀

Veterinarian's Signature: \_\_\_\_\_  
 Date: \_\_\_\_\_  
 Title: \_\_\_\_\_

Animals must retain a copy of this VFD for 3 years from the date of issuance.

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### Affirms his/her intent on VFD

(i) "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."

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(iii) "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."

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**VFD example**

**Veterinary Feed Directive**

Veterinarian: \_\_\_\_\_ Client: \_\_\_\_\_  
 Address: \_\_\_\_\_ Address: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Phone: \_\_\_\_\_  
 Fax or email (optional): \_\_\_\_\_ Fax or email (optional): \_\_\_\_\_

Drugs/Name(s): \_\_\_\_\_ Strength Level: \_\_\_\_\_ g/lb. Duration of use: \_\_\_\_\_  
 Species and Production Class: \_\_\_\_\_ Number of animals (public) authorized to receive this feed: \_\_\_\_\_  
 Indications for use (as approved): \_\_\_\_\_  
 Caution (describe the indicated feed form): \_\_\_\_\_

**USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE OVER FEEDS IN A MANNER OTHER THAN AS DIRECTED ON THE LABEL IS UNLAWFUL AND IS NOT PERMITTED**

VFD Date of Issuance: \_\_\_\_\_ Month/Day/Year VFD Expiration Date: \_\_\_\_\_ Month/Day/Year (do not extend beyond 600 days)  
 Appropriate Number of Animals: \_\_\_\_\_  
 Position: \_\_\_\_\_  
 Other identification (e.g., tag, weight) Label: \_\_\_\_\_  
 Special Instructions (if any): \_\_\_\_\_

**Authorization of Issuance (for combination VFD Drugs) (check one box):**  
 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 drug.  
 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 \_\_\_\_\_  
 Example: Drug X + Drug Y 40 g/ton + 100 g/ton

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 if any. This VFD Feed must be withdrawn \_\_\_\_\_ days prior to slaughter ◀

Veterinarian's Signature: \_\_\_\_\_  
 Date: \_\_\_\_\_  
 Title: \_\_\_\_\_

Animals must retain a copy of this VFD for 3 years from the date of issuance.

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### Affirms his/her intent on VFD

(i) "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."

If a VFD drug is not approved in a combination, only first of the three statements could be included on the VFD order

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**VFD example**

**Veterinary Feed Directive**

Veterinarian: \_\_\_\_\_ Client: \_\_\_\_\_  
 Address: \_\_\_\_\_ Address: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Phone: \_\_\_\_\_  
 Fax or email (optional): \_\_\_\_\_ Fax or email (optional): \_\_\_\_\_

Drugs/Name(s): \_\_\_\_\_ Strength Level: \_\_\_\_\_ g/lb. Duration of use: \_\_\_\_\_  
 Species and Production Class: \_\_\_\_\_ Number of animals (public) authorized to receive this feed: \_\_\_\_\_  
 Indications for use (as approved): \_\_\_\_\_  
 Caution (describe the indicated feed form): \_\_\_\_\_

**USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE OVER FEEDS IN A MANNER OTHER THAN AS DIRECTED ON THE LABEL IS UNLAWFUL AND IS NOT PERMITTED**

VFD Date of Issuance: \_\_\_\_\_ Month/Day/Year VFD Expiration Date: \_\_\_\_\_ Month/Day/Year (do not extend beyond 600 days)  
 Appropriate Number of Animals: \_\_\_\_\_  
 Position: \_\_\_\_\_  
 Other identification (e.g., tag, weight) Label: \_\_\_\_\_  
 Special Instructions (if any): \_\_\_\_\_

**Authorization of Issuance (for combination VFD Drugs) (check one box):**  
 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 drug.  
 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 \_\_\_\_\_  
 Example: Drug X + Drug Y 40 g/ton + 100 g/ton

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 if any. This VFD Feed must be withdrawn \_\_\_\_\_ days prior to slaughter ◀

Veterinarian's Signature: \_\_\_\_\_  
 Date: \_\_\_\_\_  
 Title: \_\_\_\_\_

Animals must retain a copy of this VFD for 3 years from the date of issuance.

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### VFD Rule – Veterinarian Responsibilities (21 CFR 558.6(b))



- (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
  - be licensed to practice veterinary medicine
  - be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)
- (2) Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug
- (3) Includes fully and accurately all required information
- (4) Includes the following optional information
- (5) Includes the drug-specific information for each VFD drug used in the combination
- (6) Affirms whether the VFD drug(s) may be used alone or in an approved combination with over-the-counter drug(s)
- (7) Issues VFD in writing (nonverbally)

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### VFD Rule – Veterinarian Responsibilities (21 CFR 558.6(b))



- (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
  - be licensed to practice veterinary medicine
  - be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)
- (2) Issues a VFD in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug
- (3) Includes fully and accurately all required information
- (4) Includes the following optional information
- (5) Includes the drug-specific information for each VFD drug used in the combination
- (6) Affirms whether the VFD drug(s) may be used alone or in an approved combination with over-the-counter drug(s)
- (7) Issues VFD in writing (nonverbally)
- (8) VFD could be hardcopy or electronic and must be sent to the distributor

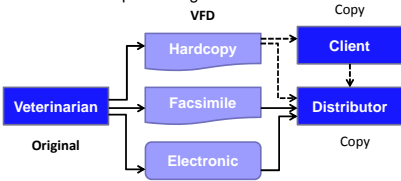
### VFD Rule – Veterinarian Responsibilities (21 CFR 558.6(b))



- (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:
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  - be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing requirements, and in the context of a VCPR (State or Federal)
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- (3) Includes fully and accurately all required information
- (4) Includes the following optional information
- (5) Includes the drug-specific information for each VFD drug used in the combination
- (6) Affirms whether the VFD drug(s) may be used alone or in an approved combination with over-the-counter drug(s)
- (7) Issues VFD in writing (nonverbally)
- (8) VFD could be hardcopy or electronic and must be sent to the distributor
- (9) Provides a copy to the client

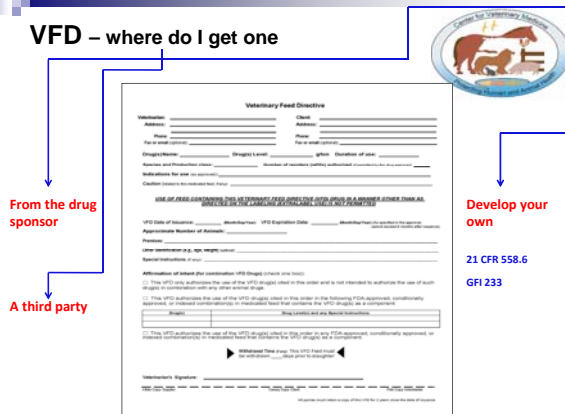
### VFD – how do I transmit it

- VFD is a written (non verbal) statement and can be hardcopy or electronic
- If the VFD is transmitted electronically, the veterinarian is not required to send the original in hardcopy to the distributor
- The veterinarian keeps the original VFD




The diagram shows a Veterinarian (Original) sending a VFD through three channels: Hardcopy, Facsimile, and Electronic. The Hardcopy channel sends a Copy to the Client and a Copy to the Distributor. The Facsimile and Electronic channels send Copies to the Distributor. The Client also receives a Copy from the Distributor.

### VFD – where do I get one




The diagram shows a Veterinary Feed Directive form with three arrows pointing to sources: 'From the drug sponsor' (pointing to the top left), 'A third party' (pointing to the bottom left), and 'Develop your own' (pointing to the top right). The form includes fields for Veterinarian, Client, Address, Phone, Fax, Email, and various checkboxes for use of VFDs.

### New Rule – Distributors Responsibilities (21 CFR 558.6(c))




- is permitted to fill a VFD only if the VFD contains all the required information

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- must keep records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years**

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- must keep records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years
- In addition to other applicable recordkeeping requirements found in this section, if the distributor manufactures the animal feed bearing or containing the VFD drug, the distributor must also keep VFD feed manufacturing records for 1 year in accordance with part 225 of this chapter. Such records must be made available for inspection and copying by FDA upon request.**

### Distributors Record Keeping

**Distributor**

**Only distributes VFD feed**

If VFD feed is shipped to	Record	
	Required	Retained for
Client only	VFD (encler)	2 years
Other distributor only	Acknowledgment letter(s)	2 years
Both client and other distributor	VFD (encler) and acknowledgment letter(s)	2 years

**Manufactures and distributes VFD feed**


If VFD feed is shipped to	Record	
	Required	Retained for
Client only	VFD (encler)	2 years
Other distributor only	Acknowledgment letter(s)	2 years
Both client and other distributor	VFD (encler) and acknowledgment letter(s)	2 years

+


Manufacturing Record	
Required per	Retained for
21 CFR 225 (GMP)	1 year

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### New Rule – Distributors Responsibilities (21 CFR 558.6(c))




- must notify FDA prior to the first time it distributes animal feed containing a VFD drug. The notification is required one time per distributor and must include the following information:
  - (i) The distributor's complete name and business address;
  - (ii) The distributor's signature or the signature of the distributor's authorized agent; and
  - (iii) The date the notification was signed.



```

            graph LR
            A[Distributor] --> B[Notification Letter]
            B --> C[FDA]
            
```


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  - (i) The distributor's complete name and business address;
  - (ii) The distributor's signature or the signature of the distributor's authorized agent; and
  - (iii) The date the notification was signed.
- must also notify FDA within 30 days of any change in ownership, business name, or business address. The notifications must be submitted to:
 


Food and Drug Administration,  
Center for Veterinary Medicine,  
Division of Animal Feeds (HFV-220),  
7519 Standish Pl.  
Rockville, MD 20855  
FAX: 240-453-6882

### New Rule – Distributors Responsibilities (21 CFR 558.6(c))

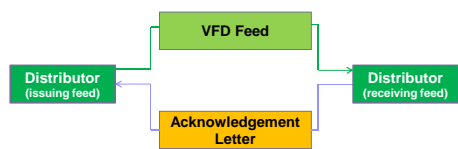


- A distributor is permitted to distribute a VFD feed to another distributor only if the originating distributor (consignor) first obtains a written (nonverbal) acknowledgment letter, as defined in § 558.3(b)(11), from the receiving distributor (consignee) before the feed is shipped. Consignor distributors must retain a copy of each consignee distributor's acknowledgment letter for 2 years

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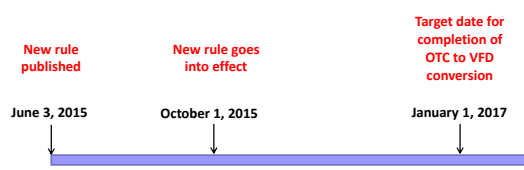


### Drugs approved for feed use

Amprolium.	Coumaphos.	Ivermectin.	Novobiocin.	Salinomycin.
Amprolium and ethopabate.	Decoquinolate.	Laidlomycin.	Nystatin.	Semduramicin.
Apramycin.	Dicloxacil.	Lasalocid.	Oleandomycin.	Sulfadimethoxine, trimetoprim
Aulamycin.	Dichlorvos.	Lincomycin.	Oxytetracycline.	Sulfamerazine.
Bacitracin methylenedisalicylate.	Efrotromycin.	Maduramicin.	Oxytetracycline and neomycin.	Sulfaguanoxaline.
Bacitracin zinc.	Famphur.	Mibolerone.	Penicillin.	Thiabendazole.
Bambermycins.	Fenbendazole.	Monensin.	Poloxalene.	Tiamulin.
Carbadox.	Florfenicol.	Morantel tartrate.	Poloxalene free-choice liquid Type C feed.	Tilmicosin.
Chlortetracycline.	Halofuginone.	Narasin.	Pyrantel.	Tylosin.
Chlortetracycline and sulfamethazine.	Hygromycin B.	Neomycin sulfate.	Ractopamine.	Tylosin and sulfamethazine.
Clopidol.	Iodinated casein.	Nequinolate.	Robenidine.	Virginiamycin.
		Nicarbazin.		Zilpaterol.
				Zoalene.

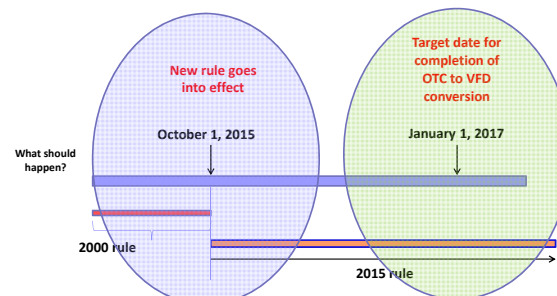
— OTC  
— Approved as VFD  
— Becoming VFD on 1/1/17  
— Part of VFD feed combination on 1/1/17

### Important Dates



New rule published: June 3, 2015  
 New rule goes into effect: October 1, 2015  
 Target date for completion of OTC to VFD conversion: January 1, 2017

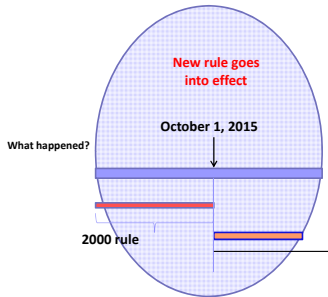
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### Important Dates

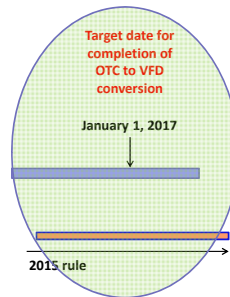
#### October 1, 2015



- The VFD drugs
  - At this time will apply *only* to drugs that are already approved as VFD (avilamycin, florfenicol, and tilmicosin)
- The veterinarian issues VFD according to the new rule
  - Keeps the original VFD
  - Follows up with no hard copy
  - Affirms his/her intent...

### Important Dates

#### January 1, 2017



- 2015 rule in effect
- Conversion of certain antimicrobial drugs from OTC to VFD has **completed**
- The list of VFD drugs has expanded substantially
- The veterinarian continues to issue VFD according to the new rule
  - Keeps the original VFD
  - Follows up with no hard copy
  - Affirms his/her intent...

## Conclusions

- Veterinary Feed Directive is an invaluable tool in ensuring proper use of antimicrobial drugs in animal feed
- Veterinarians are key in minimizing the potential for rise in antimicrobial resistance
- New rule clarifies and updates the old rule
- VFD – where the veterinary practice meets medicated feed

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## Where to look for more information

- “Veterinary Feed Directive (VFD)” at
  - <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>



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