

## Overview of the Veterinary Feed Directive (“VFD”)

American Agriculture Law Association (“AALA”) Annual Educational Symposium

October 6, 2016  
Oklahoma City, OK

By Cari B. Rincker, Esq.



---

---

---

---

---

---

---

---

## Who I Am

- Grew up on a beef cattle farm in Illinois
  - Advanced degrees in animal science
- Past-Chair of the ABA, General Practice, Solo & Small Firm Division’s Agriculture Law Committee
- Client bases ranges from livestock producers & food entrepreneurs to mid-size agri-businesses



---

---

---

---

---

---

---

---

## Overview

### Background

- Definitions
- Players
- Regulatory Framework

(Second) Veterinary Feed Directive (“VFD”) Rule



---

---

---

---

---

---

---

---

## Background



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

## Definitions

### Antibiotic

- Can inhibit the growth of bad bacteria that cause infections and illness.
- Antibiotics belong to a class of drugs called "antimicrobials."

### Antimicrobial

- Any substance of natural, semisynthetic or synthetic origin that kills or inhibits the growth of microorganisms but causes little or no damage to the host
- All antibiotics are antimicrobials, but not all antimicrobials are antibiotics

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---


---

---

---


---

## The Players



U.S. Department of Agriculture ("USDA") regulates antibiotics in meat, poultry, and eggs via two sub-agencies.

- Food Safety Inspection Service ("FSIS") (Primarily)
- Agriculture Marketing Service ("AMS")
- Animal and Plant Health Inspection Service ("APHIS")



Food & Drug Administration is an agency of the Department of Health and Human Services ("HHS").

- FDA regulates food and drugs in livestock animals excluding meat, poultry, and eggs (regulated by USDA).
- Center for Veterinary Medicine ("CVM") is a sub-agency which oversees the safety and effectiveness of animal drugs and the approval process.



Centers for Disease Control and Prevention ("CDC") is also under the HHS umbrella and safeguards health by monitoring antibiotic resistance.

- National Antimicrobial Resistance Monitoring System ("NARMS") is a sub-agency of the CDC composed of the FDA, CDC, USDA's FSIS.

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

## Approval of Antibiotics

**FDA Must Approve Antibiotics**

- Federal Food, Drug, and Cosmetic Act ("FDCA" or "FDCA") prohibits an animal drug to be sold into interstate commerce unless it has been approved by an **Approved New Animal Drug Application** ("NADA").
- FDA does approve the use of antibiotics in livestock and **must approve all antibiotics** (for humans, animals, and livestock). See 21 CFR § 530.
- This requirement still exists with VFD.



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---


## Background

Prior to 1996, FDA had 2 options for distributing animal drugs:

- Over-the-Counter ("OTC")
- Prescription (Rx)

Federal Food, Drug and Cosmetic Act ("FDCA") didn't require prescriptions for animal feeds.

- Viewed as being impractical because feed mills would need to have a pharmacist onsite to dispense prescription drugs; thus feeds were OTC.



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

## Background

Statutory History

- In 1996, Congress enacted the **Animal Drug Availability Act** ("ADAA") to facilitate the approval and marketing of new animal drugs and medicated feeds.
- This law created a new regulatory category for animal drugs used in animal feed – **veterinary feed directive** ("VFD") drugs.
- First VFD Rule by Food & Drug Administration ("FDA") was published in the Code of Federal Regulations in 2000.
- The Second VFD Rule was published on June 3, 2015

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---


---

---

---


---

### Background



Under ADAA, **VFD drugs** are **new animal drugs** intended for use in or on animal feed, which are limited by an approved application, conditionally approved application or index listing to use under professional supervision of a licensed veterinarian.

- VFD drug requires a VFD document by licensed veterinarian who authorizes the use.
- Although a similar concept, VFD drugs are not prescription (Rx) drugs.



---

---

---

---


---

---

---


---

### Background



A VFD is a **written statement** issued by a licensed veterinarian in the court of a the veterinarian's professional practice that orders the use of a VFD drug or combination VFD drug in an animal feed.

- This **authorizes the livestock producer** to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the producer's livestock in accordance with the approved, conditionally approved application or index.



---

---

---

---

---

---


---


---

### Background

Currently there are a few VFD drugs (mostly OTC).

- FDA received responses saying that the VFD process was overly burdensome.
- FDA also received public comment about public health, use of antimicrobials/antibiotics in meat producing animals, and concern for antibiotic residence.
- New VFD “responded” to these concerns.





---

---

---

---

---

---

---


---

### Background

The final rule on VFD is the third of three core documents that the FDA is using on its judicious use policy for antibiotics.

**Publication 1:** Guidance for the Industry (GFI) #209 "The Judicious Use of Medically Important Antimicrobial Drugs in Food Producing Animals"

**Publication 2:** Guidance for the Industry GFI #213 "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209"



---

---

---

---

---

---


---

---

### Background

**Publication 1:** Guidance for the Industry (GFI) #209 "The Judicious Use of Medically Important Antimicrobial Drugs in Food Producing Animals"

- Published around April 2012
- Described the overall policy direction.
- This publication focused on 2 key principles:
  - Limit use of medically important antimicrobial drugs in food-producing animals to those uses (1) considered necessary for assuring animal health and (2) that include veterinary oversight or consultation



---

---

---

---

---

---


---

---

### Background

**Publication 2:** Guidance for the Industry GFI #213 "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209"

- Published in December 2013
- Outlined a detailed process and timeline for implementing the measures identified in GFI #209.
- This document discussed the transition of OTC antimicrobial drugs to VFD marketing status.
- This publication noted that December 2016 was the target for drug sponsors to implement changes to use conditions of "medically important" antimicrobials in food and water to:
  - (1) voluntarily withdraw approved production uses such as "increased rate of weight gain" or feed efficiency and
  - (2) after the label changes these production uses will no longer be legal; however, therapeutic uses are to be retained for treatment, control and prevention indications.



---

---

---

---

---

---

---

---

### Background

Publication 2: Guidance for the Industry GFI #213 "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209"

- A key principle noted in this publication was to include a veterinarian in the decision-making process.
- It doesn't require direct veterinarian involvement in the drug administration but it does require use to be authorized by a licensed veterinarian in the context of a VCPR.
- This includes water soluble products to Rx ("medicated drinking water") and products used in or on feed to VFD ("medicated feed")

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Background

VFD – final rule published in the Federal Register on June 3, 2015

FDA focusing now on stakeholder education

- Veterinarians
- Livestock producers
- Feed mill distributors

Builds off of GFI #213 ("Publication 2")

Provides for a phased enforcement of the implementation of the rule as OTC become VFD

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Background – Effective Date

**First VFD Rule** (December 8, 2000) was in effect until October 1, 2015

**Second VFD Rule** (June 2, 2015) went into effect after October 1, 2015

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---


---

---

---

### Background

What drugs are affected? (Look for 2 things)



Those that are considered "medically important" AND

Administered in feed or drinking water

- I.e., injectables, boluses and other dosage forms are not affected

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

(GFI # 213)

---

---

---

---

---

---

---

---

---

---

### Background

So what are "medically important" antimicrobials?

- GFI #213 defined "medically important" to include all antimicrobial drugs/drug classes that are listed in Appendix A of FDA's Guidance #152
- Put simply, it includes all antimicrobial drugs that are considered important by the FDA for therapeutic uses

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

---

---

### Background: Affected Antimicrobials Administered via Feed

Antimicrobial Class	Specific Drugs Approved for Use in Feed
Aminoglycosides	Apramycin, Hyppromycin B, Neomycin, Streptomycin
Diaminopyrimidines	Ormetoprim
Lincosamides	Lincomycin
Macrolides	Erythromycin, Oleandomycin, Tylosin
Penicillins	Penicillin
Streptogramins	Virginiamycin
Sulfas	Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline
Tetracycline	Chlortetracycline, Oxytetracycline

See FDA "Medically Important Antimicrobials in Animal Agriculture" at 15

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

---


---

### Background:

#### Affected Antimicrobials Administered via Water

Antimicrobial Class	Specific Drugs Approved for Use in Water
Aminoglycosides	Apramycin, Gentamicin, Neomycin, Spectinomycin, Streptomycin
Diaminopyrimidines	NONE
Lincosamides	Lincomycin
Macrolides	Erythromycin, Oleandomycin, Tylosin
Penicillins	Penicillin
Streptogramins	NONE
Sulfas	Sulfachlorophyrazine, Sulfachlorpyridazine, Sulfadimethozine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline
Tetracycline	Chlortetracycline, Oxytetracycline, Tetracycline

See FDA "Medically Important Antimicrobials in Animal Agriculture" at 16




---

---

---

---

---

---

---

---

---

---

---


---

### Background

What drugs aren't affected?

- **Antimicrobials that are already VFD**
  - Avilamycin, florfenicol, tilimicosin
  - Rx Tylosin
- **Antimicrobials that are not "medically important"**
  - Ionophores (e.g., monensin, lasalocid)
  - Bacitracin (e.g., bacitracin zinc)
  - Bambermycins
  - Carbadox
- **Non-antimicrobial drugs**
  - Anthelmintics
  - Beta agonists
  - Coccidiostats

See FDA "Medically Important Antimicrobials in Animal Agriculture" at 17




---

---

---

---

---

---

---

---




---

---

---

---

### Background






Feed-use drugs are assigned to one of two categories

- **Category I** – Drugs having the lowest potential for residues
- **Category II**– Drugs having the highest potential for residues
- VFD drugs are no longer automatically Category II

This category determines whether a facility needs to be licensed to handle the drug in the Type A form

See FDA "Medically Important Antimicrobials in Animal Agriculture" at 17




---

---

---

---

---

---

---

---

---

---

---

---



## Veterinary Feed Directive (VFD)



RINCKER  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

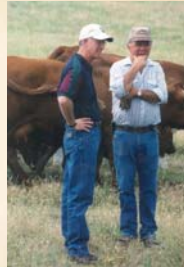
---

---

---

## Stakeholder Requirements

- Veterinarians
- Livestock Producers
- Feed Distributors
- Drug Manufacturers



RINCKER  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

## Veterinary Requirements

Must be in compliance with the state's **veterinarian-client-patient relations** ("VCPR") requirements pursuant to § 530.3(i)

If state doesn't require a VCPR then FDA now requires that the VFD be issued within context of Federally defined VCPR, which requires:

- **Engage with livestock producer** and assume responsibility for making medical judgment about the animal's health.
- Have **sufficient knowledge** of the animal by virtue of examination and/or visit the facility where the animal is managed to initiate a preliminary diagnosis.
- Provide for any necessary **follow-up evaluation** or care.

RINCKER  
*Law* PLLC RINCKERLAW.COM

21 § CFR 558.6(b)

---

---

---

---

---

---

---

---

### Veterinary Requirements

The veterinarian must also provide a written **veterinary feed directive** ("VFD").

The VFD must be in compliance with the conditions for approved use, conditionally approved use or indexed use under the ADAA.



21 CFR 558.6(a)

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Veterinary Requirements

Extra-labeling Use is not permitted

- I.e., Use of feed containing a VFD drug in a manner other than as directed on the label is not permitted.



21 C.F.R. 558.6(a)

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---


---

---

---

---

### Veterinary Requirements



**VFD Information**

- Required information
- Optional information

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---


---

---

### Veterinary Requirements

Required Information

- Vet's and livestock producer/client's
  - Name
  - Address
  - Telephone number
- Premises at which the animals are located
- Date of VFD issuance
- Species and production class of animals to be fed the VFD feed



---

---

---

---

---

---

---

---


---


---

### Veterinary Requirements

VFD must include the name of the VFD drug

- could be the generic name
- can state that a substitution drug is or isn't allowed (optional info)
- if substitution is allowed then the feed distributor may choose to substitute if the generic VFD is part of an approved combination





21 CFR 558.6(b)

---

---

---

---

---

---

---

---

---

---

### Veterinary Requirements

VFD must include an expiration date

- The vet can write a date up to 6 months from the date the VFD is initiated.
- Duration determines the length of time the VFD is allowed to be fed to the animals as specified on the product label.





---

---

---

---

---

---

---

---


---

---

### Veterinary Requirements

VFD Must Include

- Approximate/potential number of animals to be fed by the expiration date of the VFD on a premises
  - Also needs the expiration date
- Indication for which the VFD is issued
- Drug level
- Duration of use
  - Note: Duration is different than expiration date
- Withdrawal time
- Special instructions/cautions
- Number of reorders (refills) authorized – if permitted by the drug approval



---

---

---

---

---

---

---


---

### Veterinary Requirements

Note that expiration date and the duration of use are 2 different concepts

Few examples:

- Avilamycin has an expiration date of 90 days but should only be used for 21 days
- Florfenicol for wine has an expiration date of 90 days but has a typical duration of only 5 days
- Tilmicosin for cattle has an expiration date of 45 days but typically prescribed for 14 days



---

---

---

---

---

---

---

---

### Veterinary Requirements

VFD Must Include this Statement

- “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel) is not permitted.”



---

---

---

---

---

---

---

---

## Veterinary Requirements

VFD must include:

- An affirmation of intent for combination VFD drugs
- Veterinarian's electronic or written signature





---

---

---

---

---

---

---

---

## Veterinary Requirements

**Affirming Intent on the VFD**

**Choice 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 drugs in combination with any other animal drugs."

---

**Choice 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 specifics \_\_\_\_\_]

---

**Choice 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."

---



---

---

---

---

---

---


---


---

## Veterinary Requirements

VFD must include premises ID but may include more information of the animals

- This is so someone can locate the animals, if needed.
- May include specific information, such as the **pen** or description of where the animals are currently located.
- If the VFD is intended to authorize the use of a VFD feed in a group of animals that are located at more than one physical location, then the VFD can specify more than one pen so long as the feed is supplied by a single feed distributor.





---

---

---

---

---

---

---

---

### Veterinarian Requirements

VFD may provide the following additional information:

- Approximate age/weight range of the animals
- Any other information the veterinarian deems appropriate to identify the animals specified in the VFD



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Veterinary Requirements

Please note that the VFD no longer requires the veterinarian to state the amount of feed to be fed to the animals

- Instead, the burden is on the distributor to determine the proper amount of feed to manufacture and distribute to the producer



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Veterinary Requirements

Importantly, is not a required VFD Form

- Guidance for the Industry ("GFI") #233 lists several recommended common formats for the VFD
- Veterinarian can create his/her own VFD form but should have it reviewed by an attorney for compliance



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Veterinarian Requirements

Copy of the VFD must go to the client (producer) and feed distributor

- Can be delivered hard-copy, facsimile or electronic (e.g., email)
- Transmitted to the distributor and client gets copy

Must maintain VFD records for 2 years

- Must retain original VFD
- Other segments can keep copies but VFD must keep original



21 C.F.R. 558.6(a)

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Producer Requirements

Feed animal feed containing a VFD drug only to animals based upon a duly issued VFD from a licensed veterinarian

Maintain all VFD records for 2 years

- Keep copy in original form (hard copy v. original)
- Must be available for inspection and copying by FDA upon request



21 CFR 558.6(a)

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Producer Requirements

Prohibited from feeding a VFD after an expiration date

- The expiration defines the period of time for which the authorization to provide an animal feed containing a VFD drug is lawful.
- Expiration date specifies the last day the VFD feed can be fed to a group of animals.



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Producer Requirements

#### Veterinary Feed Directive Issuance


VFD should state the expiration date.

Medicated feed being delivered in different increments

### Feeding

Expiration Date

Note: Was the **duration** prescribed different than the expiration date?



---

---

---

---

---

---

---

---


---


---

### Who is a Feed “Distributor”?

Any person who distributes a medicated feed containing a VFD drug to either:

- Another distributor or
- Client-recipient of VFD (livestock producer).





---

---

---

---

---

---

---

---

---

---

### Feed Distributor Requirements

Shall only provide a VFD feed if the VFD contains all the required information and conforms to product approval

Maintain records for 2 years

- Keep copy in original form (hard copy v. original).
- Must be available for inspection and copying by FDA upon request.
- Note that manufacturing records only need to be kept for 1 year under 21 CFR Part 225 if distributor also manufacturers.



21 CFR 558.6(c)



---

---

---

---

---

---

---

---

---

---



### Feed Distributor Requirements

#### Provide one-time notifications

- To the FDA of the distribution of VFD feeds stating that it intends to handle/distribute VFD drug-containing medicated feeds
- Acknowledgment of distribution limitations for VFD feeds that the purchasers will sell the VFD feeds only to producers with valid VFD orders or to other distributors for whom they have acknowledgement notices




---

---

---

---

---

---

---

---

### Feed Distributor Requirements

#### Notification must include:

- Distributor's name and business address
- Distributor's signature (or agent's signature)
- Date the notification was signed

#### Must notify FDA within 30 days of any change in ownership or business info

- Must send notification to FDA, Center of Veterinary Medicine, Division of Animal Feeds




---

---

---

---

---

---

---

---

### Feed Distributor Requirements

If the distributor is distributing the VFD feed to another distributor, then an **acknowledgement letter** must be sent from the receiving distributor under 21 CFR 558.3(b)(11) before shipment of feed.



Consigner distributor must retain copy of acknowledgement letter for 2 years.




---

---

---

---

---

---

---

---

### Drug Manufacturers

All labeling and advertising for (combination) VFD drugs, feeds containing (combination) VFD drugs must have the following cautionary 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.”

21 CFR 558.6(a)

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

### Drug Manufacturers

#### Substitution of Drugs

- If the VFD doesn't specify that a generic version may be substituted then the manufacturer may use an approved generic VFD drug to manufacture the VFD feed
- However, the manufacturer may not substitute a generic VFD drug for a pioneer VFD drug in a combination VFD feed if the generic VFD drug is not part of an approved combination VFD drug

**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---


---

---

---

### FDA Enforcement

General surveillance and for-cause inspection assignments



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

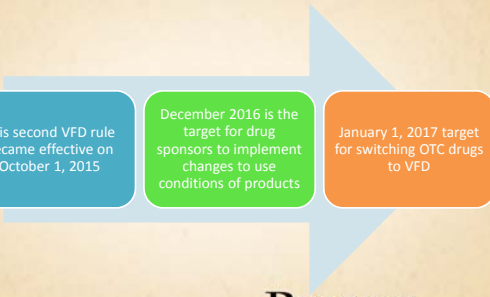
---

### Effective Date Clarification

This second VFD rule became effective on October 1, 2015

December 2016 is the target for drug sponsors to implement changes to use conditions of products

January 1, 2017 target for switching OTC drugs to VFD



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---


---

---

### Oh, P.S. – I Wrote a Book

Cari B. Rincker & Patrick B. Dillon, “Field Manual: Legal Guide for New York Farmers & Food Entrepreneurs” (2013)

Available at  
<http://www.amazon.com/Field-Manual-Legal-Farmers-Entrepreneurs/dp/1484965191> & Kindle



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

---

---

### Please Stay in Touch

**New York Office:**  
 535 Fifth Avenue, 4<sup>th</sup> Floor  
 New York, NY 10017  
 (212) 427-2049  
[cari@rinckerlaw.com](mailto:cari@rinckerlaw.com)  
[www.rinckerlaw.com](http://www.rinckerlaw.com)

**Illinois Office:**  
 701 Devonshire Drive C12  
 Champaign, IL 61820  
 (217) 254-5458

@CariRincker @RinckerLaw  
[www.facebook.com/rinckerlaw](http://www.facebook.com/rinckerlaw)  
<http://www.linkedin.com/in/caririncker>  
 Snapchat + Periscope: CariRincker



**RINCKER**  
*Law* PLLC RINCKERLAW.COM

---

---

---

---

---

---

---

---

---

---