1 January 2017, It is Coming

Preparation for VFD Changes Beginning 1 January 2017
CHAPTERS

• Background: Food and Drug Administration (FDA) guidance documents

• Introduction: Veterinary Feed Directive (VFD) regulation

• VFD: Key requirements

• VFD: Steps to implement by Jan. 1, 2017

• VFD: Key takeaways and resources
BACKGROUND: FOOD AND DRUG ADMINISTRATION (FDA) GUIDANCE DOCUMENTS
CENTER FOR VETERINARY MEDICINE’S ULTIMATE GOAL

Judicious use of medically important antimicrobial drugs in food animals.

1) Phase out use of all medically important antibiotics in feed for growth claims. Moves water-soluble powders with these same antibiotics to prescription (Rx).

2) Bring therapeutic uses of all medically important antibiotics under oversight of veterinarians.

Help ensure safe food and sustainable use of antimicrobials for humans and animals.
FDA GUIDANCE DOCUMENTS

GUIDANCE 152  
Oct. 23, 2003  
Defines Medically Important Antibiotics

GUIDANCE 209  
April 13, 2012  
Defines Judicial Use of Antibiotics

GUIDANCE 213  
Dec. 12, 2013  
Defines Process to Implement 209 and Veterinary Feed Directive Regulation
# GUIDANCE 152 — MEDICALLY IMPORTANT ANTIBIOTICS

<table>
<thead>
<tr>
<th>IMPORTANT</th>
<th>HIGHLY IMPORTANT</th>
<th>CRITICALLY IMPORTANT</th>
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<tr>
<td><em>First-generation Cephalosporins</em></td>
<td><em>Natural Penicillins</em></td>
<td><em>Third-generation Cephalosporins</em></td>
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<td><em>Second-generation Cephalosporins</em></td>
<td><em>Penase Resistant Pens</em></td>
<td><em>Fluoroquinolones</em></td>
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<td><em>Cephamycins</em></td>
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<td><em>Macrolides</em></td>
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<td><em>Monobactams</em></td>
<td><em>Aminopenicillins</em></td>
<td><em>Trimethoprim/Sulfa</em></td>
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<td><em>Quinolones</em></td>
<td><em>Fourth-generation Cephalosporins</em></td>
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<td><em>Sulfonamides</em></td>
<td><em>Carbapenems</em></td>
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<td><em>Aminoglycosides</em></td>
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<td><em>Clindamycin</em></td>
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<td><em>Rifamycins</em></td>
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<td><em>Chloramphenicol</em></td>
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<td><em>Polymyxin</em></td>
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### Non-Medically Important
* Coccidiostats
* Ionophores
* Bacitracins
* Carbadox
* Flavomycins
* Tiamulin

* Zoetis antimicrobials in addendum
## VFD Impact on Product Categories

<table>
<thead>
<tr>
<th>Antibiotics</th>
<th>By December 2016</th>
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<tr>
<td>Medically important feed additive antibiotics</td>
<td>Affected by Guidance #213 and VFD regulation</td>
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<tr>
<td>Coccidiostats, ionophores and bacitracin when in combination with medically important antibiotics</td>
<td>Affected by Guidance #213 and VFD regulation</td>
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<tr>
<td>Coccidiostats, ionophores and bacitracin</td>
<td>Unaffected by Guidance #213 and VFD</td>
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<tr>
<td>Medically important water-soluble antibiotics</td>
<td>Convert to prescription status</td>
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<td>Extra-label use of medically important feed additive antibiotics</td>
<td>Continued prohibition</td>
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<tr>
<td>Medically important antibiotics used for growth promotion and/or feed efficiency</td>
<td>Not allowed</td>
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VFD: KEY REQUIREMENTS
OVERVIEW OF THE REVISED VFD REQUIREMENTS

- The regulation outlines the responsibilities of veterinarians, distributors and producers.
- Six months is the maximum length of time a VFD can be issued for by a veterinarian.
- Veterinarians, feed suppliers and producers must keep a copy of each VFD for two years.
- Extra-label use of medicated feed, including medicated feed containing a VFD drug or combination VFD drug, is not permitted.
### VFD REQUIREMENTS

**Issued by a licensed veterinarian based on a valid veterinarian-client-patient relationship (VCPR)**

**Complies with approved label**

**Includes required key components**

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A copy of the regulation can be found here: [https://www.federalregister.gov/articles/2015/06/03/2015-13393/veterinary-feed-directive](https://www.federalregister.gov/articles/2015/06/03/2015-13393/veterinary-feed-directive)
VFD REQUIREMENTS

Issued by a licensed veterinarian based on a valid veterinarian-client-patient relationship (VCPR)

• Issuing DVM must:
  – Be licensed to practice veterinary medicine in state where animals are fed
  – Be operating in the course of the veterinarian’s professional practice and in compliance with all applicable veterinary licensing and practice requirements
  – Issue a VFD in the context of a VCPR as defined by the state where the animals are fed

  – The following link provides a state by state list:
    • [http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm](http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm)
VFD REQUIREMENTS

Complies with approved label

- Extra-label use of medicated feed, including medicated feed containing a VFD drug or a combination VFD drug, is not permitted.

- The VFD must include the statement: “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra-label use) is not permitted.”
VFD REQUIREMENTS

Includes required key components

- Veterinarian/Client information
- Medication information
- Animal information
Aureomycin VFD

Veterinary Feed Directive for Cattle

Aureomycin® (chlortetracycline)

Veterinarian: ____________________________
Client: ____________________________
Address: ____________________________
Phone #: ____________________________
Fax or email: ____________________________

Indications, Drug Level in Medicated Feed, and Duration of Use (select one and specify additional required information)

1) Growing Cattle (over 400 lb): For the reduction of the incidence of true abscesses.
   Drug Concentration: __________ gton (to provide 70 mg/head/day)
   Duration of Feeding: __________ days

2) Beef Cattle: Control of bacterial pneumonia associated with shipping fever complex caused by Pasteurella spp. susceptible to chlortetracycline.
   Drug Concentration: __________ gton (to provide 350 mg/head/day)
   Duration of Feeding: __________ days

3) Beef Cattle (under 700 lb): Control of active infection of anaplasmosis caused by Anaplasma marginale susceptible to chlortetracycline.
   Drug Concentration: __________ gton (to provide 350 mg/head/day)
   Duration of Feeding: __________ days

4) Beef Cattle (over 700 lb): Control of active infection of anaplasmosis caused by Anaplasma marginale susceptible to chlortetracycline.
   Drug Concentration: __________ gton (to provide 0.5 mg/lb body weight/day)
   Duration of Feeding: __________ days

5) Beef and Non-Isolating Dairy Cattle: As an aid in control of active infection of anaplasmosis caused by Anaplasma marginale susceptible to chlortetracycline when delivered in a free-choice feed.
   Drug Concentration: ____________________________
   6000 gton (to provide 0.5 to 2.0 mg/lb body weight/day)
   5000 gton (to provide 0.5 to 2.0 mg/lb body weight/day)
   5000 gton (to provide 0.5 to 2.0 mg/lb body weight/day)
   7000 gton (to provide 0.5 to 2.0 mg/lb body weight/day)
   Duration of Feeding: __________ days

6) Calves, Beef and Non-Isolating Dairy Cattle: Treatment of bacterial enteritis caused by Escherichia coli and bacterial pneumonia caused by Pasteurella multocida organisms susceptible to chlortetracycline.
   Drug Concentration: ____________________________
   Complete Feed __________ gton (500 to 4,000 gton to provide 10 mg/lb body weight/day)
   Top Dress __________ gton (0.006 to 0.001 gton to provide 10 mg/lb body weight/day)
   Duration of Feeding: __________ days (Feed for not more than 5 days)

Use of Feed containing this Veterinary Feed Directive (VFD) drug in a manner other than as directed on the labeling (extra-label use) is not permitted.

Affirmation of Intent (for combination VFD drugs): check the appropriate 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 drugs.

☐ This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indigested combination(s) in medicated feed that contains the VFD drug(s) as a component.


☐ This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or needed combination(s) in medicated feed that contains the VFD drug(s) as a component.

Warning: No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Date of VFD issuance: ____________________________
Date of VFD expiration: ____________________________

Veterinarian’s signature: ____________________________

Premise or Location of cattle: ____________________________
Special Instructions and other animal identifications: ____________________________

Color Copy – Verifiable
Color X Copy – Dropship
Color Y Copy – Client
Veterinary Feed Directive for Beef Cattle
AUREO® S 700 Granular
(chlortetracycline and sulfamethazine)

Veterinarian: ________________________________  Client: ________________________________
Address: ________________________________  Business or Home Address: ________________________________
Phone #: ________________________________  Phone #: ________________________________
FAX or email: (optional) ________________________________  FAX or email: (optional) ________________________________

Drug Levels: ________________________________ g/day each for chlortetracycline and sulfamethazine (specify level to provide 350 mg/head/day chlortetracycline and 350 mg/head/day sulfamethazine)

Duration of Use: Feed for 28 days

Indications for Use:
Beef Cattle: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRA-LABEL USE) IS NOT PERMITTED.

Approximate number of Beef Cattle to be treated: ________________________________
Premise or Location of animals: ________________________________

Special Instructions and/or other animal identifications:

Affirmation of Intent (for combination VFD drugs):
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.

Warning: Withdraw 7 days prior to slaughter.

A withdrawal period has not been established for this product in pre-ruminating calves.
Do not use in calves to be processed for veal.

Date of VFD Issuance: _______(dd/mm/yyyy)   Date of VFD Expiration: _______(dd/mm/yyyy)
(Cannot exceed 6 months after issuance)

Veterinarian’s signature: ________________________________

Color 2 Original – Veterinarian    Color X Copy – Supplier    Color Y Copy – Client
All parties must retain a copy of this VFD for 2 years after issuance
Veterinary Feed Directive for Swine
AUREOMIX® S 40/40 Granular
(chlortetracycline and sulfamethazine)

Veterinarian: ___________________________________  Client: ___________________________________
Address: ___________________________________  Business or
Home Address: ___________________________________
Phone #: ___________________________________  Phone #: ___________________________________
FAX or email: (optional) ___________________________  FAX or email: (optional) ___________________________

Drug Levels: 100 g chlortetracycline and 100 g sulfamethazine per ton.
Duration of Use: ______ days

Indications for Use: Swine: For reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis
(salmonellosis or necrotic enteritis caused by Salmonella choleraesuis and vibriotic dysentery); prevention of these
diseases during times of stress; and maintenance of weight gains in the presence of atrophic rhinitis.

USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS
DIRECTED ON THE LABELING (EXTRA-LABEL USE) IS NOT PERMITTED.

Approximate number of Swine to be treated: _______________________
Premise or Location of animals: ________________________________

Special Instructions and/or other animal identifications:

Affirmation of Intent (for combination VFD drugs):
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.

Warning: Withdraw 15 days prior to slaughter.

Date of VFD Issuance: _______ (dd/mm/yyyy)  Date of VFD Expiration: _______ (dd/mm/yyyy)
(Cannot exceed 6 months after issuance)

Veterinarian’s signature: ___________________________

Color Z Original – Veterinarian  Color X Copy – Supplier  Color Y Copy – Client
All parties must retain a copy of this VFD for 2 years after issuance
VFD: STEPS TO IMPLEMENT BY JAN. 1, 2017
SUGGESTED NEXT STEPS FOR PRODUCERS

- Get ready to implement by Jan. 1, 2017
- Establish a valid veterinarian-client-patient relationship (VCPR)
- Review list of current medications to determine what might require a VFD
- Begin discussions about how the new VFD regulation will impact use of products
- Have operations create a VFD “lead”
- Discuss record-keeping procedures

WE ARE COMMITTED TO SUPPORTING YOU IN THE RESPONSIBLE USE OF ANTIBIOTICS AND PREPARING FOR A SMOOTH TRANSITION TO THE NEW VFD REQUIREMENTS.
Transition labeling will begin to appear in the market early to mid-2016.

- **June 2016**: Sponsors must submit all revised labeling to Center for Veterinary Medicine.
- **Dec 8-10, 2016**: Removal of growth promoting claim from medically important medicated feed additives begins.
- **Jan 1, 2017**: New VFD label requirements are instituted.
New Callouts
TRANSITION LABELING DURING 2016*

Beginning January 1, 2017:
This product will require a veterinary feed directive issued by a licensed veterinarian and will be subject to the following restriction:

"Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian."¹

This product will no longer be approved for the indications of: increased rate of weight gain and improved feed efficiency which means the use of this product for these purposes will no longer be legal after that date.

¹ 21 CFR 558.6 (a) (6)

Beginning January 1, 2017, this product will require a veterinary feed directive issued by a licensed veterinarian and will be subject to the following restriction:

"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) (6))

Effective January 1, 2017, this product will no longer be approved for the indications of: increased rate of weight gain and improved feed efficiency which means the use of this product for these purposes will no longer be legal after that date.

* Transition labeling could be seen during the first half of 2016
“Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.”

“Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra-label use) is not permitted.”
FDA Inspection (Feed Distributor/DVM)

• First Stop is the Feed Dealer/Distributor and they will obtain several VFD’s
  – The inspector will review the VFD’s for accuracy (Is the form filled out correctly)
  – At the feed dealer the inspector will also check for the submission of a distribution letter, possession of necessary acknowledgement letters, proper VFD document storage (2 years), proper label statements, and then routine feed mill GMP issues.

• DVM Questions:
  – Is the DVM licensed in the states VFD is being fed?
  – Does the DVM know the VCPR requirements in their state and or federal requirements and can they demonstrate proper VCPR with the location getting medicated feed?
  – Does the veterinarian keep copies of the VCPR as required by regulation.
FDA Inspection: Producer

• Does the client keep copies of VFD orders for at least 2 years?
• Did the client feed the VFD feed to the authorized number of animals on the VFD order?
• Did the client feed the VFD feed for the identified duration on the VFD order?
• Did the client stop feeding the VFD feed prior to the expiration date on the VFD order?
• Did the client follow the withdrawal period for the VFD feed, if any?
• Did the client follow any special instructions or caution statements on the VFD order, if any?
• If a combination VFD feed was fed, was its use consistent with the affirmation statement on the VFD order?
• Does the client have labels for VFD feeds? If Yes,
  – Does the feed label contain the VFD Caution statement?
  – Did the drug level on the label match the drug level on the VFD form?
  – Is the drug level and indication on the VFD form consistent with the approval?
VFD: KEY TAKEAWAYS AND RESOURCES
VFD: KEY TAKEAWAYS

☑ As of Jan. 1, 2017, all medicated feed additives containing medically important antibiotics must be prescribed through a VFD.

☑ No extra-label use of products.

☑ All VFDs will have a maximum of a six-month expiration date (unless otherwise noted on the product label).

☑ The veterinarian, distributor and client all must maintain a copy of VFD records for two years.

☑ A VCPR should be established.

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

John W. Hallberg, D.V.M., PhD
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