VETERINARY FEED DIRECTIVE

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Zoetis
AGENDA

• What is the VFD
• How did we get here --- Judicious Use
• Guidance Documents
• VFD Update
  – Final ruling
  – Notable changes
  – Products
WHAT IS THE VETERINARY FEED DIRECTIVE (VFD)?
VETERINARY FEED DIRECTIVE

STATUS

- Who has not heard of the VFD?

WHAT IT IS

- Establishes requirements relating to the distribution and use of VFD (veterinary feed directive) drugs and animal feeds containing such drugs

- A ‘prescription’ to use antibiotics in the feed
HOW DID WE GET HERE ---
JUDICIOUS USE
VFDs, ANTIBIOTIC RESISTANCE – HOW DID WE GET HERE?

SPECIAL INTEREST GROUPS

Drug dependent.
Factory farms feed antibiotics to offset crowding and bad sanitation.

Human antibiotics are fed routinely to livestock.
And it’s making human diseases harder to cure.

Contamination Alert: Superbugs in our food
90% of meat sold in stores is exposed to dangerous antibiotic-resistant bacteria.

LEARN MORE
VFDs, ANTIBIOTIC RESISTANCE – HOW DID WE GET HERE?

LEGISLATION

PAMTA (PRESERVATION OF ANTIBIOTICS FOR MEDICAL TREATMENT ACT)

- Introduced 2007, again in 2013, and 2015
- Bans growth, prevention, and control uses of feed administered antibiotics of shared classes

**Disease Treatment**
Administration to an animal or group of animals which exhibit clinical disease

**Disease Control**
Administration to an animal or group of animals which exceed baseline expected health outcomes

**Disease Prevention**
Administration to an animal or group of animals which are considered at risk prior to onset of clinical disease

**Growth, Nutrition, Health Maintenance**
Administration to an animal or group of animals that results in improved performance
VFDs, ANTIBIOTIC RESISTANCE – HOW DID WE GET HERE?

LEGISLATION

PRESIDENTIAL FORUM FOR ANTIBIOTIC RESISTANCE

- September 2014 Prioritizes federal efforts to combat the rise in antibiotic-resistant bacteria
  - Executive Order 13676
  - National Strategy on Combating Antibiotic-Resistant Bacteria issued
  - President’s Council of Advisors on Science and Technology (PCAST)

- March 2015
  - Administration released the National Action Plan for Combating Antibiotic-Resistant Bacteria

- June 2, 2015
  - White House Forum on Antibiotic Stewardship
  - Presidential Memorandum signed
GUIDANCE DOCUMENTS
## GUIDANCE DOCUMENTS

### GOVERNMENT AGENCIES

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GUIDANCE 152 – THE WHO

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<td>Penase Resistant Pens</td>
<td>(Sulfadimethoxine/ormetoprim)</td>
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<td>Antipseudomonal Pens</td>
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<td>Aminopenicillins</td>
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<td>4&lt;sup&gt;th&lt;/sup&gt; Gen Cephalosporins</td>
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<td>Carbapenems</td>
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<td>Aminoglycosides</td>
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<td>Pyrazinamides</td>
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<td>Pyrazinamide</td>
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<td>Bacintracins</td>
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<td>Flavomycins</td>
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GUIDANCE 209 – DESTINATION

• Finalized April 13, 2013

• Judicious Use of Antibiotics Principles

  “Limiting medically important antimicrobial drugs in food-producing animals that are considered necessary for assuring animal health”

  “Limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation”
GUIDANCE 209 – DESTINATION

• Judicious use applies to:
  – Medicated feed antibiotics
  – Water soluble antibiotics
  – Treatment, control and prevention of disease

• Judicious use does not apply to:
  – Growth promotion or improving feed efficiency
VFDs, ANTIBIOTIC RESISTANCE – HOW DID WE GET HERE?

GUIDANCE 209 – JUDICIOUS USE

THERAPEUTIC USES

- Disease Treatment: Administration to an animal or group of animals which exhibit clinical disease
- Disease Control: Administration to an animal or group of animals which exceed baseline expected health outcomes
- Disease Prevention: Administration to an animal or group of animals which are considered at risk, but prior to onset of clinical disease

Growth, Nutrition, Health Maintenance: Administration to an animal or group of animals which results in improved performance
GUIDANCE 213 – ROAD MAP

• Finalized December 12, 2013

• Process for industry to implement 209
  – Remove growth promoting claim
  – Move OTC to VFD for medically important feed antimicrobials
  – Move OTC to Rx for medically important water antimicrobials

• 3 year transition period
VETERINARY FEED DIRECTIVE
VFD – FINAL RULING

• Over 2000 individual comments received
  – Veterinary, feed manufacturing, and animal production associations
  – Consumer advocacy groups and individuals

• Clarify
  – Definitions
  – General requirements for VFD drugs
  – Responsibilities of the VFD drug sponsor
  – Responsibilities of the veterinarian issuing the VFD
  – Responsibilities of any person who distributes an animal feed containing a VFD drug
VFD – NOTABLE CHANGES

CATEGORY II

• Category I
  – Do not require a withdrawal period

• Category II
  – Require a withdrawal period
  – Zero tolerance because of a carcinogenic concern, regardless of whether withdrawal period is required

• Definition of "Category II" is revised
  – Removes the automatic Category II designation for VFD drugs
  – Categorization of VFD drugs will be determined on a case-by-case basis based on the likelihood that the drug will produce an unsafe residue in edible products derived from treated animals
VFD – NOTABLE CHANGES

DISTRIBUTOR DEFINITION

- The term "distributor" is revised to use "distributes" instead of "consigns" as had been proposed.

- A person who distributes a medicated feed containing a VFD drug to another distributor or end user.

- Distributor
  - Maintains receipt and distribution records for two years.
  - Maintains manufacturing records for one year.
VFD – NOTABLE CHANGES

RECORD KEEPING REQUIREMENTS

• Clarifies the veterinarian is required to keep original VFD (hardcopy or electronically) and distributor and client must keep a copy of the VFD (hardcopy or electronically)

• VFD copies and records of receipt and distribution of VFD feed must be kept for 2 years
VFD – NOTABLE CHANGES

VETERINARIAN-CLIENT-PATIENT RELATIONSHIP

- Veterinarian must issue VFD in the context of a valid veterinarian-client-patient relationship (VCPR) as defined by State requirements applicable to where the veterinarian practices veterinary medicine
  - FDA determines which states have VCPR with the key elements
    - Engage with client to assume responsibility for making clinical judgments about patient health
    - Sufficient knowledge of patient by virtue of patient exam and/or visits to facility
    - Provide any necessary follow up evaluation or care
  - In States that lack appropriate VCPR requirements applicable to VFDs, the veterinarian must issue the VFD consistent with the Federally defined VCPR standard
VFD – NOTABLE CHANGES

LICENSURE

- The veterinarian needs to be in compliance with licensing requirements in the state(s) in which they practice veterinary medicine

- Veterinary licensure information is not required on the VFD
VFD – NOTABLE CHANGES

LABELING

- All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs must prominently and conspicuously display the following cautionary statement:
  - “Caution: Federal law restricts medicated feed containing this VFD drug to use by or on the order of a licensed veterinarian”
VFD – NOTABLE CHANGES

PIONEER OR GENERIC

• Veterinarian must specify that substitution is NOT allowed
  – If not specified the manufacturer can use either the pioneer or generic

• May NOT substitute a generic for a pioneer if generic does not have the approved combination
VFD – NOTABLE CHANGES

EXPIRY DATE

- Expiration date is the date that authorization to feed the VFD feed to animals expires
- Use expiry date specified on the approval
- No longer than 6 months, when not specified on approval
- Animals must not be fed VFD feed after expiration date on VFD
- Calculate based on calendar…not number of days
  - Written July 10, 2017 expires January 10, 2018
  - Written August 31, 2017 expires February 28 (29), 2018
VFD – NOTABLE CHANGES

APPROXIMATE NUMBER OF ANIMALS

- Potential number of animals that will be fed the VFD feed at the specified premises by the expiration date of the VFD

- No requirement to calculate amount of feed to be fed
  - Identify duration of use
  - Identify level of drug
VFD – NOTABLE CHANGES

COMBINATION APPROVALS

- Clarifies affirmation of intent statements to be used in VFDs

- Indicates whether a VFD drug may be used in conjunction with another drug in an approved, combination VFD feed
  - Any approved combination
  - Only specific approved combinations
  - May not be used in approved combinations
VFD example

Veterinary Feed Directive

Veterinarian: _____________________  Client: _____________________
Address: _________________________  Address: _________________________
Phone: _____________________________  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): ______________________________

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

VFD Date of Issuance: __________ (Month/Day/Year)  VFD Expiration Date: __________ (Month/Day/Year) (As specified in the approval; cannot exceed 6 months after issuance)

Approximate Number of Animals: ________________________________

Premises: ________________________________

Other Identification (e.g., age, weight) (optional): ________________________________

Special instructions (if any): ________________________________

Affirmation of intent (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 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:

<table>
<thead>
<tr>
<th>Drug(s)</th>
<th>Drug Level(s) and any Special Instructions</th>
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☐ 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: ________________________________

White copy: Supplier  Canary copy: Client  Pink copy: Veterinarian
VFD – NOTABLE CHANGES

SPECIFIC OBLIGATIONS TO PROTECT PUBLIC HEALTH

• Veterinarian
  – Professional judgment to determine whether a VFD should be issued and what terms it should contain
    • No extra-label use in feed additives is allowed
  – Licensed to practice veterinary medicine and operating in compliance with state’s requirements
  – Ensure all VFD information is complete and accurate
  – Provide copy to distributor and client
  – Maintain records for two years
VFD – NOTABLE CHANGES

SPECIFIC OBLIGATIONS TO PROTECT PUBLIC HEALTH

• Distributor
  – Only fill VFDs if they contain all required information
  – Must notify FDA prior to first distribution of VFD feed
  – Must notify FDA of any address or ownership changes
  – Must obtain an AOD letter prior to distributing VFD feed to another distributor
  – Must have a copy of client’s VFD prior to selling VFD feed
  – Maintain records (receipt and distribution) for two years
  – Maintain manufacturing record for one year
VFD – NOTABLE CHANGES

SPECIFIC OBLIGATIONS TO PROTECT PUBLIC HEALTH

• Client
  – Feed VFD fed as indicated
  – Not fed VFD feed upon expiration
  – Maintain records for two years
ESTIMATED TIMELINE

2013

December, 2013: VFD Proposed Rule Published

March 12, 2014: VFD Comments Due

2014

June 2, 2015: Release of Final VFD

September 30, 2015: Rule is Effective

2015

December 8-10, 2016: FDA approves all VFD labels sequentially (Estimated)

January 1, 2017: Implementation

2016
QUESTIONS AND DISCUSSION
VETERINARY FEED DIRECTIVE

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