VFD
Veterinary Feed Directive

Agenda
• Background
• FDA regulations
• VFD
• Veterinary Client Patient Relationship (VCPR)
• Minor species
So how did we get here??

Antibiotic Usage Reporting – FDA 2012

95% of all antibiotic usage is in feed and water
FDA Guidance for Industry 152
Finalized 2003
“Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern”

- Discusses the use of antibiotics in herds or flocks for production purposes
- Classified all antibiotics into 2 classes
  - Medically Important for Human Use
  - Non-medically Important for Human Use

### Medically Important Antimicrobial Drugs

- **Critically Important**
  - Ceftiofur
  - Fluoroquinolones
  - Macrolides
  - Sulfas

- **Important**
  - Everything else

- **Highly Important**
  - Penicillins
  - Tetracyclines
  - Phenics

- **Not Important**
  - Ionophores
  - Bambermycins
  - Bacitracin
FDA Guidance for Industry 209
Released in 2010, Finalized 2012
“The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”

• Specifically addresses use of antibiotics in food producing animals for production or growth-enhancement purposes

FDA Rational

• Misuse and overuse of antimicrobial drugs enables antimicrobial resistant bacteria to increase in numbers
• Human important drugs must be used judiciously in both animal and human medicine to slow the development of resistance.
**Key Principles from GFI 209**

**Principle 1: The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health.**

**FDA Guidance for Industry 209**

Released in 2010, Finalized 2012

- FDA believes the use of medically important antimicrobial drugs in food-producing animals for **production** purposes (e.g., to promote growth or improve feed efficiency) represents an **injudicious (not judicious)** use of these important drugs
FDA Guidance for Industry 209
Released in 2010, Finalized 2012

- FDA considers uses that are associated with the treatment, control, or prevention of specific diseases, including administration through feed or water, to be uses that are necessary for assuring the health of food-producing animals

Key Principles from GFI 209

**Principle 2:** The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.
FDA Guidance for Industry 209
Released in 2010, Finalized 2012

• Most of the feed-use antimicrobial drugs are currently approved for over-the-counter use in food-producing animals for purposes that include the treatment, control, and prevention of disease as well as for production purposes

FDA Guidance for Industry 213
Released 2012, Finalized December 2013

• “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”
Summary of GFI 213

• Identifies medically important antimicrobials
  – All drugs listed in GFI 152 Appendix

• Describes the process for voluntarily phasing out antibiotics for production purposes

• Discusses the phasing in of veterinary oversight for all therapeutic uses of antibiotics in the feed or water

• Also provides a timeline for implementation (December 2016)

Take Home Message?

• Label indications for production purposes will be removed
  – Voluntary change
  – Effective December 2016
Take Home Message?

• Restrictions on OTC feed-grade or OTC water soluble antibiotics
  – Water soluble products will become Rx
  – Products used in or on feed will become VFD
• DOES NOT APPLY to injectable antibiotics

Take Home Message?

A Veterinary Feed Directive (VFD) will be required to:
  – Obtain and use antibiotics that are delivered in the feed
  – Obtain and use products that already contain an antibiotic
    • Bagged feeds, mineral blocks, milk replacer, etc.

• A prescription will be required to:
  – Obtain and use antibiotics that are delivered in the water
## Affected feed-use antibiotics

<table>
<thead>
<tr>
<th>Antimicrobial Class</th>
<th>Specific drugs approved for use in feed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminoglycosides</td>
<td>Apramycin, Hygromycin B, Neomycin, Streptomycin</td>
</tr>
<tr>
<td>Diaminopyrimidines</td>
<td>Ormetoprim</td>
</tr>
<tr>
<td>Lincosamides</td>
<td>Lincomycin</td>
</tr>
<tr>
<td>Macrolides</td>
<td>Erythromycin, Oleandomycin, Tylosin</td>
</tr>
<tr>
<td>Penicillins</td>
<td>Penicillin</td>
</tr>
<tr>
<td>Streptogramins</td>
<td>Virginiamycin</td>
</tr>
<tr>
<td>Sulfas</td>
<td>Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfapyridine, Sulfadiazine</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>Chlortetracycline, Oxytetracycline</td>
</tr>
</tbody>
</table>
### Affected water-use antibiotics

<table>
<thead>
<tr>
<th>Antimicrobial Class</th>
<th>Specific drugs approved for use in water</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminoglycosides</td>
<td>Apramycin, Gentamicin, Neomycin, Spectinomycin, Streptomycin</td>
</tr>
<tr>
<td>Lincosamides</td>
<td>Lincomycin</td>
</tr>
<tr>
<td>Macrolides</td>
<td>Carbomycin, Erythromycin, Tylosin</td>
</tr>
<tr>
<td>Penicillins</td>
<td>Penicillin</td>
</tr>
<tr>
<td>Sulfas</td>
<td>Sulfachloropyrazine, Sulfachlorpyridazine, Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfadoxinealine</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>Chlortetracycline, Oxytetracycline, Tetracycline</td>
</tr>
</tbody>
</table>

### Antibiotics NOT affected by Guidance 209/213

- Antibiotics that are already VFD or Rx based:
  - avilamycin, florfenicol, tilmicosin; or Rx - Tylosin.

- Antibiotics that are not medically important:
  - Ionophores (monensin, lasalocid, narasin (Skycis, etc.)
  - Bacitracin (BMD, bacitracin zinc)
  - Bambermycins (Flavomycin, GainPro)
  - Carbadox (Mecadox)

- Other drugs (that are not antibiotics), including:
  - Anthelmentics: Coumaphos, Fenbendazole, Ivermectin
  - Beta agonists: Ractopamine, Zilpaterol
  - Coccidiostats: Clopidol, Decoquinate, Diclazuril
Caveat

- While FDA believes that all medically important antimicrobial new animal drug products should be marketed with the appropriate professional oversight restriction, at this time FDA is most concerned with medically important antimicrobial new animal drugs and combination new animal drug products intended for use in or on the feed or water of food-producing animals.

Veterinary Feed Directive

- 1996 Animal Drug Availability Act
- Alternative status for feed medication
- Written directive
- Requires VCPR
Veterinary Feed Directive (VFD)

• An order for utilizing “medically important” antibiotics in animal feed.
  – Functionally works just like a prescription
  – Technically not a prescription

• It requires a VFD from a veterinarian with whom the producer has a valid VCPR.
  – Veterinarian is responsible for filling it out correctly, based on the correct information from the producer.

• Producer (or the veterinarian) will need to get the VFD to the feed mill to manufacture the feed.

Veterinary Feed Directive (VFD)

• New Requirements:
  – VCPR
    • State or Federal
  – Electronic signature and transmittal acceptable
    • Telephone VFDs still not allowed
  – Estimate of tons of feed no longer required
    • Replaced by estimate of number of animals
Extra-Label Drug Use (ELDU)

- Extra-label use of feed additive antibiotics is **illegal**
  - Extra-label use is using a drug at a **dose**, by a **route**, for a **condition or indication**, in a **species**, or for a **duration** not described on the label

Implementation Timeline Summary

- **January 1, 2017**
- Implementation date for all medically important antimicrobials for use in or on feed to require a VFD
What do you need to do for a VFD

• Working relationship with your veterinarian (VCPR)

Veterinarian-Client-Patient-Relationship (VCPR)

1. A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

2. There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

3. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.
VCPR Clarification

• Veterinarian must be licensed in state where animals reside
• Veterinarian does not need to make diagnosis but responsible for disease diagnosis protocol and training
• Livestock producer/management willing to abide by protocol

Veterinary Feed Directive

Veterinarian: Grant Dewell
Address: 1600 S 16th Street
Ames, IA 50011
Phone: 515-284-7595
Fax or email (optional):

Client: XYZ Feedlot
Address: 1234 B Ave
Ames, IA 50011
Phone: 515-123-4567
Fax or email (optional):
Drug(s): Tylosin Phosphate

Drug Level: 10 g/ton

No substitutions allowed

Duration of Use: Continuously

Species and production class: Beef cattle

Indications for use: Reduction of incidence of liver abscesses associated with Fusobacterium necrophorum and Arcanobacterium pyogenes

Caution (if any): No refills/reorders authorized

IOWA STATE UNIVERSITY
Extension and Outreach

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

Approximate number of animals: 999
Premises: 234 B Ave, Ames, IA 50011
Other identification (e.g., age, weight) (optional):

Special instructions (if any):

IOWA STATE UNIVERSITY
Extension and Outreach
Affirmation of intent (for combination of VFD drugs) (mark one statement)

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>
</tr>
</thead>
<tbody>
<tr>
<td>Drug(s)_Row_1</td>
<td></td>
</tr>
</tbody>
</table>

Affirmation of intent (for combination of VFD drugs) (mark one statement)

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.
Producer Responsibilities

- Only use feed containing VFD drug with a valid VFD issued by licensed veterinarian
- Follow VFD/label directions in terms of dose, duration, etc.
- Do not feed VFD feed after expiration date
- Provide a copy VFD order to feed distributor if necessary
- Maintain copy of VFD for 2 years
- Provide VFD orders to FDA on request
FDA Expectations

• Expect reduction in quantity of medically important antibiotics
• Expect Veterinarians to be gatekeeper

Inspections

• FDA beginning VFD inspections “Pilot Project”
• First inspect distributors
  – Will evaluate 3 randomly selected VFD forms
  – Will pick 1 to trace back to veterinarian and producer
• Looking for all the required information, evidence of VCPR, feed records, etc.
Enforcement

• Focus will initially be on education and guidance

Minor Species

• CPG Sec 615.115 Extra-Label Use of Medicated Feeds for Minor Species
  • The use or intended use of medicated feeds for treating animals in any manner other than in accordance with the approved labeling causes the drug used in the feed to be adulterated
Minor Species

- Nevertheless, extra-label use of medicated feed for treatment of minor species may be considered when the health of animals is threatened and suffering or death would result from failure to treat the affected animals. In instances of this nature, the agency will not ordinarily consider regulatory action against the veterinarian or animal producer provided all of the circumstances listed below exist.

Minor Species

- Only for treatment of minor species
- Drug approved for major species
- Feed approved major species
- Express prior written recommendation veterinarian, oversight, VCPR
Minor Species

- FDA currently reviewing this policy
- Expect a new policy related to ELDU VFD drugs for Minor Species

Minor Species

- Feedmills are unwilling to formulate VFD feed ELDU
- Expect it will still be allowable in the future
- Source?
Thank You