What’s Next With Antibiotic Use on Farms?

VFDs: What/Why/How/What next?

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Antibiotics

• Medications kill disease causing bacteria
• Veterinary Access: OTC & Rx: topical, injectable

Use of all antimicrobials, in human or animals alike, contributes to the development of antimicrobial-resistant bacteria, considered a global threat to public health. It could be fatal if enter human body through improperly prepared food.
Access to Antibiotics

• Human Medical Community
  • AMA Continues Efforts to Combat Antibiotic Resistance, Nov. 16, 2015

Access to Antibiotics

• Veterinary Medical Community
  • the prevention and relief of animal suffering
  • AVMA Judicious Therapeutic Use of Antimicrobials
Access to Antibiotics

• Consumer Attitudes
  • Experts warn about scary new antibiotic-resistant bugs. Published: July 02, 2015 02:00 PM: Consumer Reports

In the world of food consumers purchase....

WHAT THEY TRUST!
Access to Antibiotics

• A public health issue
• Access to effective antibiotics:
  - Critical for public health
  - Vital for livestock & poultry production
  - Essential for animal well-being

Access to Antibiotics

• U.S. Food and Drug Administration:
  - Antibiotic resistance issues in livestock
  - Concerned overuse in animals may reduce effectiveness in humans

Goal

- promote judicious use
- protect public health
- curb resistance development
When did the FDA really start working with antibiotic resistance issues in livestock?

- Drugs like Oxytetracycline, PenG, Tylan and Erythromycin had become less and less effective for treating diseases such as pneumonia.
- AMDUCA became law in 1994, gave vet the opportunity to write prescriptions.

What came with AMDUCA?

- Extra Label Drug Use” (ELUD).
- It applied to over the counter (OTC) medications like Penicillin G.
- Causing a violative drug residue is a criminal offense.
Access to Antibiotics

• 1996: Congress enacted the Animal Drug Availability Act
• Facilitate approval and marketing of new animal drugs and medicated feeds
• New category: veterinary feed directive drugs
  • Under veterinary order and professional supervision

FDA developed an antibiotic resistance potential grid (GFI 152)

<table>
<thead>
<tr>
<th>ANTIBIOTIC IMPORTANCE</th>
<th>LENGTH OF TIME BACTERIA ARE EXPOSED TO THE ANTIBIOTIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critically Important Antibiotic</td>
<td>Less than 7 days</td>
</tr>
<tr>
<td>(Ex: Ciprofloxacin, Baytril)</td>
<td>Would allow in livestock if a veterinarian was involved</td>
</tr>
<tr>
<td>Antibiotic Important to Humans</td>
<td>Allowed in livestock ONLY for disease treatment, prevention or control</td>
</tr>
<tr>
<td>(Ex: PenG, Tetracyclines, Macrolides such as Tylan)</td>
<td>Allowed in livestock</td>
</tr>
<tr>
<td>Antibiotic Not Important to Humans</td>
<td>Allowed in livestock</td>
</tr>
<tr>
<td>(Ex: Monensin, Bambermycin)</td>
<td></td>
</tr>
</tbody>
</table>
Livestock Producers ... Stuck would get no new feed use antibiotics

• nothing new was going to be available to help manage health problems in their livestock.
• It is important to remember we have very good products to control coccidia ...
  • Bovatec
  • Deccox
  • Rumensin

Access to Antibiotics

• FDA issues 3 documents proposing to modify use of medically important antibiotics in food-producing animals

Guidance for Industry (GFI) #209  Guidance for Industry (GFI) #213  CFR 558
What is a VFD Drug?

- Medically Important Drug
- Antimicrobial
- Medically important to humans
  - Used by both animals and humans

VFD Modernization

- Final rule June 3, 2015
- Effective Oct. 1, 2015
- Enforceable Jan 1, 2017

Two Overarching Principles:
- Judicious Use: treatment, control, prevention
- Veterinarian oversight: VCPR
Guidance for Industry #209

- **Use of medically important antimicrobial drugs** in food-producing animals should be limited to:

  1. Uses necessary to assure animal health
     - Prevention
     - Control
     - Treatment

  2. Uses that include veterinary oversight
     - Feed: OTC to VFD
     - Water: Rx

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Phase Out Performance Indications

- **Therapeutic uses (still allowed)**
  - Disease treatment
    - Administration of an antimicrobial to an animal or group of animals that exhibit clinical disease
  - Disease control
    - Administration of an antimicrobial to an animal or group of animals in which morbidity or mortality has exceeded baselines
  - Disease prevention
    - Administration of an antimicrobial to an animal or group of animals that are considered to be at risk, but prior to onset of clinical disease

- **Performance uses (prohibited)**
  - Growth, nutrition, health maintenance
    - Administration of an antimicrobial to an animal or group of animals that results in improved performance, ie, weight gain or feed conversion
## Products Affected vs. Unaffected

<table>
<thead>
<tr>
<th>Unaffected</th>
<th>Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-Medically Important</strong></td>
<td><strong>Medically Important</strong></td>
</tr>
<tr>
<td>- Ionophores (Rumensin®)</td>
<td>- Penicillins</td>
</tr>
<tr>
<td>- Coccidiostats</td>
<td>- Cephalosporins</td>
</tr>
<tr>
<td>- Polypeptides</td>
<td>- Quinolones</td>
</tr>
<tr>
<td>- Carbadox</td>
<td>- Fluoroquinolones</td>
</tr>
<tr>
<td>- Bambermycin</td>
<td>- Tetracyclines</td>
</tr>
<tr>
<td>- Pleuromutilin</td>
<td>- Macrolides</td>
</tr>
<tr>
<td></td>
<td>- Sulfas</td>
</tr>
<tr>
<td></td>
<td>- Glycopeptides</td>
</tr>
<tr>
<td></td>
<td>- Others</td>
</tr>
</tbody>
</table>

Therapeutic uses — still allowed under veterinary supervision
- Treat
- Control
- Prevent

Production uses allowed
Production uses Not allowed

### What will the new labels look like?

![Image of labeled products]
What is a Veterinary Feed Directive?

- Written statement
  - issued by a licensed veterinarian in the course of his/her professional practice
  - Valid VCPR
  - orders the use of a VFD drug or combination VFD drug
VFD Paper Work: “Will be a #@! Pain”

- FDA has streamlined some required paper work
- Free enterprise has stepped up

VALID Veterinary Client/Patient RELATIONSHIP

- DVM
  - Engage with the client to assume responsibility for making clinical judgements about patient health
  - Have sufficient knowledge of the patient
    - Examination
    - Appropriate visits to the facility where patient is managed
  - Provide necessary follow-up evaluation or care
Client’s Responsibilities

- Ensure only those intended animals covered under the VFD receive the VFD feed
  - Fed per label: duration date
  - Fed prior to the VFD order expiration date
- Copy of VFD to the feed distributor
- Maintain each VFD copy for two years
- Provide VFD orders for inspection if requested by FDA

### Client’s Responsibilities Table

<table>
<thead>
<tr>
<th>Date began feeding</th>
<th>Location Description and/or Premis ID</th>
<th>Animal Description and ID</th>
<th>VFD Drug and how applied</th>
<th>Date finished Duration from the label</th>
<th>Withdrawal date Calculate from the label</th>
<th>Veterinarian</th>
<th>VFD Expiration date</th>
<th>Where Purchased From</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/2/2017</td>
<td>Dad’s heifer barn</td>
<td>ear tags 301-334</td>
<td>Aureomycin Feed</td>
<td>28 days: 3/2/17</td>
<td>7 days: 3/9/17</td>
<td>Dr. VCPR</td>
<td>5/4/2017</td>
<td>Sunshine Feeds</td>
</tr>
</tbody>
</table>

access the VFD Summary Sheet
Visit WI Beef Information Center
http://fyi.uwex.edu/wbic
Client’s Responsibilities

- On-farm evaluations
  - Inventory
  - HACCP
  - BQA Certification

- Find, hire, keep .......

VALID VETERINARY RELATIONSHIP
Do you “enthusiastically endorse” these new rules?

- With “production use” labeling gone ...
  - Comes opportunity for FDA approval of several new VFD medications.
  - The one VFD made available thus far is far superior for treatment of pneumonia than any antibiotic that has been available in the past.
  - Very realistic that others can be approved

What’s are you giving up?

- The data is so lacking ...
- NCBA’s “Antibiotic Prudent Use Guidelines”:
  - Sub-therapeutic antibiotic use is discouraged:
    - Antibiotics should be limited to prevent or control disease
    - And should not be used if the principle intent is to improve performance
Bottom Line … a decade from now

• If decreased antibiotic resistance ... we will all be glad we participated in helping the effort.

• If no change in antibiotic resistance ... the world will know the problem they blamed on us wasn’t of our making.

• FOR US ... new feed usage antibiotics

What’s Next?

• FDA Priority: collect more data about antimicrobial drug use in food-producing animals
  • Currently: sales and distribution
  • Next: species specific information
What’s Next?

California bans OTC antibiotics in food animals
October 12, 2015  By: Christy Corp-Minami, DVM  For The VIN News Service

• Bottles of penicillin and tetracycline on feed store shelves soon will be a thing of the past
• removing medically important antibiotics from all over-the-counter (OTC) use.

Thank-you!!

For Gracious use of slides used in this PowerPoint presentation
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• Larry Baumann, DVM, Professor and Extension Veterinarian, University of Wisconsin

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Visit WI Beef Information Center http://fyi.uwex.edu/wbic