Using Feed-Grade Antibiotics in Livestock: What Changes Should We Prepare For?

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Animal Antibiotics: Currently

- Injectable
- Oral Bolus
- Drinking Water
- Feed

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Animal Antibiotics: Currently Labeled Uses:
• Treatment of disease
• Control of disease
• Prevention of disease
• Feed efficiency
• Growth promotion

Animal Antibiotics: Currently

OTC
Injectable
OTC
Oral Bolus
OTC
Drinking Water
OTC
Feed

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**Animal Antibiotics: Currently**

**Veterinary Involvement**
- Rx injectables
- VFD feeds
- Extra-label use of OTC or Rx

**Veterinary Client Patient Relationship (VCPR)**
- Veterinarian has assumed responsibility for medical judgments about the animals and the client has agreed to follow the vet's instructions.
- 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 timely visits.
- Veterinarian is available for follow-up in case of adverse reactions or treatment failure

**Veterinary Involvement**
- Rx injectables
- VFD feeds
- Extra-label use of OTC or Rx
Veterinary Feed Directive

- Filled out by vet (VCPR in place)
- Feed mill must have VFD before feed can be distributed
  - Hard copy or fax
- Feed mills must notify FDA (once)
- Feed mills can sell VFD feeds to other feed mills if they get an acknowledgement letter
- Records kept for 2 years
Pulmotil® (tilmicosin) Swine Veterinary Feed Directive

Client: 
Address: 
Phone #: 
Fax #: 
Veterinarian: 
Address: 
Phone #: 
Fax #: 
Swine to be treated (number and location): 
Special instructions: 

Mix into Type C medicated feed to provide:

- total lbs. Type C feed at 181 g/ton
- total lbs. Type C feed at 272 g/ton
- total lbs. Type C feed at 363 g/ton

VFD expiration date: 
Month/Day/Year (not to exceed 90 days)
Amount of feed (Type C): 
Veterinarian’s signature: 
Date of treatment: 
License #: and state: 
Date written: 

Veterinary Feed Directive

Animal Antibiotics: Currently

Drinking Water 
Feed

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Antibiotic Resistance: “One of Our Most Serious Health Threats”

Estimated minimum number of illnesses and deaths caused by antibiotic resistance*:
At least 2,049,442 illnesses, 23,000 deaths

*bacteria and fungus included in this report

Urgent Threats
- Clostridium difficile
- Carbapenem-resistant Enterobacteriaceae (CRE)
- Drug-resistant Neisseria gonorrhoeae

Serious Threats
- Multidrug-resistant Acinetobacter
- Drug-resistant Campylobacter
- Fluconazole-resistant Candida (a fungus)
- Extended spectrum β-lactamase producing Enterobacteriaceae (ESBLs)
- Vancomycin-resistant Enterococcus (VRE)
- Multidrug-resistant Pseudomonas aeruginosa
- Drug-resistant Non-typhoidal Salmonella
- Drug-resistant Salmonella Typhi
- Drug-resistant Shigellosis
- Methicillin-resistant Staphylococcus aureus (MRSA)
- Drug-resistant Streptococcus pneumoniae
- Drug-resistant tuberculosis

Concerning Threats
- Vancomycin-resistant Staphylococcus aureus (VRSA)
- Erythromycin-resistant Group A Streptococcus
- Clindamycin-resistant Group B Streptococcus
Examples of How Antibiotic Resistance Spreads

- Animals get antibiotics and develop resistant bacteria in their guts.
- Drug-resistant bacteria can remain on meat from animals. When not handled or cooked properly, the bacteria can spread to humans.
- Drug-resistant bacteria in the animal feces can remain on crops and be eaten. These bacteria can remain in the human gut.
- George gets antibiotics and develops resistant bacteria in his gut.
- George stays at home and in the general community. Spreads resistant bacteria.
- Patients go home.
- Drug-resistant bacteria spread directly to other patients or indirectly on unclean hands of healthcare providers.
- Patients go home.
- Resistant bacteria spread to other patients from surfaces within the healthcare facility.
- George gets care at a hospital, nursing home or other inpatient care facility.

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

Pew Campaign on Human Health and Industrial Farming
FDA's Proposals

- Guidance for Industry #209
  - "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals"

- Guidance for Industry #213
  - "Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209"

- Veterinary Feed Directive proposed rule
FDA Guidance for Industry #209

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.

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: Medically Important Antibiotics

<table>
<thead>
<tr>
<th>Class of antibiotic</th>
<th>Feed-Grade Examples</th>
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</thead>
<tbody>
<tr>
<td>Aminoglycosides</td>
<td>Neomycin, Streptomycin</td>
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<tr>
<td>Lincosamides</td>
<td>Lincomix®</td>
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<tr>
<td>Macrolides</td>
<td>Pulmotil®</td>
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<tr>
<td>Penicillins</td>
<td>Penicillin, CSP</td>
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<tr>
<td>Streptogramins</td>
<td>Stafac®</td>
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<tr>
<td>Sulfonamides</td>
<td>Sulfamethazine, Aureomix®</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>Aureomycin®, CTC</td>
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</tbody>
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FDA Guidance for Industry #213

- Final as of December 2013
- For the drug companies
- For “medically important antibiotics”
- Asks companies to voluntarily revise their product labels to remove growth promotion and feed efficiency
- Provides for moving OTC products to Rx or VFD status
So… What will change?

- Growth promotion uses in feed no longer allowed
  1. Tetracyclines: CTC, Aureomycin, NeoTerra
  2. Stafac (virginiamycin)

- Use of “medically important” feed antibiotics will need a VFD

- Can only use for treatment, control, prevention
  1. Tetracyclines (CTC, Aureomycin, NeoTerra)
  2. Tylan
  3. Sulfamethazine (Aureomix)
  4. Stafac for liver abscesses
  5. Medicated milk replacers (w/ oxytetracycline, neomycin…)
So... What will change?

- Changes to the VFD process
  - Still under comment period
  - No longer need to estimate amount of feed consumed
    - Inclusion rate, animals to feed, duration
  - Expiration dates up to 6 months (maybe longer)
  - Electronic delivery
  - Reduce bookkeeping requirement to 1 year

So... What will Change?

- Who defines a valid Veterinary Client Patient Relationship
  - Will be left to each state's regulations or veterinary board
  - Veterinarian must be licensed in state where the animals are

- "Medically important" water medications will move to prescription status
What Won’t Change

- Use of non-“medically important” drugs:
  - Ionophores (Bovatec, Rumensin, etc.)
  - Coccidiosis treatments (Corid, Deccox, etc.)
  - Bacitracin (BMD)

- Ability to use the same products currently used for treatment, control, prevention
  - But will need a VFD now

- Injectable medication uses

- Extra-label uses of feed-grade medications
  - Is illegal now, will continue to be illegal

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What Won’t Change

- Ability for current feed mill operators to supply feed medications
  - VFD documentation and records need to be kept
  - VFD drugs will not automatically need to be handled only by licensed feed mills

- Need for veterinarians to be involved in medication decisions

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