Changes in Antibiotic Labeling
Veterinary Feed Directive

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Changes in Antibiotic Regulations

• How did we get here?
• What changes will occur?
• Getting prepared
Concerns with Antibiotic Use

• Antibiotic residues
• Contribution to antibiotic resistance in humans

Monitoring System for Residues

• USDA – Food Safety Inspection Service (FSIS)
• The domestic sampling plan includes:
  – Scheduled Samples
  – Inspector Generated Samples
Scheduled Samples

- Consists of random sampling of tissue from healthy appearing food animals who have passed ante-mortem inspection

Results from 2012 – All Species

- Approximately 5400 samples taken
- 12 violations (0.02%) – 9 of which were found in bob veal calves
Inspector Generated Samples
(High Risk Population for Antibiotic Use)

- Test animals with active lesions
  - Respiratory System (Pneumonia)
  - Reproductive System (Uterine Infection)
  - Musculo-skeletal System (Lame or Swollen Joints)
  - Secretory System (Mastitis)
  - Lymphoreticular (Liver disease, including abscess)
  - Wounds (open sores or lacerations)

- Test animals with apparent injection lesions
- Test animals from previous violators

Results from 2012 – All Species

- Approximately 215,000 samples taken
- Approximately 940 or 0.04% of samples were confirmed positive for a violative residue
- These carcasses never entered the food supply
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
- Contains the list of antibiotics used in livestock industry that FDA considers medically important in human medicine
Medically Important Antimicrobials

- Penicillins
- Tetracyclines
  - Chlortetracycline
  - Oxytetracycline
- Macrolides
  - Tylosin
  - Tilmicosin
  - Erythromycin
- Lincosamides
  - Lincomycin
- Streptogrammins
  - Virginiamycin
- Aminoglycosides
  - Gentamicin
  - Neomycin
- Sulfonamides
  - Only potentiated sulfonamides are listed in GFI 152 however the FDA-CVM has indicated all sulfas are medically important

Not listed in 152: Ionophores, Bacitracin, Bambermycins, Carbadox, Coccidiostats, Laidlomycin

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
Summary of GFI 209

• Begins with trying to build a case that production uses are detrimental to human health
• Transitions to discussing that administration of medically important antimicrobials to entire herd or flocks for production practices poses a qualitatively higher risk to public health (GFI 152)

Recommended 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.

**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 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

• Defines medically important antimicrobials
  – All drugs listed in GFI 152 Appendix
  – Does not include ionophores

• 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 – 3 years from the date of publication of the guidance (December 2016)
What does this Mean?

Increased rate of weight gain/improved feed efficiency indications removed from labels:

– Tetracyclines –
  • Chlortetracycline (Aureomycin®)
  • Oxytetracycline (Terramycin®)
  • Chlortetracycline/Sulfamethazine (AS-700®)

– Aminoglycosides
  • Neomycin w/ oxytet combos (Neo-Terramycin®)

– Streptogramins
  • Virginiamycin (V-Max®)

What does this Mean?

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
Important Points

• These changes **DO NOT** apply to ionophores such as Rumensin®, Bovatec®, Deccox® or Corid®

• A Veterinary Client Patient Relationship (VCPR) is required before a veterinarian can write a VFD or prescription

Missouri VCPR

"Veterinarian-client-patient relationship", the veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal and the need for medical treatment, and the client, owner or owner's agent has agreed to follow the instructions of the veterinarian. There is sufficient knowledge of the animal by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal. Veterinarian-client-patient relationship means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination or by medically appropriate and timely visits to the premises where the animal is kept. The practicing veterinarian is readily available for follow-up care in case of adverse reactions or failure of the prescribed course of therapy"
Important Points

• Extra-label use of feed grade antibiotics is illegal
  • Extra-label use is using a drug at a dose, by a route, for a condition or indication, or in a species not on the label
• Aureomycin® example
  • In cattle Aureomycin® is labeled for control of anaplasmosis, treatment of pneumonia and treatment of bacterial enteritis

Important Points

• Length of expiration date on a VFD is not to exceed 6 months if not specified on the antibiotic label
• The producer, veterinarian and distributor will need to keep a copy of the VFD on file for 2 years
Important Points

• Information your veterinarian will need from you to fill out a VFD
  – Production class – weaned calves, cows, etc
  – Approximate number of animals to be fed the medicated feed prior to the expiration date
  – Location of animals
  – If you are using other feed additives
  – Where you will get the medicated feed

Producer Responsibilities

21 CFR Part 558.6

1. Can only feed VFD feed upon receipt of valid VFD from vet
2. Follow VFD exactly, including withdrawal times
3. Do not feed VFD feed past the VFD expiration date
4. Do not transfer VFD feeds to another user
5. Feed only to the species/classes of animals specified on the VFD
6. Do not mix VFD feed with other medicated feeds unless authorized by the VFD
7. No off label or extra-label use
8. Keep VFD records a minimum of 2 years
9. Make records available to FDA for inspection upon request
Questions?