

Antimicrobial Resistance, FDA Draft Guidance 209 and Producer Planning

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What is a producer to do??

- Understand current issues
 - residues
 - resistant microbes
- Review history/global pressures
- Consider impacts on operation
- Evaluate alternatives
- **Act now!!**

Antimicrobial Resistance

- Swann Report – UK – 1969 – first salvo
- Not new USA issue – FDA proposed subtherapeutic Pen/tetracycline ban in 1977 – Congress acted
- Worldwide concern growing in developed countries
- Resistance selection happens – natural occurrence
- Critical question – Does antimicrobial use in animals cause a human public health risks??
- Research – equivocal?? Depends on reader interpretation/experiences and risk tolerance??

Draft Guidance 209

- Purpose
 - Outline FDA public health concerns
 - summarize key scientific reports
 - outline recommendations for “judicious” use in food-producing animals
- What is it??
 - NOT legally binding recommendations
 - Discussion document – indicates future actions
 - Recommendations apply to food-producing animals

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- Terms to remember
 - medically important drugs = drugs important as therapeutics in humans
 - Judicious use = used for treatment, control and prevention of animal diseases under rules
 - Injudicious use = all other animal drug usages
 - Therapeutic drugs – used to treat specific diseases
 - Subtherapeutic = low level animal drugs used for growth promotion and feed efficiency

Draft Guidance 209

- Principles for guidance – food producing animals
 - medically important drugs should be limited to uses necessary for assuring animal health
 - use should include veterinary oversight
- Factors for prevention use
 - evidence of drug effectiveness
 - use consistent with accepted veterinary practices
 - use linked to specific etiologic agent
 - use appropriately targeted
 - no reasonable alternatives

Supplemental activities

- Guidance #152
 - risk-based approval testing process for NADA
 - applies to food-animal uses primarily
 - makes use other than targeted to small groups or individual treatment difficult
- PAMTA – Preservation of Antibiotics for Medical Treatment Act – HR 1549
 - phase out of non-therapeutic use of medically important antibiotics in farm animals
 - currently stalled; but will be back????

International Activities

- 1986 – Sweden banned all AGP
- 1997 – EU ban of Avoparcin xrx @ vancomycin
 - VRE treatment – Vancomycin resistant Entrococcus
- 1998 - EU ban for AGP drugs – Tylan, spiramycin, zn bacitracin and virginiamycin
- 1999 – Danish removal of AGP drugs in grow-fin
- 2000 – Danish removal of AGP drugs in all ages
- 2005 – Danish ban on FQs; 2008 -cephalosporin

What is a producer to do today??

- Inventory of herd health – look for surprises
 - Gut health will be first victim
 - Chronic respiratory signs increase
 - Many current problems will be worsened
- Consider loss of feed additives in post-wean
- Consider impact of limited OTC availability
- Consider impact that further legal uses will be restricted for veterinarians and producers

What is a producer to do today??

- Consider weaning age – later = more adaptive
- Examine facilities for pig comfort
 - Warm, dry, draft-free mantra
 - Feed and water availability ; > competition for space
 - Reduce stress impacts on immune system
 - Biosecurity to limit disease entry
 - AIAO management and sanitation to reduce loads
- Consider immuno–suppressive diseases
 - PRRS
 - PCV2 and circovirus associated diseases

What is a producer to do today??

- Resident diseases – strategies needed
 - Non-antimicrobial control strategies
 - Vaccination capabilities
 - Control/eradication of microbes
 - Management/facilities changes
 - Treatment medication strategies – equipment??
 - Water medication – accurate and effective
 - Individual treatments - protocols

What is a producer to do??

- **Plan ahead!!!!**

- Issues will not go away – long history worldwide
- Public health concerns will be immediate emphasis
- **Environmental exposure will be recognized**
- Current feed antimicrobial practices will be curtailed
- Greater on-farm oversight will occur
- May become a trade issue for some countries

- **Don't shoot the messenger!!**