

Judicious Use Guidance: Current Thinking

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Purpose of Draft Guidance

- Discuss FDA's public health concerns with the use of medically important drugs in food-producing animals and impact on antimicrobial resistance
- Summarize key scientific findings on use of drugs in animal agriculture
- Outline FDA's recommendations for judicious use of these drugs in animal agriculture so the drugs remain effective in humans and animals

Importance of the Draft Guidance

- Medically important drugs must remain effective for use in humans and animals
- Antimicrobial resistance is a growing public concern
- Numerous scientific reports have raised concern over the use of these drugs in animal agriculture
- Proactive approach to address concerns

Definitions

- For purpose of document
 - Antimicrobial=antibacterial=antibiotic
 - Focus is on drugs directed at bacteria
- Medically important drugs
 - Antimicrobial drugs that are important in treating infectious diseases in people, particularly those caused by bacteria
 - Includes drugs like penicillin and tetracycline but a specific list of drugs has not yet been defined

Definitions

➤ Judicious use

- Using an antimicrobial drug only when necessary and appropriate
- Implied in the above is the use for treating, controlling or preventing an identified disease and the involvement of a person with knowledge to assure that the use is necessary and appropriate
- Production use is not a judicious use


Guiding Principles

- 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
- The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation
 - Possible improvements to VFD process important here

Antimicrobial Drugs of Most Concern

- Approved before implementation of GFI 152 in 2003
- Use in food-producing animals to increase production
- Are available over-the-counter (OTC) and can be given without veterinarian involvement
- Given continuously through feed or water to groups of animals

Implementation

- Actively work with drug sponsors, veterinary, public health and Ag communities
 - Implement in a way that protects animal and human health and
 - Minimizes impact on animal health or disruption to the animal agriculture industry
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Key Issues

- Effectiveness of collaboration with drug sponsors
- How to leverage the limited number of food-animal veterinarians
- Role of efficient VFD process
- How to prevent “prevention” from becoming the new production use
- Will regulatory action be necessary
- Congressional action?

Information

- Judicious use guidance document
 - www.fda.gov/animalveterinary
 - Under Key Topics select antimicrobial resistance
 - On antimicrobial resistance page select judicious use of antimicrobials
- Comments on draft
<http://www.regulations.gov>
- Comment period open until Aug 30, 2010

Salmonella CPG

- Revised version publishes 8/2/2010
- Applies to pet food and animal feed
- End points
 - Pet food—human health
 - Animal feed and feed ingredient—animal health
- Pet food
 - Any serotype detected can result in regulatory action

Salmonella CPG

- Animal feed and feed ingredients
 - Action based on serotypes known to cause disease in animals
 - Some exceptions (milk replacer)
- Poultry feed—pullorum, gallinarum, enteritidis
- Swine—choleraesuis
- Sheep—abortusovis
- Horse—Abortusequi
- Dairy & beef—dublin, newport