U.S. Food and Drug Administration

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CENTER FOR VETERINARY MEDICINE

FDA Initiatives Regarding the Judicious Use of Antibiotics in Food-Producing Animals

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Topics

- The public health concern
- Risk management measures (GFI #209)
- Implementation



The Public Health Concern -

- The use of antimicrobial drugs contributes to antimicrobial resistance development – leading to loss of effective therapies
  - All uses are contributors – human, animal, horticulture, other
  - However, the use of antimicrobial drugs in food-producing animals has been a particular focus of concern

The Public Health Concern -

- To address this concern –
  - In 1980's - FDA began approving all "new" antimicrobial products as Rx or VFD
  - In 1996 – National Antimicrobial Resistance Monitoring Program established
  - 1999 to 2003 – Process developed for addressing safety issue as part of animal drug approval process

The Public Health Concern -

- Since 2003, a process has been in place to provide assurance that new antibiotic products are safe and are used appropriately
  - Guidance (GFI #152) formalized a process for assessing resistance risks as part of the animal drug approval process – with focus on foodborne bacteria
  - Process has worked well to provide pathway for approving new products – while addressing public health concern

The Public Health Concern -

- Gap remaining – concerns about products that pre-date current assessment process
  - FDA believes this gap needs to be addressed
  - Congress – legislative initiatives
  - Public concerns

Managing Risks

The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals (GFI #209)

- Published as draft in June 2010
- "Guidance" represents agency current thinking on an issue; nonbinding recommendations

Why Guidance #209?

- Decision to take more proactive approach
- Provides framework for managing risk – addressing the “gap”
- Sets broad objectives around which to build consensus for progress forward
- As guidance – sets stage for implementing changes through a voluntary/collaborative approach

Draft Guidance #209 - Objectives

- Based on underlying principle that use is a driver of resistance – using drugs “judiciously” can help curb resistance emergence
  - Through more targeted drug use
  - By reducing unnecessary or inappropriate use
- Therefore, key objective is to identify measures for assuring that drugs are used as judiciously as possible

Draft Guidance #209 - Objectives

- Objective is not to ban drugs
- But rather to mitigate risks associated with their use
- While maintaining continued availability of drugs to combat disease in animals
  - including treatment, control, and prevention

Draft Guidance #209 - Scope

- Not all antimicrobials are affected
- Focus is on antimicrobial drugs that are:
  - considered medically important
  - administered through feed or water
- Others – use conditions unchanged
  - e.g., ionophores
  - Other drugs/classes to be determined

Key Recommendations of GFI #209

- Limit use of *medically important* antimicrobial drugs to those uses that
  - 1) are considered necessary for assuring animal health (i.e., to treat, control, or prevent disease) and
  - 2) include veterinary involvement/consultation

First Recommendation:

"*Limit use of medically important antimicrobial drugs to those uses that are considered necessary for assuring animal health*"

"*Necessary for assuring animal health*" is meant to refer to:

- uses directed at specifically identified disease
- to treat, control, or prevent disease
- including feed or water administration
- targeted to animals with clinical signs of disease or at risk of disease
- limited duration/targeted time period

"Production uses" (growth promotion/feed efficiency)

- Not considered "necessary for assuring animal health"
  - Do not target an identified disease
- Administered herd-wide or flock-wide
- Administered for extended durations

Implementing first recommendation

- Means phasing-out the use of medically important antimicrobials for production purposes
- But it also means maintaining the continued availability of these drugs to treat, control, and prevent disease

Implementation Concerns

- FDA acknowledges the concern raised that discontinuing growth promotion (GP) use of certain drugs may lead to increase in animal disease
- As part of developing implementation strategy, we have and continue to seek input on how best to address this concern
- Desire is to identify potential unmet animal health needs that may result when GP uses cease – and fill those gaps

Assuring that animal health needs are met

- Important element of strategy
  - take into consideration the question - When GP use is removed, are new/additional treatment, control, or prevention label indications needed – to fill a gap?
  - if so, seek to update product labels with new therapeutic indications in conjunction with removing GP use
  - actively working with animal pharmaceutical industry
  - your input is needed

Second Recommendation:

"*Limit use of medically important antimicrobial drugs to those uses that involve veterinary involvement/consultation*"

Veterinary involvement/consultation

- Veterinarians play critical role as diagnosticians and as consultants to producers to develop and implement measures to treat, control, and prevent disease
- Such involvement is valuable for helping to assure that these drugs are used as judiciously as possible

Background – Veterinary Oversight

- Currently, most feed and water use antimicrobials are available OTC
  - Most approved as OTC >30 years ago
  - Two most "recent" feed products approved as "veterinary feed directives" (VFDs)
    - Tilmicosin, florfenicol
- No "new" injectable antimicrobials have been approved as OTC in >25 years

Background - Veterinary Feed Directive

- Existing framework for veterinary oversight of feed use drugs is the *veterinary feed directive* (VFD)
- FFDCA requires that medicated feeds needing veterinary oversight be designated VFDs
- FDA finalized regulations regarding distribution and use of VFDs in January 2001

Implementing second recommendation to "*include veterinary involvement/consultation*"

- Practically means changing marketing status from OTC to Rx or VFD
- Primary objective is to include veterinarian in decision-making process
- Not meant to mandate direct veterinarian involvement in drug administration

Concerns expressed to FDA about implementing greater veterinary involvement include:

- Veterinary workforce limitations
  - Are there enough food animal vets to administer?
- Existing VFD process too burdensome
  - Further impacts limited workforce concern
  - Impacts on feed industry
- Potential impacts on producers
  - access to drugs
  - increased costs

Workability of VFD process

- Have been seeking input on how to make process more efficient and less burdensome
  - issued ANPRM in March 2010
  - effort ongoing to streamline process
  - seeking input from stakeholders – including AVMA steering committee
  - revising current process is critical element of overall implementation strategy

Updating VFD Process

- Changes intended to make process more efficient/workable
- Critically evaluating all current requirements
  - Information required on VFD form
  - Transmitting VFD
  - Recordkeeping requirements
  - definition of valid client patient relationship (VCPR)

Implementing greater veterinary involvement

- Seeking to minimize negative impacts/burdens
  - streamlining VFD process important factor
    - Impacts veterinarians, producers, and feed industry
  - how VCPR is defined is particularly relevant
    - Working closely with AVMA to clarify
  - Enable veterinarians to provide service, consultation to producers in an effective and cost efficient way

Next steps

- Finalize Guidance #209
- Develop more details on implementation
- Complete rulemaking to update VFD

Draft Guidance #209: Next steps

- Completed review of public comments
  - Received approx 1200
- Intend to issue “final” guidance
- But, more detailed guidance needed on implementation of key principles

More details on implementation: Next steps

- Developing additional guidance that provides more details on:
  - Defining “medically important”
  - Process for updating product labels
  - Data requirements for adding new therapeutic indications
  - Timeline for implementation

Veterinary Feed Directive – Next Steps

- Completed review of public comments
  - Received approx 250 comments
- Based on comments/input - developing revised regulation (21 CFR 558.6)
- Continuing to seek opportunities for input
- Recognize importance of improving the efficiency of the VFD process

Timeline

- Recognize need to provide for an approach that phases-in changes over time
- To minimize disruption and provide time for orderly transition
- Would expect transition to occur over a number of years
- Considering setting target date
  - Bring order to process
  - Ensure establishment of equity across products

Overall Strategy – in summary

- For medically important antimicrobial drugs:
  - *phase out* production uses and
  - *phase in* greater veterinary involvement
- Focus of strategy is to implement changes through a voluntary approach – seeking collaboration with key stakeholders
- Implement changes over a number of years to provide for adequate transition period

Overall Strategy – in summary

- Transition period provides time to:
  - Assure that animal health needs are met
    - Seek new therapeutic label indications as needed
  - Explore alternatives
    - Alternatives to AGPs, management practices
  - Address veterinary practice issues
    - Implement streamlined VFD process
  - Minimize disruption/impacts on industry

Thank You