Update on FDA’s Antimicrobial Resistance Activities

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Topics

- Guidance #209
- Draft Guidance #213
- Veterinary Feed Directives
- NARMS
- Drug sales/use data
Judicious Use of Antimicrobials

- Guidance 209 – “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”
  - Published as draft in June 2010
  - Finalized April 11, 2012
  - States overall policy direction
Judicious Use: Guidance 209

- Focus is not on banning drugs in food-producing animals
- Goal: preserve availability of effective drugs (for both humans and animals)
- Antimicrobials must continue to be available to combat disease in animals,
  - including treatment, control, and prevention
- Emphasis is on assuring drugs are used as judiciously as possible
- Primary concern are “medically important” drugs
Judicious Use: Guidance 209

- Two key principles outlined in Guidance 209:
  - Limit use of medically important antimicrobial drugs to those uses considered necessary for assuring animal health (i.e., therapeutic purposes)
  - Increase veterinary involvement/consultation
Draft Guidance 213

- Provides more detailed guidance on implementation of key principles in Guidance 209
  - Published April 2012
  - Proposes a definition for “medically important”
  - Process for updating product labels
  - Data requirements for adding new indications
  - Proposes implementation timeline
Draft Guidance 213

- Proposed definition of “medically important”
  - Those drugs listed in GFI #152, Appendix A regardless of their ranking
  - Medically important drugs currently used for GP purposes include penicillins, tetracyclines, macrolides, lincosamides, streptogramins and aminoglycosides
Draft Guidance 213

- Potential new therapeutic indication
  - Treatment, control, prevention
  - Includes data requirements for obtaining approval of new uses
  - Involves filing of supplemental NADA
  - Any new prevention uses expected to:
    - Have defined dosing duration
    - Effective therapeutic dose level
    - Be targeted as much as possible to at-risk population
    - Include veterinary oversight
Draft Guidance 213

Implementation timeframe

- 3 months from finalization of 213
  - Hear from drug sponsors as to their intentions
- 3 years from finalization of 213
  - Target for implementing changes to use conditions of affected products
- VFD streamlining
  - Intent is to implement revised VFD regulation within 3-year timeframe, but will adjust timeframe as necessary if VFD changes not yet in effect
Veterinary Oversight

- One of two key principles described in Guidance 209 –

- Limit the use of medically important antimicrobial drugs to those uses that include veterinary oversight/consultation
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
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
Veterinary Feed Directive

- The proposal for greater veterinary oversight of feed use antimicrobials...

- Has raised concerns about VFD requirements - including:
  - Limited experience with process
  - Administrative burden concerns
  - Veterinary workforce limitations
  - Increase costs to producers
  - Impacts on feed industry
Workability of VFD process

- Have been seeking input on how to make process more efficient and less burdensome
  - Recognize that streamlining current process is critical to facilitating transition of marketing status from OTC to VFD
  - Issued ANPRM in March 2010
  - Received detailed comments/recommendations on how to improve existing regulation
Draft text for proposed VFD regulation

- As interim step, comments received on March 2010 ANPRM were used to develop draft text.
- Draft text published April 11, 2012.
- Provides an additional opportunity for comment on the proposed changes.
- Input received will be used to develop a formal proposed rule (which in turn will be subject to comment prior to issuance of final rule).
Updating VFD Process

- Changes intended to make process more efficient/workable
- Critically evaluated all current requirements
  - Information required on VFD form
  - Transmitting VFD
  - Recordkeeping requirements
  - Specificity of order
Key Proposed Changes Include:

- Requirement to provide amount of feed required to treat the identified animals
  - Replaced by requirement to provide approximate number of animals to be fed the medicated feed prior to expiration of VFD

- Expiration date provision
  - Unless specified on the approved labeling of the drug, expiration date cannot exceed 6 months after issuance
Process Improvements – Practical Implications

- Existing process requires VFD orders be written for a specific amount of medicated feed to be delivered to specifically identified animals.

- With proposed revisions, veterinarian could opt for this level of specificity, but has latitude to issue a broader “standing order”:
  - For up to 6 months
  - And limited by approximate number of animals specified by veterinarian
Next Steps

- Comment period on Draft guidance 213 and VFD draft text closed July 12, 2012
NARMS: Science Board comments

- Sampling needs to be nationally representative
- Sampling biases occur as processing plants are not randomly selected
- On-farm data are essential in understanding movement of resistance from farm to fork
NARMS: Examining sampling strategies

- 5 pilot studies initiated in Sept. 2011
  - Demonstrate the feasibility of a pre-harvest (live animal) sampling approach for NARMS in dairy and feedlot cattle, poultry and swine
  - Provide preliminary data for estimating sample size for prevalence and identify sources of variations
- Slaughter samples
  - Working with FSIS on strategy to acquire intestinal samples at slaughter
- Goal is a random representative and sustainable animal sampling scheme
Antimicrobial sales/use data

- Public input requested on:
  - Enhancements to existing sales/distribution data
  - Format of FDA’s annual summary
  - Other sources of information on use
- Comment period extension
Thank You