



U.S. Food and Drug Administration



CENTER FOR VETERINARY MEDICINE

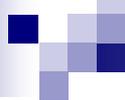
Update on FDA's Antimicrobial Resistance Activities



Mike Murphy

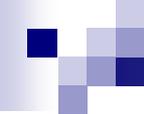
**Veterinary Medical Officer
Center for Veterinary Medicine
Food and Drug Administration**

**One Medicine – Bugs and Drugs
Durham, NC
December 6, 2012**



Topics

- Guidance #209
- Draft Guidance #213
- Veterinary Feed Directives
- NARMS
- Drug sales/use data



Judicious Use of Antimicrobials

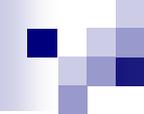
- Guidance 209 – “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”
 - Published as draft in June 2010
 - Finalized April 11, 2012
 - States overall policy direction

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Draft Guidance 213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Draft Guidance 213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

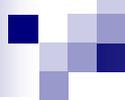
Implementation timeframe

- 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





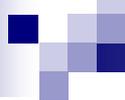
Implementing second recommendation to
“include veterinary involvement/consultation”

- 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

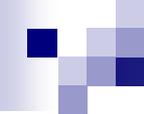
- Existing framework for veterinary oversight of feed use drugs is the *veterinary feed directive* (VFD)
- FFDCFA requires that medicated feeds needing veterinary oversight be designated VFDs
- FDA finalized regulations regarding distribution and use of VFDs in January 2001





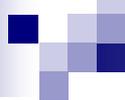
Veterinary Feed Directive

- 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



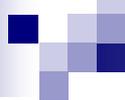
Workability of VFD process

- 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



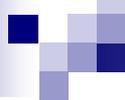
Draft text for proposed VFD regulation

- As interim step, comments received on March 2010 ANPRM were used 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

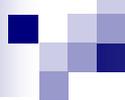


Key Proposed Changes Include:

- 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

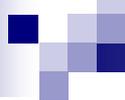
NARMS: Science Board comments

- 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

- ANPRM published July 27, 2012
- 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

The image shows a presentation slide. The background is a solid dark blue color. On the left side, there is a decorative graphic consisting of several overlapping, semi-transparent squares in various shades of light blue and white, arranged in a stepped, staircase-like pattern. In the center of the slide, there is a white rectangular box with a thin black border. Inside this box, the words "Thank You" are written in a bold, orange, sans-serif font. The text is centered horizontally and vertically within the white box.

Thank You