

CVM Update

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Future of Feed Regulation

- Risk based
- Identification of Hazards
 - Industry
 - FDA
 - Our government partners
- Mechanisms to control hazards required
- Increased budget / increased emphasis on food and feed safety
- More oversight
- Legislation to address current gaps in enforcement authorities

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

GRAS Notification

- CVM's program is similar to CFSAN's
 - GRAS Notification represents a **firm's** determination that a particular use of a substance is GRAS
 - Firm accepts responsibility for safety of use, not FDA
 - Firm's notice and FDA response posted on CVM web page
- AAFCO OP and GRAS Notification
 - Aware of issues

Veterinary Feed Directive

- Procedures for issuing VFDs are currently spelled out in regulation
 - e.g., recordkeeping requirements, information that must be included on actual VFD
- Existing framework for veterinary oversight of feed use drugs is the *veterinary feed directive* (VFD)

Veterinary Feed Directive

- CVM issued an advance notice of proposed rulemaking (ANPRM)
 - Limited experience with VFD process
 - Administrative burden concerns
 - Veterinary workforce limitations

Judicious Use

- There is little disagreement that drug use is a driver of resistance
- “Judicious” use can help curb resistance emergence
 - through more targeted drug use
 - by reducing unnecessary or inappropriate use
- Two key factors CVM thinks are important for assuring “judicious” use of medically-important drugs
 - Focus use on treatment, control and prevention
 - Veterinary involvement/consultation

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

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?

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

Animal Feed Safety 2010 Actions

- Draft guidance being developed for safe feeding practices on-farm for receiving, storing, and feeding
- Process control standards proposed rule (under review pending legislation)
- Pet food label regulation (2010/2011)
- Feed and feed ingredient definitions (2010/2011)