U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR VETERINARY MEDICINE

Update on FDA Activities Related to Antibiotic Use in Food-producing Animals

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Key areas of focus include:

- Implementing changes under FDA's Guidance 213
- Enhancing collection of data on antibiotic use and resistance
- Additional measures to reinforce antibiotic stewardship

Implementing FDA Guidance 213

Accomplishes two significant changes:

- Limits use of medically important antimicrobial drugs to those uses considered necessary for assuring animal health (i.e., therapeutic purposes)
- Brings all remaining therapeutic uses under the oversight of licensed veterinarians

Affects seven classes of antibiotics used in feed/water

- aminoglycosides, lincosamides, macrolides, penicillins, streptogramins, sulfonamides, and tetracylcines

Implementing FDA Guidance 213

- Approx. 280 approved drug applications affected
  - All need to change from OTC to Rx or Veterinary Feed Directive (VFD)
  - Some need to have growth promotion indications removed
  - Not all are currently being marketed
- All (25) affected drug sponsors confirmed their intent to voluntarily change their products
- Working with animal pharmaceutical industry to coordinate changes as much possible
- Some changes have occurred, but expect most to occur at end of the timeline (December 2016)

Implementing FDA Guidance 213

Updating Veterinary Feed Directive (VFD) Regulation

- critical element of implementing Guidance 213 changes
- legal framework for veterinary oversight of drugs administered to animals via feed
- updates needed to facilitate transitioning large number of OTC drug products to VFD marketing status

Current status: expect final regulation to publish spring 2015

Next steps:

- Work with key stakeholders on education/training efforts to support effective implementation of the new regulation

Enhancing data collection on use and resistance

Having sufficient data on use and resistance is critical so that meaningful metrics are in place to assess impact of measures being implemented

- Important for assessing impact of changes under FDA Guidance 213
- It is also important for helping to gauge success of stewardship efforts more broadly

Enhancing data collection on use and resistance

Enhancements of existing data sources:

- National Antimicrobial Resistance Monitoring System (NARMS)
  - Increasing number of samples processed by existing sites
  - Increasing number of sites participating in program
  - This effort is ongoing now
- Antimicrobial sales and distribution data
  - FDA recently enhanced the level of detail provided in its annual summary reports
  - Enhanced report format used for 2012 reporting year
  - Expect summary report for 2013 to be published very soon
  - FDA expects to publish a proposed regulation this spring to enhance sales data collection for food-producing animals

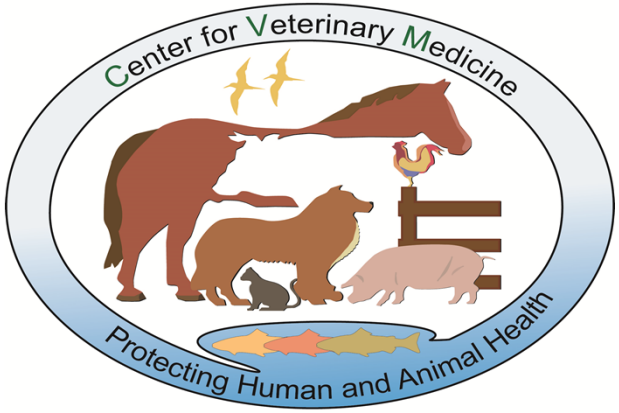
Enhancing data collection on use and resistance

- Plans for collecting additional data
  - Additional data is needed to provide a more comprehensive understanding about use and resistance
  - Focusing on gathering on-farm data
  - FDA is collaborating with USDA and CDC to develop effective and practical approaches for collecting such data – including leveraging existing systems
  - Planning a public meeting for Spring 2015 to seek public input

Reinforcing Stewardship

- Perform training/outreach to support new VFD rule
  - Veterinarians, producers, feed distributors, FDA/state compliance officers
- Promote judicious use principles
  - Veterinary and producer organizations, academia, others, have a role
  - Particular focus on ensuring that remaining therapeutic use (including prevention use) is appropriate/judicious

Thank You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