U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR VETERINARY MEDICINE

FDA Antibiotic Resistance Strategy

NIAA Antimicrobial Use and Resistance Symposium

November 14, 2014

William T. Flynn, DVM, MS
Center for Veterinary Medicine (CVM)
U.S. Food and Drug Administration (FDA)

Outline

- Background
- CVM's Judicious Use Strategy
  - Goals
  - Components
- Next Steps

Current AR Understanding

- Complex, multi-factorial issue
  - Naturally occurring vs. acquired
- Use (exposure) as a driver of acquired resistance
  - All uses (human, animal, horticultural, other) can contribute
- Gaps in our understanding of the issue remain – the science continues to evolve
- But, these complexities and uncertainties don't mean that steps can't be identified to mitigate risk

Antibiotic Use in Animal Agriculture

- Has been the subject of scientific and policy debate for decades
- Consumers, public health advocates, Congress, and others continue to be concerned about public health impacts
- Goal: while debate continues, identify measures that address public health concern and that continue to assure animal health needs are met

Previous Measures to Address AR Risks

- Since late **1980's** – All "new" antibiotics have required veterinary oversight
- **1996** – National Antimicrobial Resistance Monitoring System (NARMS) established
- **1997** – Extralabel use of fluoroquinolones and glycopeptides prohibited
- **2003** – FDA established framework for assessing antimicrobial resistance risks as part of drug approval (Guidance #152)
- **2005** – Withdrawal of enrofloxacin in poultry
- **2010** – initiated "judicious use" effort with issuance of draft Guidance #209
- **2012** – prohibited certain extralabel uses of cephalosporins

Remaining Concerns

- With implementation of Guidance #152 in 2003, a process is in place that evaluates the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern
- However, concerns remain about products that pre-date current assessment process
- Focus of recent efforts is on taking steps to ensure that existing antibiotics (particularly those that predate 2003 assessment process) are used as judiciously as possible

CVM's Judicious Use Strategy

- Guidance 209
  - Describes overall policy direction
  - Two key principles:
    1. Limit use of medically important antimicrobial drugs to those uses considered necessary for assuring animal health (i.e., therapeutic purposes).
    2. Increase veterinary involvement/consultation.
  - Calls for a voluntary/collaborative approach

Judicious Use Strategy: Goal

- Focus is on initiating steps to assure that medically important antimicrobial drugs are used as judiciously as possible
- While maintaining their availability to combat disease in animals,
  - including treatment, control, and prevention
- Goal: preserve availability of effective drugs
  - for both humans and animals

Judicious Use Strategy: Components

I. Implementing Changes
II. Reporting Progress
III. Assessing Impacts
IV. Reinforcing Stewardship

Implementing Changes: Guidance 213

- Published December 2013
- Provides more detailed guidance on implementation of key principles in Guidance 209
  - Target for implementing changes to use conditions of affected products within 3 years (by December 12, 2016)
  - 283 affected applications
- All 26 affected sponsors confirmed their intent to voluntarily engage in Guidance #213
  - Once these changes are complete it will be illegal to use medically important antimicrobials in the feed or water of food animals for production purposes or without veterinary oversight

Implementing Changes: VFD

- Veterinary Feed Directive is the legal framework for veterinary oversight of medicated feeds
  - Corollary to prescription status for non-feed products
- CVM is updating the existing VFD regulation to facilitate transition to increased veterinary oversight of medicated feeds
- Intent is to implement revised VFD regulation within 3-year timeframe
  - Current target Spring 2015

Reporting Progress

- List of Affected Products
- Periodic progress reports
  - every 6 months
- Evaluation at end of 3-year period
  - December 2016
- Continuing assessment reports
  - 2017 and beyond

Assessing Impacts

- Continue collecting, reporting, and enhancing existing data
  - NARMS
  - Annual sales/distribution data
  - Other data (NAHMS, ARMS, National Residue Program, etc.)
- Collecting additional data
  - On-farm use and resistance

Reinforcing Stewardship

- Perform training/outreach to support new VFD rule
  - Veterinarians, producers, feed distributors, FDA/state compliance officers
- Promote judicious use principles
  - Particular focus on ensuring prevention use is appropriate/judicious

A Collaborative Approach

- The changes outlined in Guidance #213 represent major changes to way antibiotics have been used in animal agriculture for decades
- CVM believes that a collaborative approach is the fastest way to implement these changes
- We have worked with stakeholders, including animal pharmaceutical companies, to encourage their cooperation on this important public health issue, and we are confident in their support

Guidance #213: Next Steps

I. Implement Changes
   - Change labels (remove production claims, require vet oversight)
   - Finalize VFD rule (Spring 2015)

II. Apprise public of progress
   - Periodic progress reports (every 6 months)
   - Evaluation at end of 3-year implementation period (December 2016)

III. Assess Impacts
   - Continue collecting data (sales and resistance)
   - Collect additional data (on-farm use and resistance)

IV. Reinforce Stewardship
   - Perform training/outreach to support new VFD rule
   - Promote judicious use principles

CVM AR Websites

- Judicious Use of Antimicrobials:
  - http://www.fda.gov/AntimicrobialJudiciousUse
- NARMS
  - http://www.fda.gov/NARMS
- ADUFA 105 Reports:
  - http://www.fda.gov/AnimalAntimicrobialSales

Thank You


Center for Veterinary Medicine
Protecting Human and Animal Health