Progress Update

2017 NIAA Antibiotic Symposium

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Goals and Objectives

• Have we made progress?
  – Need to answer in context of desired outcome

• Focus on curbing resistance through fostering antibiotic “stewardship”

• Consensus is forming around core principles of “stewardship” in veterinary settings

**Answer:** Yes, important progress has been made
Antibiotic Stewardship

Antibiotic Use:
- Minimize use/need
- Optimize how use

Slow Resistance Emergence

What is the goal?

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Supporting Stewardship

Important areas where CVM is contributing:

• **Align products** - Align approved use conditions of medically important antimicrobial products with judicious use principles

• **Use practices** – support efforts to implement/reinforce antimicrobial stewardship in all veterinary settings

• **Monitor progress** - Enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals

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Strategy to align products

• Guidance #209 - defined policy goals
  – Limit medically important antimicrobials to those uses that:
    1) are considered necessary for assuring animal health and
    2) that include veterinary oversight or consultation

• Guidance #213 - outlined implementation plan
  – How products need to change to align with policy goals
  – Established 3 year timeline

• Veterinary feed directive (VFD) regulation
  – Identified as obstacle to implementation
  – Needed to update rule to make VFD process more efficient
Scope of Strategy

Risk-based approach; focus actions or mitigations on drugs/uses of greatest concern

• “Medically important” antimicrobials
  – Drugs that are important human therapies
  – Where risk to public health most significant

• Products approved for use in feed and water
  – Greatest exposure potential
  – Included production (growth promotion uses)
Strategy approach

• Collaborative approach
  – Significant outreach to build support for effort
  – Engaged industry to develop plan framework and identify obstacles to implementation

• “Voluntary” approach
  – Drug sponsors voluntarily updated their products
  – Once changes made, new use conditions mandatory
Outcome of Strategy

Completed strategy on January 1, 2017

Of the **292** new animal drug applications initially affected by Guidance for Industry #213:

- **84** were completely withdrawn

Of the remaining **208** applications:

- **93** water-use NADAs – converted from OTC to Rx
- **115** feed-use NADAs – converted from OTC to VFD
- Production (e.g., growth promotion) indications were withdrawn from all **31** applications that included such indications for use
Significant accomplishment

• Unprecedented level of engagement and collaboration over 3-year implementation period
• January 2017 target was established and met
• **Result:** fundamental change to how antimicrobials have been distributed and used in animal agriculture for decades
  – Shift to veterinary oversight – foundational for supporting stewardship
  – All feed/water uses of medically important antimicrobials now under veterinary oversight
While significant progress made, more work still needed:

• Consider further product updates
  – products that do not currently have an explicitly defined duration of dosing

• Other products that are still OTC
  – Bring all dosage forms of medically important antimicrobials under veterinary oversight

• Companion animal uses
  – Identify and implement strategy for promoting antimicrobial stewardship in companion animals
In Closing

• Goal is to curb resistance through optimizing antimicrobial use practices (stewardship)

• Significant progress has been made; changes implemented January 1 was important milestone

• Supporting stewardship efforts requires engagement of many stakeholders; incremental steps are needed to phase-in changes

• Continued collaboration is key to continued progress