

FDA Efforts to Support Antimicrobial Stewardship in Veterinary Settings

Kansas State University
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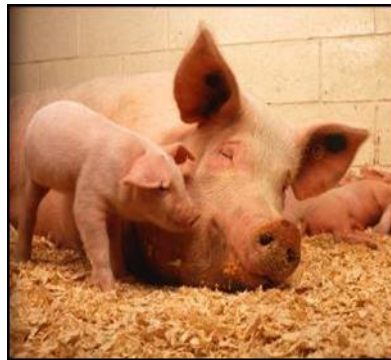
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Topics – FDA Activities

- Antimicrobial Resistance – Recent changes
 - Guidance 209/213
 - VFD regulation
- Antimicrobial Resistance – Next Steps
 - Scope of CVM's 5 year plan
 - Goal 1
 - Goal 2
 - Goal 3

Antimicrobial Resistance

- Complex, multi-factorial issue
- All uses are drivers of resistance
 - One Health approach needed
- Goal: implement measures that address public health concern while assuring animal health needs are met



FDA's Judicious Use Strategy

- Two key principles outlined in Guidance #209
- Limit use of medically important antimicrobial drugs in food-producing animals to those uses that:
 1. are considered necessary for assuring animal health and,
 2. that include veterinary oversight or consultation

Guidance #213: Overview

- January 2017 - Target date to implement changes to use conditions of medically important antimicrobials in food and water
 - Voluntarily withdraw approved production uses
 - such as “increased rate of weight gain” or “improved feed efficiency”
 - preserve therapeutic uses
 - Change marketing status from OTC to VFD/Rx



Guidance #213: Veterinary Oversight

- Key principle is to include veterinarian in decision-making process
 - Does not require direct veterinarian involvement in the drug administration
 - Does require use to be authorized by a licensed veterinarian in the context of a VCPR
- Marketing status changed from OTC to Rx or VFD
 - Water soluble products to Rx
 - Products used in or on feed to VFD

“Medically Important” antimicrobials

- Includes antimicrobial drugs that are considered important for therapeutic use in humans
- Guidance #213 defines “medically important” to include:
 - All antimicrobial drugs/drug classes that are listed in Appendix A of FDA’s Guidance #152 (published 2003)
 - A complete list of affected drug applications is posted on FDA/CVM website

Veterinary Feed Directive

- Existing framework for veterinary oversight of feed use drugs is the veterinary feed directive (VFD)
- In 1996 Congress passed the ADAA stating that a drug intended for use in animal feed which requires professional supervision (oversight) of a licensed veterinarian is a VFD drug
- In 2000 FDA finalized regulations for authorization, distribution and use of VFDs

Updates to VFD regulation

- Changes intended to make the process more efficient while continuing to provide public health protections
- VFD Final Rule
 - June 3, 2015 – VFD final rule published
 - October 1, 2015 – VFD final rule became effective

When did this go in effect?



Implementation Timeline Summary

- October 1, 2015 – Updated VFD regulation went into effect
- January 1, 2017 –
 - As of this date, all medically important antimicrobials for use in or on feed require a VFD and those for use in drinking water require a Rx
 - And, it is no longer legal to use these drugs for production (growth promotion) purposes

Summary of Changes

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 products) – converted OTC to Rx
- **115** (feed products) – converted OTC to VFD

Production (e.g., growth promotion) indications were withdrawn from **31** applications

Antimicrobial Resistance – Next Steps



Antimicrobial Resistance – Next Steps

- On 9/14/2018, CVM published a 5-year plan for [Supporting Antimicrobial Stewardship in Veterinary Settings](#) that outlines the key goals and objectives that will be our focus during fiscal years 2019 – 2023
- We have divided our approach into two phases:
 - phase 1 actions initiated between fiscal years 2019 – 2021
 - phase 2 actions initiated between fiscal years 2022 – 2023
- Phases identified are meant to be target for initiating work and does not necessarily represent when the actions will be completed



Goals of 5 Year Plan

1. Align antimicrobial **drug product** use with the principles of antimicrobial stewardship
2. Foster **stewardship** of antimicrobials in veterinary settings
3. Enhance **monitoring** of antimicrobial resistance and antimicrobial drug use in animals



Antimicrobial Resistance – Next Steps

Goal 1: Align antimicrobial drug products with the principles of antimicrobial stewardship

- Objective 1.1: Revise, as necessary, the use conditions for approved medically important antimicrobials in **food-producing animals**
- Objective 1.2: Develop and implement a strategy for promoting antimicrobial stewardship in **companion animals**
- Objective 1.3: Enhance processes to support new **product development**



Antimicrobial Resistance – Next Steps

Goal 1 Actions include:

Updating Appendix A of GFI #152

- GFI #152, Finalized in 2003, provides a risk assessment process for evaluating impact of antimicrobial drugs on AMR as part of the animal drug application process
- Includes an appendix that ranks of antimicrobial drugs according to their importance in human medicine.
- This ranking (Appendix A) supports GFI #152 assessment process and is used to define which drugs would be considered “medically important”



Antimicrobial Resistance – Next Steps

Goal 1 Actions include:

Bring remaining dosage forms* of medically important antimicrobials under the oversight of licensed veterinarians

- **Target** - issue a draft strategy by end of September 2019
- Intent to follow similar model used in the implementation of GFI #213, including robust dialogue with stakeholders and updates to keep the public aware of progress being made throughout the process

*Includes products that are approved for routes of administration other than feed or drinking water (e.g., injectables, intramammary).

Antimicrobial Resistance – Next Steps

Goal 1 Actions include:

Defining appropriate durations of use medically important antimicrobial drugs used in the feed or drinking water of food-producing animals

- **Target** - issue a draft strategy by end of September 2020
- CVM published a Federal Register notice in September 2016 requesting comment from the public on medically important antimicrobials used in animal feed or water that have at least one therapeutic indication without a defined duration of use.
 - CVM received over 260 comments
- Plan extensive stakeholder engagement in development of this strategy



Goal 2: Support efforts to foster stewardship of antimicrobials in veterinary settings

- Objective 2.1: Support **outreach and education** by providing information on antimicrobial stewardship
- Objective 2.2: Strengthen CVM **compliance** program activities to support antimicrobial stewardship
- Objective 2.3: Support **international outreach** and collaboration to foster antimicrobial stewardship in veterinary settings

Antimicrobial Resistance – Next Steps



Goal 2 Actions include:

Collaboration with other organizations to support stewardship – including:

- Other Federal agencies including USDA and CDC
- Veterinary and animal producer organizations
- State agencies that oversee licensing/practice standards

Examples

- USDA accreditation modules
- AVMA Committee on Antimicrobials

Antimicrobial Resistance – Next Steps



Goal 2 Actions include:

Strengthen CVM compliance program activities to support antimicrobial stewardship

- Are incorporating a veterinary feed directive (VFD) inspection component into our compliance program
- Inspections include examination of VFD order, requirements for the parties involved, and recordkeeping
- Expect to publish a summary of VFD inspection pilot conducted in FY 2016 - 2018

Antimicrobial Resistance – Next Steps

Goal 3: Enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals

- Objective 3.1: Collect and analyze data on antimicrobial **drug use** in animals
- Objective 3.2: Enhance the collection and analysis of antimicrobial **resistance data**
- Objective 3.3: Increase **data sharing and reporting** to aid in the monitoring of antimicrobial drug use practices and resistance

Antimicrobial Resistance – Next Steps



Goal 3 Actions include: **Collecting Use Data**

Funding cooperative agreements

- A funding opportunity was announced in March 2016 seeking proposals for collecting information on antimicrobial use practices in various animal production settings.
 - Two projects were awarded in August 2016.
- The awardees are developing and piloting methodologies to collect detailed information on antibiotic drug use on farms, in cattle, swine, chickens, and turkeys
- Two ongoing projects:
 - Feedlot/dairy cattle
 - Broilers, turkeys, swine

Antimicrobial Resistance – Next Steps



Goal 3 Actions include: **Updating the NARMS Program**

- Implement recommendations provided by FDA's Science Board including:
 - expanding testing to other food commodities (farm-raised seafood products at retail),
 - improving understanding of AMR using advanced genomic technologies and bioinformatics,
 - expanding retail meat sampling to improve the representativeness of data



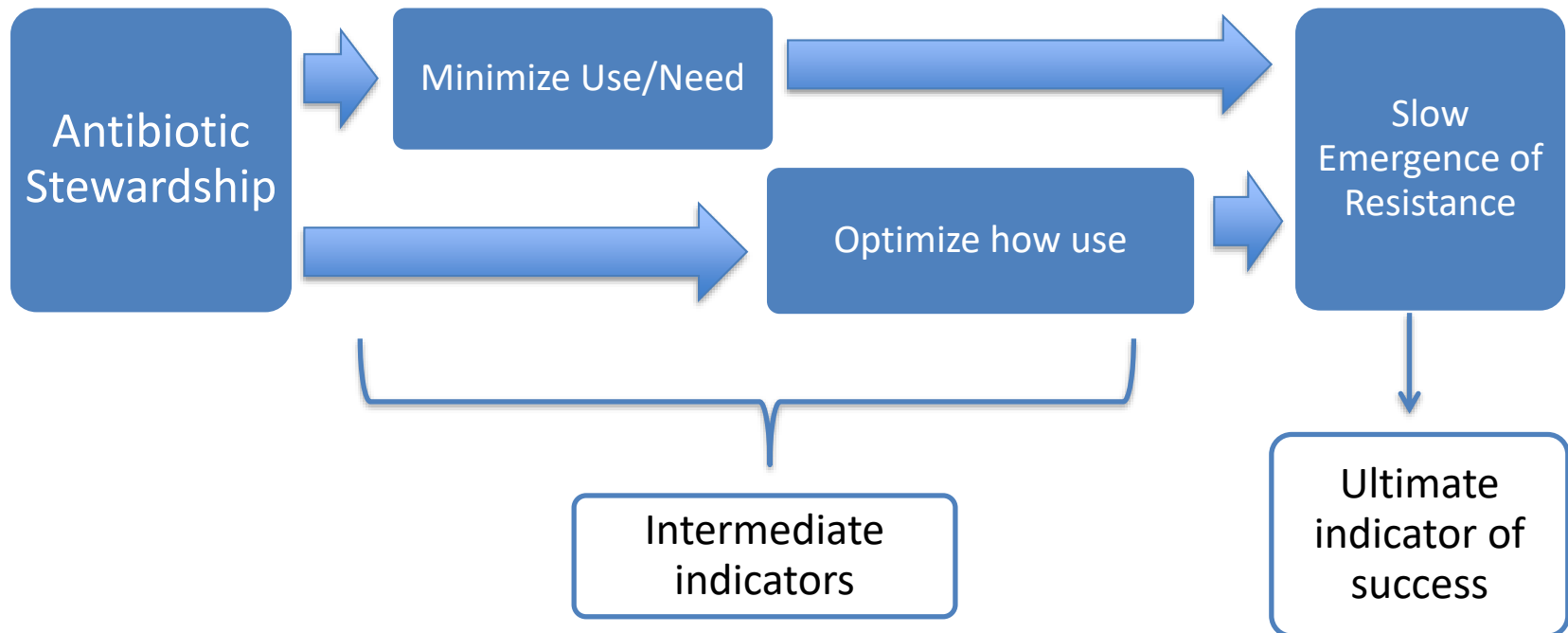
Antimicrobial Resistance – Next Steps

Goal 3 Actions include: **Issue assessment report**

- CVM intends to publish a comprehensive report that integrates and analyzes available information to assess stewardship in veterinary settings
- Including:
 - Use data captured from the cooperative agreements
 - USDA survey data
 - NARMS resistance data
 - Sales and distribution data and an appropriate method for applying a denominator to available data
 - Animal demographic/health data

Antimicrobial Resistance – Next Steps

Monitoring Progress



In Summary

- Significant progress has been made; changes implemented January 2017 was important milestone
- Antimicrobial stewardship requires the combined efforts of many stakeholders; more work is needed
- We are committed to working collaboratively with all key stakeholders; building on progress already made
- New 5-year plan intended to guide CVM's activities moving forward; plan can be adjusted as needed in response to evolving science and available data

