Outline

• Brief Background
• Why collect data?
• What data are needed?
• How will data be used?
• How will data be reported?
Background

• Antibiotic resistance is a global problem affecting both humans and animals

• Given the complexities of antibiotic resistance, no single action can be taken to “fix” the problem

• Rather, it requires a long-term commitment to multiple actions, on multiple fronts, to monitor and address the problem

• Tracking progress is critical element
GFI #209: Judicious Use Strategy

• Describes two key principles:

1. Limit medically important antimicrobials to therapeutic purposes (i.e., those uses considered necessary for ensuring animal health)

2. Require veterinary oversight or consultation for such therapeutic uses in food-producing animals
GFI #213: Implementation plan

• Finalized December 2013

• More detailed guidance on implementing key principles in Guidance #209
  – Established 3-year timeline
  – Defines medically important
GFI #213: Objectives

• By January 1, 2017, the use of medically important antibiotics in food and water will:
  • Be limited to therapeutic purposes only
    – production (growth promotion) uses of these products will no longer be legal
  • Require the authorization of a licensed veterinarian
    – Products used in water – change from OTC to Rx
    – Products used in or on feed – change from OTC to VFD
GFI #213: Important Milestones

Sept. 2015:
- Public meeting on data collection strategy

Early 2016:
- Finalize data collection plan

End of 2016:
- All changes implemented by drug sponsors

Jan. 2017:
- Changes in use practices begin

2018:
- Publish first assessment of use practices

Aligning Affected Products (June 2014 - December 2016)

Assessing Impacts of Product Changes (December 2016 – Beyond)
Why collect data?

• Without an intentional effort to assess the actions we take (e.g., GFI #213 changes), it will be difficult to know over time whether:
  – actions taken are making a difference,
  – actions taken need to be adjusted, or
  – additional actions are needed?
Why collect data?

• Question can be considered at several different levels – that may require different types of data – varying in terms of difficulty to collect and assess

• That is, actions can be assessed to determine if they are:
  1. Actually being adopted as intended
  2. Having the desired effect in terms of antibiotic use behaviors/practices (stewardship)
  3. Having the desired effect in terms of managing antibiotic resistance
Why collect data?

- **For example**: assessing the implementation of veterinary oversight under GFI #213 could include examining indicators that can help us understand whether veterinary oversight:
  1. is actually occurring as intended
  2. is having the desired effect of fostering judicious use/good stewardship
  3. is having the desired effect in terms of managing antibiotic resistance
Why collect data?

• In summary, data is needed to -
  1. Assess the rate of adoption of changes outlined in the FDA's GFI #213
  2. Help gauge the success of antibiotic stewardship efforts and guide their continued evolution and optimization
  3. Assess associations between antibiotic use practices and resistance
What data are needed?

A. Data on quantity antibiotics sold/distributed
B. On-farm antimicrobial use and resistance
C. Resistance data for pathogenic foodborne bacteria and commensal bacteria
D. Data on animal demographics/animal health
E. Data from FDA inspectional activities
What data are needed?

A. Data on quantity antibiotics sold/distributed

- Data available - summary reports published since 2009
- Annual summary substantially enhanced (Oct. 2014)
- Rulemaking underway to obtain additional detail on animal species

*Value* - indicator of quantity of antibiotics entering distribution channels

*Limitations* – not actual use; not specific for species or indication of use
What data are needed?

B. On-farm antimicrobial use and resistance data

- *Under development – limited data currently available*
- Implementation dependent on additional funding

*Value* – provide more specificity about actual conditions of use; opportunity to link use to resistance

*Limitations* – resource intensive to collect representative data
What data are needed?

C. Resistance data for pathogenic foodborne bacteria and commensal bacteria

- Data available – e.g., NARMS in place since 1996
- Enhancements made to animal sampling of NARMS
- Retail meat sampling expanded, WGS

Value – robust resistance database available

Limitations – resistance data not linked to information on antimicrobial use in animals
What data are needed?

D. Data on animal demographics/animal health

- Some data available – animal demographic indicators
- Limited animal health data currently available

*Value* – provides context for assessing antibiotic use information (e.g., appropriateness of extent of use)

*Limitations* – animal health data currently limited
What data are needed?

E. Data from FDA inspectional activities

- FDA program currently in place for inspecting licensed feed manufacturers
- Involves collaboration with state regulatory agencies
- As resources permit, plan to expand inspectional activity

*Value* – provides mechanism for inspecting VFD records; provides indicator of appropriate veterinary oversight of VFD feeds

*Limitations* – limited resources; large number of feed manufacturers
How will data be used?

• Proposed goal is to create a new USG Summary Report
  – Provide a summary of antibiotic drug use and resistance in animal agriculture
  – Integrates data on animal health, demographics, drug sales, resistance, and additional on-farm data…
Vision of New Report

• A coordinated, interagency (USG) annual report with science-based information about antibiotic drug use and resistance in animal agriculture

• Integrate an array of information on animal demographics, animal health, drug use, and resistance to provide a comprehensive picture of antibiotic use practices in animal agriculture
Purpose of New Report

• These reports will:
  – Enhance transparency regarding antibiotic use practices in food-producing animals
  – Summarize data important for:
    • assessing the adoption of changes outlined in FDA’s Guidance 209 and 213
    • gauging the success of stewardship efforts and guiding their continued evolution and optimization
Overview of Report Outline

- Introduction
- Animal Health/Demographic Indicators
- Drug Use Indicators
- Antibiotic Resistance Indicators
- Discussion
- Appendices
Report: Introduction

• Background: include discussion of...
  – interagency process for formulating report
  – significance of resistance to human/animal health,
  – current antibiotic policies/initiatives
  – stewardship initiatives (including industry-sponsored)
  – relevant changes since last reporting period

• Objectives/Purpose
  – Describe/discuss purpose
Potential Data Sources

• Animal demographic information
  – USDA/NASS

• Animal health information
  – Enhance currently collected/summarized

• Drug Use Indicators
  – FDA (sales), USDA (on-farm use)

• Resistance Indicators
  – NARMS (FDA, USDA/FSIS)
  – On-farm (USDA/APHIS)
Animal Health/Demographics

• Summarize available data on animal populations and disease incidence to provide context regarding:
  – Changes in animal populations
  – Occurrence of animal disease

• Such factors may influence antibiotic use
Drug Use Indicators

• Summarize data on extent and purpose of antibiotic use in various animal agriculture settings

• Could draw on several types of information including:
  – Sales/distribution data
  – Survey data on antibiotic use
  – other
Antibiotic Resistance Indicators

• Summarize available data on antibiotic resistance among foodborne bacterial pathogens and commensal bacteria including:
  – NARMS data (food and animal sources)
  – Potential on-farm data
  – Other

• Potential inclusion of animal pathogen data
Discussion Section

• In light of information summarized on animal demographics, animal health, drug use, and resistance
  – provide observations regarding antibiotic use practices in various animal agriculture settings
  – discuss resistance in relation to antimicrobial use
  – Identify areas of improvement and areas where further efforts are needed
Assessing the adoption of changes outlined in FDA’s Guidance 209 and 213

Feed/water use of medically important antibiotics are:

• not being used for production purposes
• only being used for legitimate/appropriate therapeutic purposes
• only being used with authorization of licensed veterinarian
Discussion Section

Gauging the success of stewardship efforts and guiding their continued evolution and optimization

– assess extent to which use indicators align with stewardship/responsible use standards and industry best practices, in light of animal demographics and animal health indicators

– identify associations between antibiotic drug use practices and resistance
Discussion Section

Gauging the success of stewardship efforts and guiding their continued evolution and optimization (continued)

– discuss/highlight areas where further efforts may be needed

  • informs Federal agencies in terms of policy development, research

  • informs industry, academia, veterinary profession
Report: Appendices

- Summary of relevant stewardship principles/standards (government, academia, veterinary, and industry-based)
- Additional information such as references, methods, data, lists of tables/figures, other reports/publications, etc.
In Summary -

• Outcomes of data collection and reporting strategy include:
  – Greater transparency regarding antibiotic use practices in food-producing animals
  – Data for assessing the rate of adoption of changes outlined in FDA’s Guidance #213
  – Data to help gauge the implementation and success of stewardship efforts and guide their continued evolution and optimization
  – Better understanding of antimicrobial use practices associated with resistance
Next Steps

- Consider comments received during public meeting and submitted to the docket
  - go to http://www.regulations.gov
  - type FDA-2015-N-2768 in the search box
- Refine plan based on input
- Will continue to seek public input
Goals

• Collect new on-farm data in 2016
  – Availability of resources a key factor
• Publish first integrated report in 2018
Thank You