

FDA's Antibiotic Strategy: Data Collection and Reporting

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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

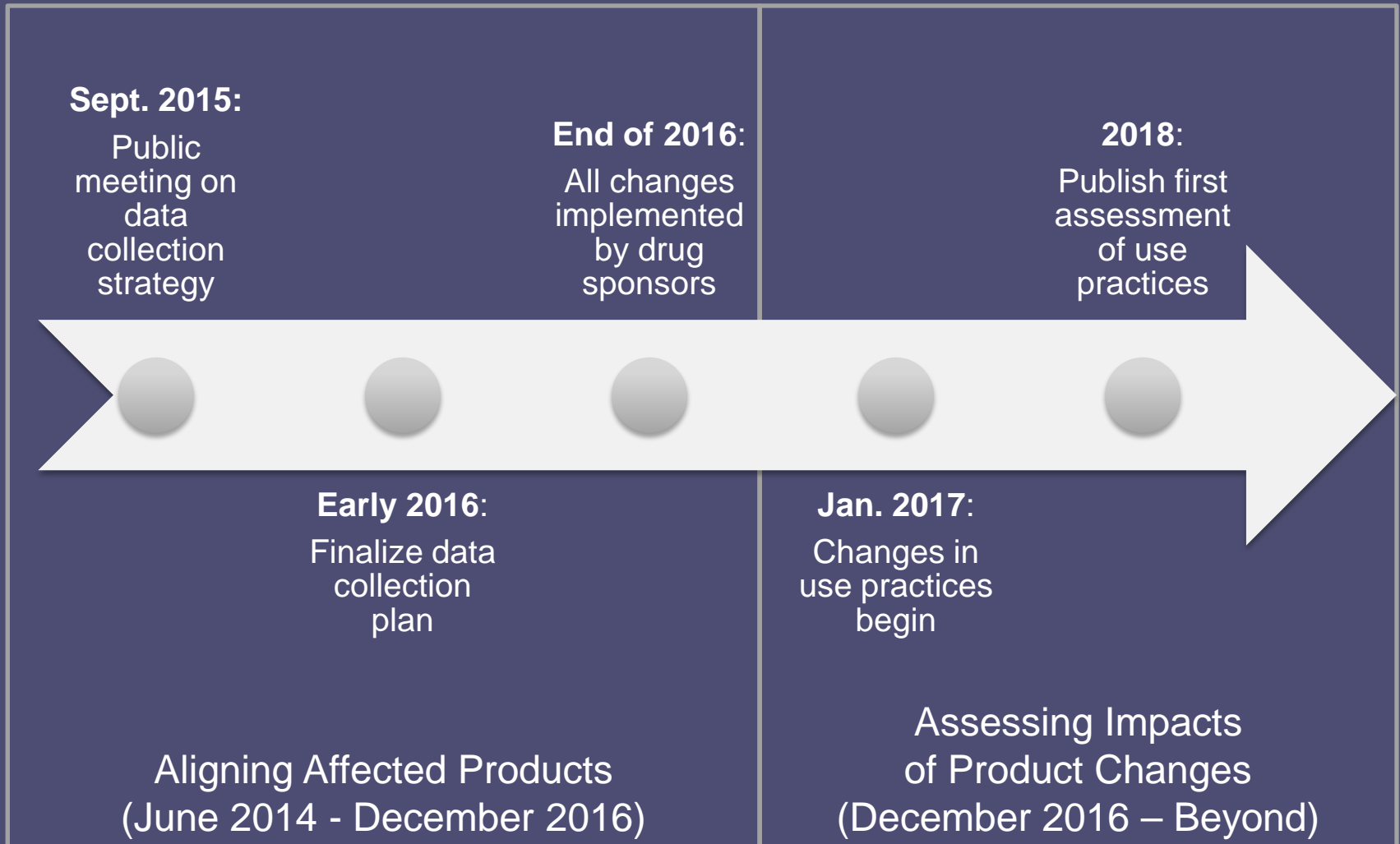
GFI #213: Implementation plan

- 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



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

Discussion Section

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

