U.S. Food and Drug Administration

CENTER FOR VETERINARY MEDICINE

Department of Health and Human Services

Goals and Objectives for Data Collection

William Flynn DVM, MS
Deputy Director for Science Policy
Center for Veterinary Medicine
U.S. Food and Drug Administration

Data Collection Public Meeting
September 30, 2015
Washington, D.C.

Outline

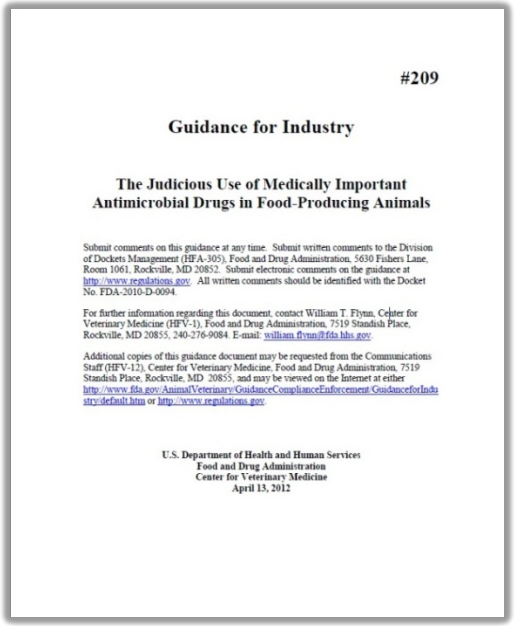
- Brief Background
- Why collect data?
- What data are needed?
- How will data be used?

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

Guidance #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



#209

Guidance for Industry

The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals

Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments on the guidance at http://www.regulations.gov. All written comments should be identified with the Docket No. FDA-2010-D-0094.

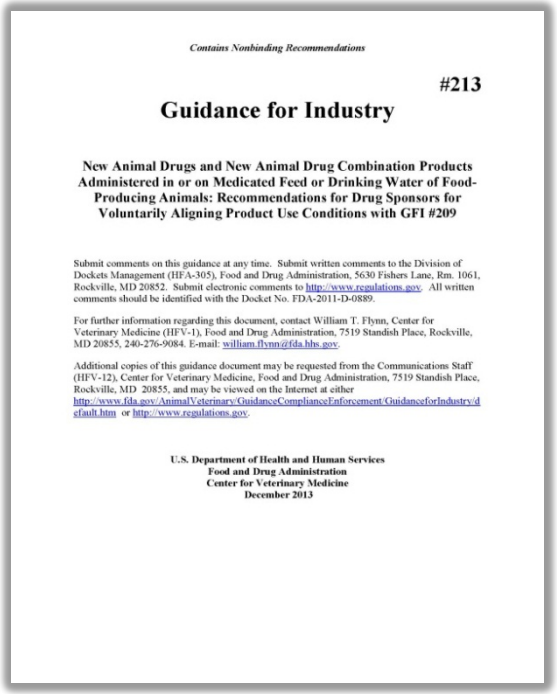
For further information regarding this document, contact William T. Flynn, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9084. E-mail: william.flynn@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
April 13, 2012

Guidance #213: Implementation plan

- Finalized December 2013
- More detailed guidance on implementing key principles in Guidance #209
  - Established 3-year timeline
  - Defines medically important



Contains Nonbinding Recommendations

#213

Guidance for Industry

New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209

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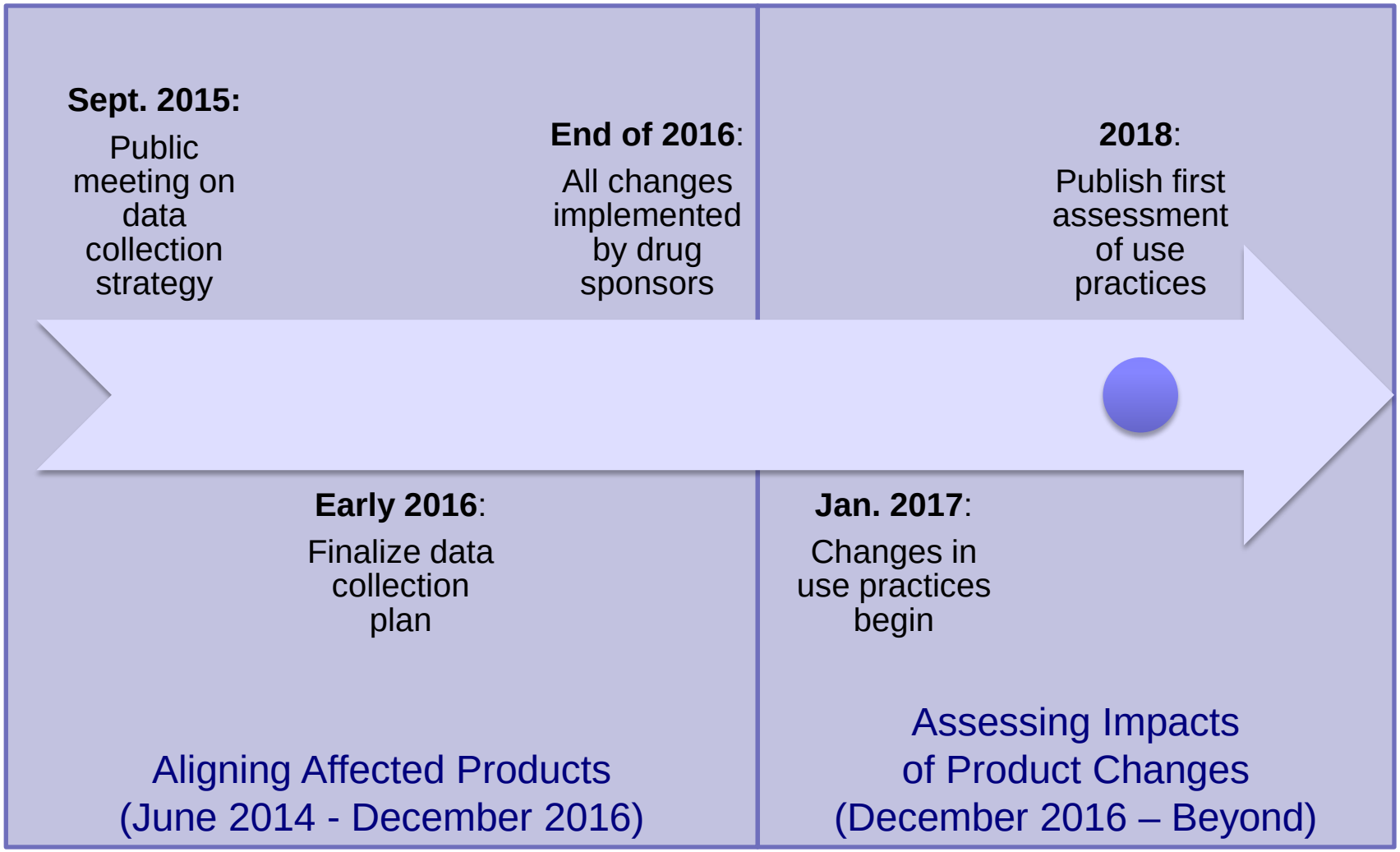
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
December 2013

Guidance #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 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/steps implemented can be assessed to determine if such actions 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?

- Progress at each of these three levels

  i.e., 1) adoption
  2) impact on behaviors/practices
  3) impact on resistance

  is important and desirable…but

- Assessing impact at <u>all</u> levels is challenging – particularly impact on resistance
  - Attribution/other drivers of resistance
  - Predictability of bacteria
  - Longer term observations needed

Why collect data?

- In summary, data is needed to -
  - assess the rate of adoption of changes outlined in the FDA's GFI #213
  - help gauge the success of antibiotic stewardship efforts and guide their continued evolution and optimization
  - assess associations between antibiotic use practices and resistance

What data are needed?

- Data is needed that provide indicators that actions/steps implemented are:
  1. Being adopted as intended
  2. Having the desired effect on antibiotic use practices
  3. Having the desired effect on antibiotic resistance
- Assessing progress at each of the above levels would require multifactorial approach
- Feasibility dependent on data availability

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
- Key focus of today's meeting
- 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…
- Focus of presentation this afternoon

In Summary -

- Outcomes of data collection 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

Thank You


Center for Veterinary Medicine
Protecting Human and Animal Health