



# FDA Perspective on Gathering Antimicrobial Use Data in Animals

**NIAA Antibiotics Council**

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# Outline

- The Need for On-farm Use Data
- FDA's Judicious Use Strategy
- Multifactorial Assessment



# The Need for On-farm Use Data

- Assessing the impacts of stewardship and policy initiatives on antimicrobial use and resistance remains a high priority
  - Shared by many stakeholders
- Additional information regarding on-farm antimicrobial use and resistance is needed to provide more meaningful metrics to supplement existing data

# FDA Guidance for Industry (GFI) #213

## ■ Policy Objectives:

1. Eliminate the use of medically important antimicrobials for production indications (such as “increased rate of weight gain” or “improved feed efficiency”)
2. Require veterinary oversight of therapeutic uses of these drugs in the feed and water of food-producing animals

## ■ Timeline: 3 years (ends December 12, 2016)

## ■ Important step towards addressing concerns about the use of antimicrobials in food-producing animals

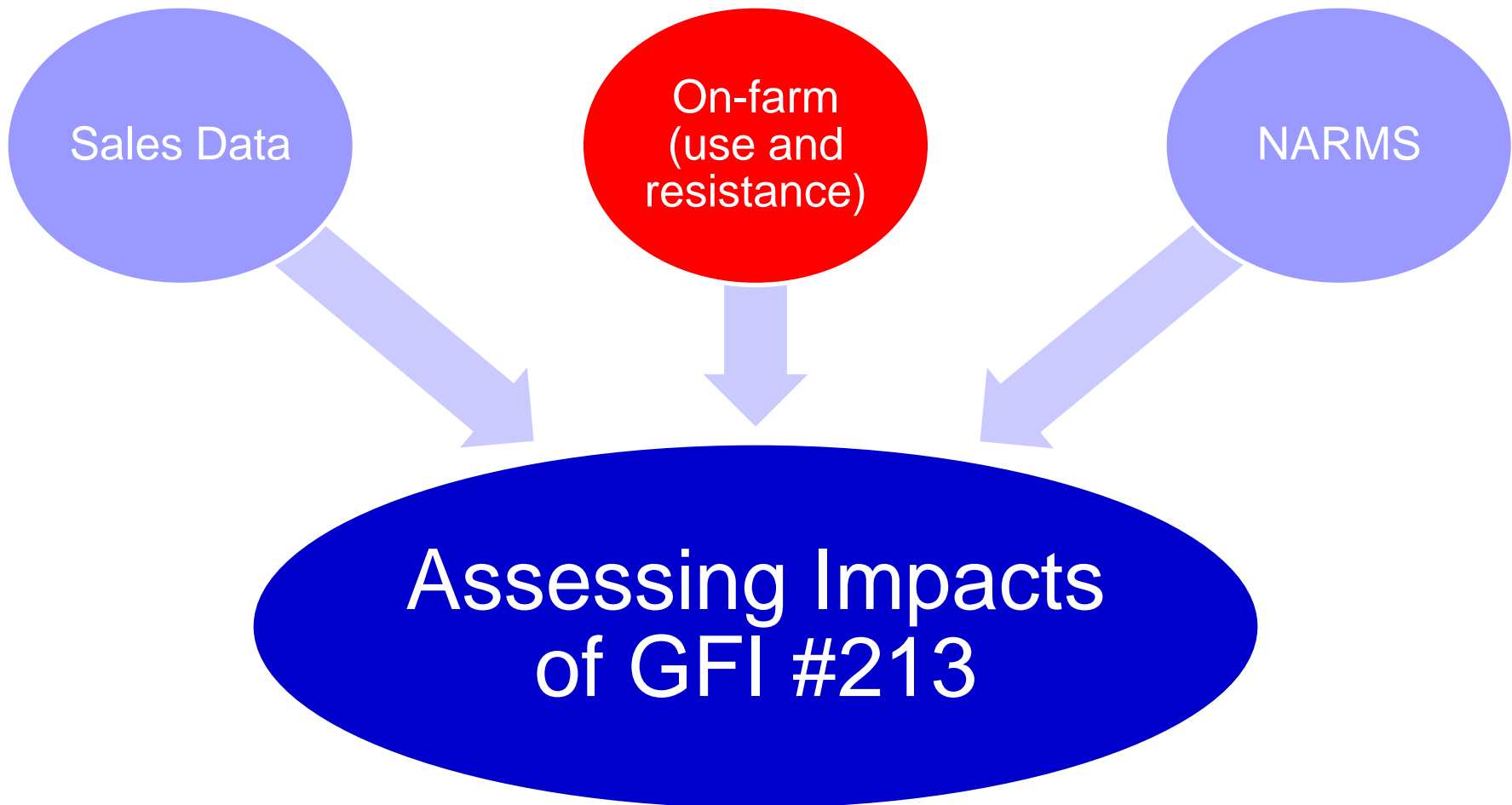
# GFI #213: Key Implementation Phases

- 1) Assessing industry engagement (Dec. 2013 – June 2014)
  - All 26 companies provided written commitment
- 2) Aligning affected drug products (June 2014 – Dec. 2016)
  - Target is to align all products by Dec. 2016
  - Expect most will occur through synchronous change in Dec. 2016
  - Biannual progress reports leading up to Dec. 2016
- 3) Assessing impacts (June 2016 – Beyond)
  - Would not expect to see impacts until after product changes are in place (Dec. 2016)
  - Multi-factorial assessment process under development

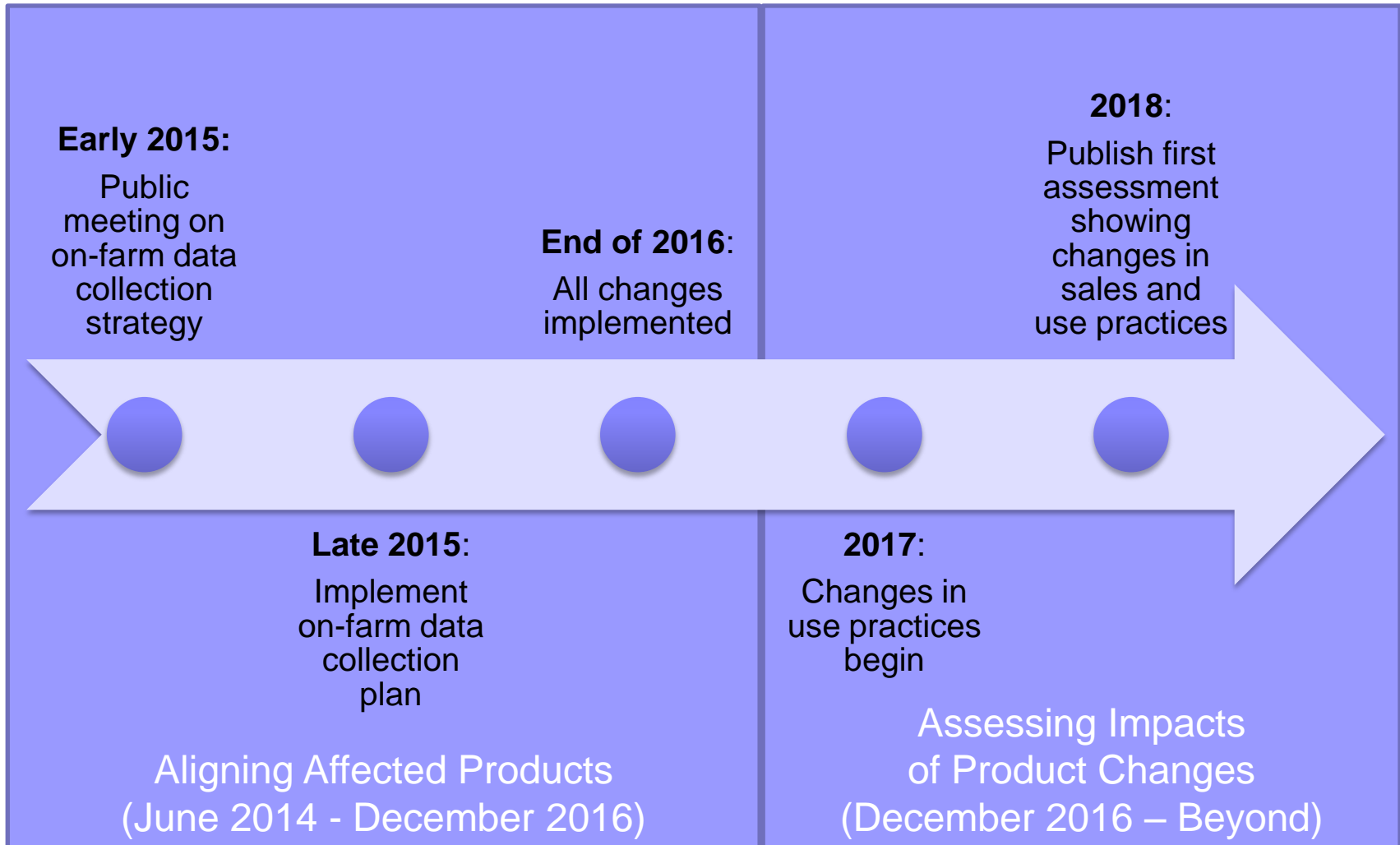
# GFI #213: Multi-factorial Assessment

- A. Data on quantity antibiotics sold/distributed (since 2009)
  - Annual summary substantially enhanced (Oct. 2014)
  - Rulemaking underway to obtain additional detail on animal species (target for NPRM is April 2015)
- B. On-farm use and resistance data (under development)
  - Developing approach for collecting such data through ongoing collaboration with USDA and CDC
  - Implementation dependent on additional funding
- C. Resistance data for foodborne bacteria (since 1996)
  - Enhancements made to animal sampling
  - Proposed expansion of retail meat sampling and use of whole genome sequencing

# GFI #213: Multi-factorial Assessment



# GFI #213: Important Milestones





Thank You

