



Animal Drugs and Antimicrobial Resistance

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Food and Drug Law Institute

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Topics

- Changes implemented
- Assessing impact
- Next steps: 5-year plan

Guidance #209/213 Initiative

Two key principles outlined in guidance (#209) in 2012

- 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 #209/213 Initiative

- Implementation plan initiated in 2013 to:
 - Eliminate production (growth promotion) uses
 - Change marketing status from OTC to Rx (for water products) or VFD (for feed products)
- Plan issued in form of a guidance (#213)
 - Voluntary changes by affected drug sponsors
 - New conditions mandatory once products updated

Summary of Changes

All affected drug sponsors worked voluntarily with FDA

Of the **292** new animal drug applications affected by **Guidance for Industry #213**:

- **84** were completely withdrawn

Of the remaining **208** applications,

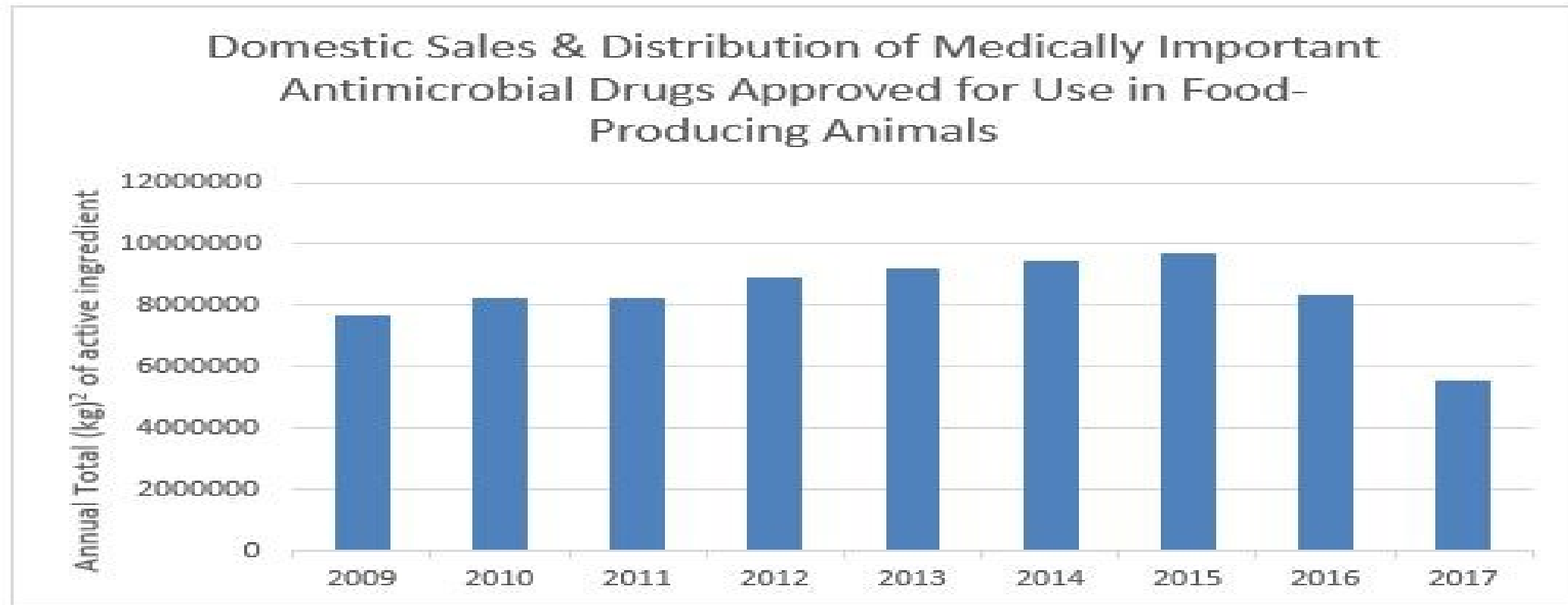
- **93** (water products) – converted OTC to Rx
- **115** (feed products) – converted OTC to VFD

Production (e.g., growth promotion) indications were withdrawn from **31** applications

Impact of Changes

- To fully assess progress, FDA believes we need to consider broad set of data
 - including data on antimicrobial resistance, antimicrobial use, animal demographics, and animal health
- FDA working on developing such an assessment
- Have reported sales/distribution data since 2009
 - does not necessarily reflect actual antimicrobial use
 - but, observed reduction in sales volume is important indicator that ongoing efforts to support antimicrobial stewardship are having a significant impact.

2017 Sales and Distribution report



Domestic sales decreased:

- 33% between years 2016 and 2017
- 43% since 2015 (peak year of sales/distribution)
- 28% since the first year of reported sales in 2009

Antimicrobial Resistance – Next Steps



Antimicrobial Resistance – Next Steps

- In September 2018, CVM published a 5-year plan for [Supporting Antimicrobial Stewardship in Veterinary Settings](#)
- Outlines the key goals and objectives that will be our focus during fiscal years 2019 – 2023
- Plan is divided into two phases:
 - phase 1 actions initiated between fiscal years 2019 – 2021
 - phase 2 actions initiated between fiscal years 2022 – 2023
- Phases meant to be target for initiating work and does not necessarily represent when the actions will be completed
- Consistent with One Health approach, scope of plan includes food-producing animals and companion animals

Antimicrobial Resistance – Next Steps



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



Key Projects

- Bring any medically important antimicrobials that remain OTC under the oversight of licensed veterinarians
 - Target: Issue a draft strategy by end of [September 2019](#)
- Update list of “medically important” antimicrobials (Appendix A, GFI #152)
 - Target: Initiate public comment process by [end of 2019](#)
- Develop and issue report assessing progress of stewardship efforts
 - Target: Issue assessment report [end of 2019](#)
- Define appropriate durations of use for 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](#)

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
- Continued collaboration is key; building on progress already made
- New 5-year plan intended to guide FDA/CVM's activities moving forward; plan can be adjusted as needed in response to evolving science and available data



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