Animal Drugs and Antimicrobial Resistance

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Animal Drugs and Antimicrobial Resistance

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- 84 were completely withdrawn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Production (e.g., growth promotion) indications were withdrawn from 31 applications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.
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
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• 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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