# Update on FDA's Guidance for Industry #213

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
June 22, 2016

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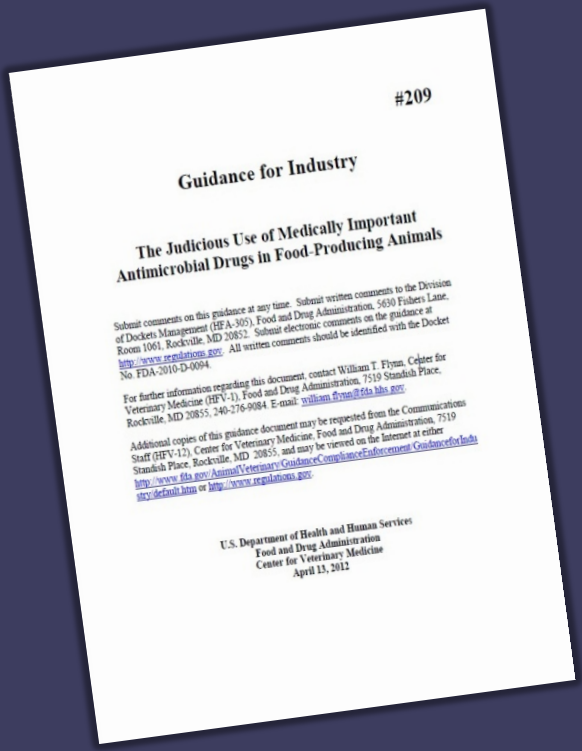
FDA Center for Veterinary Medicine

# FDA's Judicious Use Strategy

Key Documents:



#209

Guidance for Industry

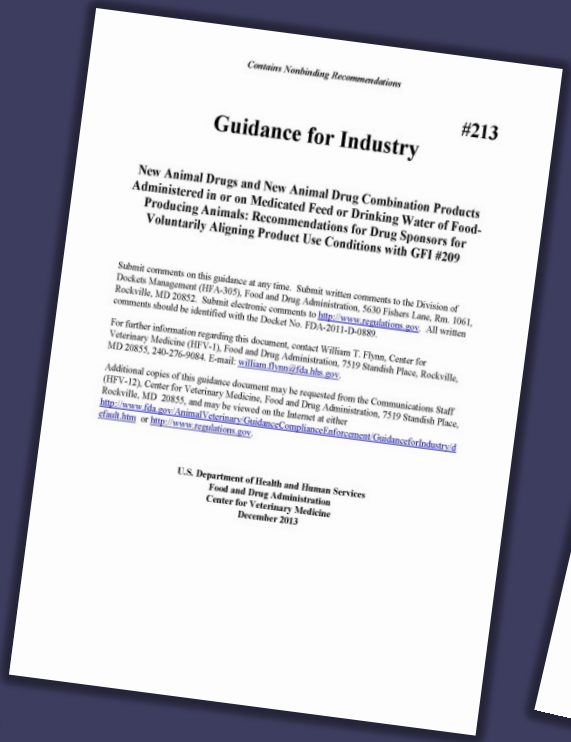
The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals

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, Rooms 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



Contains Nonbinding Recommendations

Guidance for Industry #213

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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Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 514 and 558

Veterinary Feed Directive; Final Rule

# FDA's Judicious Use Strategy

In 2012, FDA published Guidance for Industry (GFI) #209 describing the overall policy direction regarding antimicrobial drugs.

Key principles are :

Limit use of medically important antimicrobial drugs in food-producing animals to those uses

1. considered necessary for ensuring animal health. (therapeutic uses)
2. that include veterinary oversight or consultation.

# FDA's Judicious Use Strategy

In 2013, GFI #213 was published, providing more detail on implementing the key principles in Guidance #209

- Defines "medically important"
  - (i.e., define what products are affected)
- Established 3-year timeline to:
  - Voluntarily remove claims relating to production uses
  - Bring the remaining therapeutic uses under veterinary oversight by changing marketing status from over-the-counter (OTC) to veterinary feed directive (VFD) or prescription (Rx)

# FDA's Judicious Use Strategy

## Veterinary Feed Directive (VFD) Regulation

- Requirements relating to distribution and use of VFD drugs (feed-use drugs that require supervision of licensed veterinarian)
- Existing VFD regulations amended to improve efficiency of the process
- Updated regulations went into effect October 2015
- Critical step for facilitating transition to veterinary oversight

# Products affected by GFI #213

- “Medically important” antibiotics administered in feed or drinking water including:
  - Aminoglycosides
  - Lincosamides
  - Macrolides
  - Penicillins
  - Streptogramins
  - Sulfonamides
  - Tetracyclines

# Timeline Summary

- Guidance #213 established a 3-year timeline to implement changes to affected products
- Target date for aligning all affected products with the key principles is January 1, 2017
- Once changes are made to affected products, it will be illegal to use products for growth promotion or to use without the authorization of a licensed veterinarian

# Status Update

- 293 approved drug applications were identified as being affected by GFI #213
- Includes pioneer, generic, and combination approvals
- All affected drug sponsors have committed in writing to voluntarily align their products
- Detailed discussions held with pharmaceutical industry to outline a process for coordinating changes to products
- Detailed administrative process was communicated to all affected sponsors in a September 2015 letter

# Status Update

- Some changes have already been made, including:
  - 4 applications have been converted from OTC to Rx
  - Production use withdrawn from 1 application
  - 41 applications have been completely withdrawn
- However, by design, the changes are expected to occur in a coordinated fashion at the end of this year – such that all changes are in effect January 1, 2017.

# Communication and Outreach

- Since June 2015, CVM employees have:
  - Given at least 60 presentations on “Medically Important Antimicrobials in Animal Agriculture.”
    - This presentation is also posted online and has been accessed 2,413 times in the last 8 months.
  - Published and distributed stakeholder specific Veterinary Feed Directive brochures
  - Published two guidance documents to support implementation of VFD regulation
  - Updated the medicated feed label website

# Future Communication and Outreach

FDA is currently:

- Engaging USDA on the creation of a new education module specifically aimed at the VFD Rule for accredited veterinarians
- In the process of creating stakeholder specific educational videos that will be made available online

For a reference list of AMR and VFD related material, please see the following

**http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm464991.htm**

# What happens after January 2017?

- Guidance #213 will implement some very important changes to how antibiotics have been used for decades, but more work is needed
- FDA is currently developing an action plan outlining additional steps needed to build on the progress made under the GFI #213 initiative
- The goal is to publish this action plan before the end of this calendar year.

# Thank You


Center for Veterinary Medicine
Protecting Human and Animal Health