Fostering Core Stewardship Principles and VFD Animal Feed
Outline

What changes were made?
- Changes to Affected Applications
- Veterinary Feed Directive
- Major and Minor Species

Core stewardship principles and VFD Animal feed.
What changes were made and why?
Guidance #209: Outlined AMR Policy

Described overall policy direction
FDA’s Judicious Use Strategy

Two key principles outlined in Guidance #209

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 #213: Implementation

Finalized December 2013

More detailed guidance on implementing key principles in Guidance #209

- Timeline = December 2016
- Defined medically important
- In or on feed or
- in drinking water
“Medically Important” antimicrobials

In reporting year 2016 -

- For the distribution of all medically important antimicrobials:
  - approximately 72% were animal feed uses.
  - approximately 23% were drinking water uses.


www.fda.gov
Changes to Affected Products

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

— 84 were completely withdrawn

Of the remaining 208 applications,

- 93 applications – oral dosage form – converted from OTC to Rx
- 115 applications – animal feed – converted from OTC to VFD

— Production (e.g., growth promotion) indications associated with the medically important antimicrobial were withdrawn from all applications that included such indications
Changes to Animal Feed Products

- **VFD Animal Feed**
  - (21 CFR Part 558)

*Federal Law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.*
Major and Minor Species Impacts
Major vs Minor Species

The term ‘major species’ means cattle, horses, swine, chickens, turkeys, dogs, and cats, … 21 U.S.C. 321 (nn)

The term ‘minor species’ means animals other than humans that are not major species. 21 U.S.C. 321 (oo)
Extralabel Use (ELU)

Major Species

The Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994 and the regulations published at 21 CFR part 530 describe the requirements for, and restrictions on, extralabel drug use.

AMDUCA amended section 512 of the FD&C Act to permit extralabel uses of drugs under certain conditions except in animal feed. (21 U.S.C. 360b(a)(4)(A)).
Extralabel Use
Minor Species
CPG 615.115

Extralabel Use of Medicated Feeds for Minor Species

Therefore, when

- 1. there are no approved treatment options available and
- 2. the health of animals is threatened, and
- 3. suffering or death would result from failure to treat the affected animals,

extralabel use of medicated feed may be considered for minor species.
Extralabel Use
Minor Species

CPG 615.115 –
Extralabel Use of Medicated Feeds for Minor Species

In general, the Agency will not recommend or initiate enforcement action against
  − the veterinarian,
  − animal producer,
  − feed mill, or other distributor
when extralabel use is consistent with this document.
(CPG 615.115)
Outline

• What changes were made?
  – Changes to Affected Applications
  – Veterinary Feed Directive
  – Major and Minor Species

• Core stewardship principles and VFD Animal feed.
Core Stewardship Principles and VFD Animal Feed
American Veterinary Medical Association (AVMA)

Antimicrobial Stewardship Definition and Core Principles

January 2018

https://www.avma.org/KB/Policies/Pages/Antimicrobial-Stewardship-Definition-and-Core-Principles.aspx
Core Stewardship Principles and VFD Animal Feed
AVMA

Antimicrobial Stewardship Core Principles

1. Commit to stewardship
2. Advocate for a system of care to prevent common diseases
3. Select and use antimicrobial drugs judiciously
4. Evaluate antimicrobial drug use practices
5. Educate and build expertise
Core Stewardship Principles and VFD Animal Feed

1. Commit to stewardship

Relevant stakeholders have played, and will continue to play, important roles

Veterinary associations  Federal agencies
Animal producer organizations  State agencies
Feed manufacturers & distributors
Core Stewardship Principles and VFD Animal Feed

Antimicrobial Stewardship Definition and Core Principles

1. Commit to stewardship
2. Advocate for a system of care to prevent common diseases
3. Select and use antimicrobial drugs judiciously
4. Evaluate antimicrobial drug use practices
5. Educate and build expertise
Core Stewardship Principles and VFD Animal Feeds

Antimicrobial Stewardship Definition and Core Principles

2. **Advocate for a system of care to prevent common diseases**

- animal husbandry and hygiene,
- biosecurity and infection control,
- nutrition, and
- vaccination programs. (9 CFR 101.2 – Animal Biologic)
Core Stewardship Principles and VFD Animal Feeds

Antimicrobial Stewardship Definition and Core Principles

2. Advocate for a system of care to prevent common diseases

Producer “quality assurance programs”
Core Stewardship Principles and VFD Animal Feed
Antimicrobial Stewardship Definition and Core Principles

1. Commit to stewardship
2. Advocate for a system of care to prevent common diseases
3. Select and use antimicrobial drugs judiciously
4. Evaluate antimicrobial drug use practices
5. Educate and build expertise
Core Stewardship Principles and VFD Animal Feed
Antimicrobial Stewardship Definition and Core Principles

3. Select and use antimicrobial drugs judiciously
   - Use an evidence-based approach
   - NARMS – retail meat
     - Pathogens: Salmonella, Campylobacter,
     - Markers: E.coli, Enterococcus

https://www.fda.gov/animalveterinary/safetyhealth/antimicrobialresistance/nationalantimicrobialResistanceMonitoringSystem/default.htm
Core Stewardship Principles and VFD Animal Feeds

Antimicrobial Stewardship Definition and Core Principles

3. Select and use antimicrobial drugs judiciously
   - Use an evidence-based approach
   - review relevant publications
Core Stewardship Principles and VFD Animal Feed

Antimicrobial Stewardship Definition and Core Principles

1. Commit to stewardship
2. Advocate for a system of care to prevent common diseases
3. Select and use antimicrobial drugs judiciously
4. Evaluate antimicrobial drug use practices
5. Educate and build expertise
4. Evaluate antimicrobial drug use practices
   - Ensure that feedback is provided to veterinarians.
   - Resistance patterns in isolates seen in veterinary diagnostic laboratories - CVM OR
Core Stewardship Principles and VFD Animal Feed

Antimicrobial Stewardship Definition and Core Principles

1. Commit to stewardship
2. Advocate for a system of care to prevent common diseases
3. Select and use antimicrobial drugs judiciously
4. Evaluate antimicrobial drug use practices
5. Educate and build expertise
5. Educate and build expertise

- Make resources available and encourage the development of expertise in antimicrobial stewardship.
Core Stewardship Principles and VFD Animal Feed

Antimicrobial Stewardship Definition and Core Principles

5. Educate and build expertise
   - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Federal
State
Veterinary Associations
Producer Associations
Core Stewardship Principles and VFD Animal Feed

5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Federal Agencies

**CVM FDA**

<table>
<thead>
<tr>
<th>VFD Main Website</th>
<th>Since</th>
<th>“Hits” - 14 August 2018</th>
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<tbody>
<tr>
<td>Retail Establishments Letter</td>
<td>13 November 2015</td>
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<td>State/Federal VCPR</td>
<td>13 November 2015</td>
<td>7,616</td>
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<td>GFI # 233 – Common Format</td>
<td>30 November 2015</td>
<td>4,505</td>
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<td>GFI # 120</td>
<td>January 2016</td>
<td>10,710</td>
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https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm
Core Stewardship Principles and VFD Animal Feed

5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Federal Agencies

CVM FDA

<table>
<thead>
<tr>
<th>Videos</th>
<th>Since</th>
<th>“Hits” as of 14 August 2018</th>
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<tr>
<td>Overview</td>
<td>18 November 2016</td>
<td>= 8,239</td>
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<tr>
<td>Veterinarian</td>
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<td>Distributors</td>
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<td>Producers</td>
<td>20 November 2016</td>
<td>= 2,079</td>
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</table>

https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm
5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Federal Agencies

<table>
<thead>
<tr>
<th>Brochures</th>
<th>“Hits” from July 2015 as of 14 August 2018</th>
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<tr>
<td>Producers</td>
<td>17,035</td>
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<td>Distributors</td>
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<tr>
<td>Who manufacture</td>
<td>10,439</td>
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<td>Who don’t</td>
<td>8,114</td>
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<td>Veterinarians</td>
<td>15,045</td>
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<td>Students</td>
<td>4,897</td>
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</table>

Since October 2016 – also in Spanish

https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm
Core Stewardship Principles and VFD Animal Feed

5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Federal Agencies

CVM FDA

“Hits” as of 14 August 2018

Presentations:

<table>
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<tr>
<th>Presentation</th>
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<th>Hits</th>
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<tr>
<td>Fostering Stewardship</td>
<td>1 April 2017</td>
<td>713</td>
</tr>
<tr>
<td>Honey Bees</td>
<td>7 August 2017</td>
<td>1,571</td>
</tr>
</tbody>
</table>

https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm
Core Stewardship Principles and VFD Animal Feed

5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Federal Agencies

CVM FDA

Outreach: Since ~ June 2015

In-person or Webinar Presentations 179
Responsive Questions (21 CFR 10.85(k)) 360

CVM Updates:

– Anaplasmosis 20 December 2017 1,548
– Beekeepers 18 December 2017 2,124

www.AskCVM@fda.hhs.gov
Core Stewardship Principles and VFD Animal Feed

5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Federal Agencies

**USDA APHIS NVAP**

**Veterinary Accreditation**

- Module # 23 – Use of Antibiotics in Animals
- Module # 29 – Veterinary Feed Directive Rule
- Module # 30 - The Role of Veterinarians in Honey Bee Health

Core Stewardship Principles and VFD Animal Feed

5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Federal Agencies

**USDA APHIS NVAP**

<table>
<thead>
<tr>
<th>Veterinary Accreditation</th>
<th>Times Completed by Accredited Veterinarians</th>
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<tr>
<td>Module # 23 – Since 2012</td>
<td>= 27,695 CY 2018 = 3,761</td>
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<tr>
<td>Module # 29 – Since 2016</td>
<td>= 8,322</td>
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<td>Module # 30 – Since 2018</td>
<td>= 819</td>
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<tr>
<td>Totals</td>
<td>= 36,836 CY 2018 = 7,500</td>
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</table>

Core Stewardship Principles and VFD Animal Feeds

5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

State Agencies

State or Federal VCPR
https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm

American Association of Veterinary State Boards (AAVSB)

Memorandum of Understanding
https://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/othermous/ucm584198.htm
Core Stewardship Principles for VFD Animal Feed
Antimicrobial Stewardship Definition and Core Principles

5. Educate and build expertise

Professional Associations

AVMA Websites:

Since 1 July 2017 = 8,086


Since 1 July 2017 = 8,086
Core Stewardship Principles for VFD Animal Feed

Antimicrobial Stewardship Definition and Core Principles

5. Educate and build expertise

Professional Associations

AVMA Definition and Core Principles:

Since 

January 2018

As of 31 July 2018

=  2,187
Core Stewardship Principles for VFD Animal Feed

Antimicrobial Stewardship Definition and Core Principles

5. Educate and build expertise

Professional Associations

<table>
<thead>
<tr>
<th>Honey Bee</th>
<th>Since</th>
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<tr>
<td>Website</td>
<td>1 July 2017</td>
<td>=     3,921</td>
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<tr>
<td>Webinar</td>
<td>1 July 2017</td>
<td>=     872</td>
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</tbody>
</table>
Core Stewardship Principles for VFD Animal Feed

Antimicrobial Stewardship Definition and Core Principles

5. Educate and build expertise

Professional Associations – AVMA

Since  

Aquaculture

Webinar 1 July 2017  =  207

As of 31 July 2018
Core Stewardship Principles and VFD Animal Feed

5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Veterinary Associations

Associations representing veterinarians who practice cattle, swine, chicken, and turkey medicine have also published antimicrobial stewardship guidelines
5. Education - Make resources available and encourage the development of expertise in antimicrobial stewardship.

Producer - “quality assurance programs”
Core Stewardship Principles and VFD Animal Feeds

Antimicrobial Stewardship Definition and Core Principles

5. Educate and build expertise
   - use of antimicrobial alternatives
     - Drugs, enzymes
     - Phytochemicals
     - Microbial derived products
FDA Drug vs. Food

- Intended use of a substance determines if it is regulated as a food or a drug
  - Matrix listing to delineate drug vs. food
5. Educate and build expertise
   - Support research on antimicrobial drug use and resistance.
In Summary

Significant progress has been made.

All drug sponsors voluntarily met the January 2017 milestone.

Primary stakeholders for the VFD Rule are the veterinary community, animal producers, & feed manufacturers/distributors.

Substantial outreach fostering stewardship to, and by, these stakeholders has occurred. Continued engagement of VFD Rule stakeholders is critical to continued success.
In Summary

Core Principles of Antimicrobial Stewardship have been published by AVMA.

Producer Quality Assurance programs continue to support stewardship.

An education and research institute has been announced.

Sponsors are invited to consult with FDA, and our colleagues at USDA, as alternative products are developed.

www.fda.gov