

Fostering Core Stewardship Principles and VFD Animal Feed

Outline

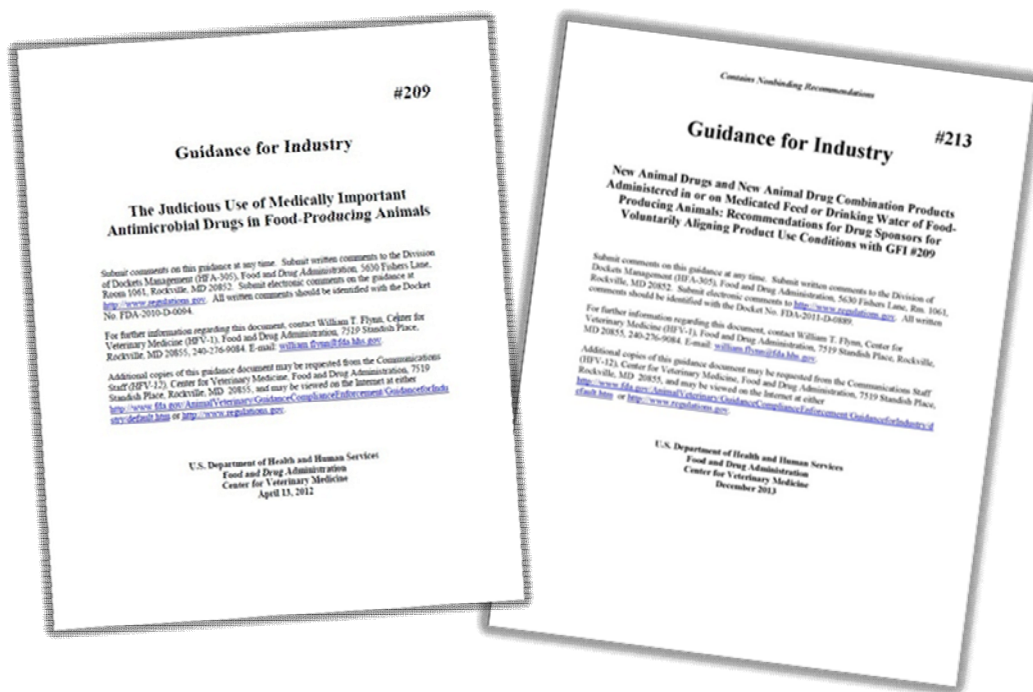


What changes were made ?

- Changes to Affected Applications
- Veterinary Feed Directive
- Major and Minor Species

Core stewardship principles and VFD Animal feed.

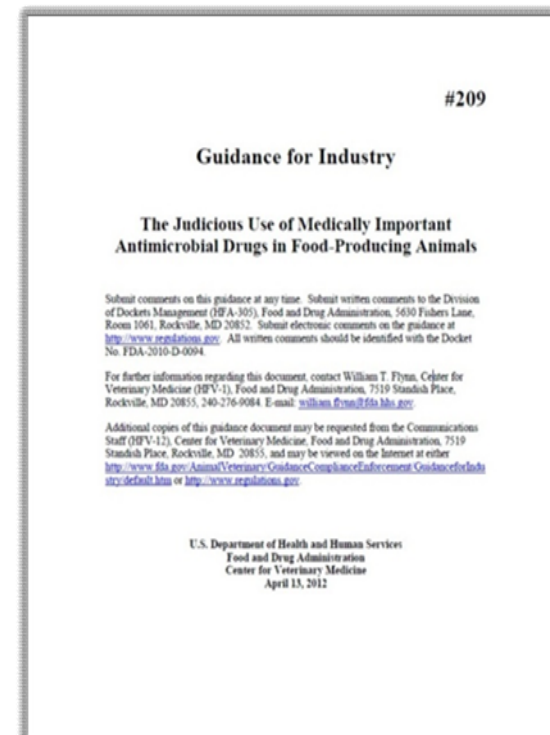
What changes were made and why?



Guidance #209: Outlined AMR Policy

FDA

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:

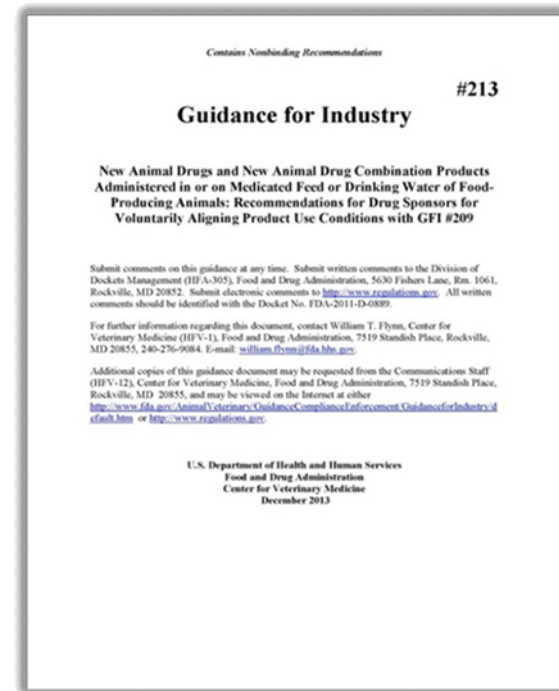
1. are considered necessary for assuring animal health and,
2. that include veterinary oversight or consultation

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.

<https://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM588085.pdf>

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— **84** were completely withdrawn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— Production (e.g., growth promotion) indications associated with the medically important antimicrobial were withdrawn from all applications that included such indications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



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

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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)

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

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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
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Core Stewardship Principles and VFD Animal Feeds

Antimicrobial Stewardship Definition and Core Principles

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
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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.**

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

	<u>Since</u>	<u>“Hits” - 14 August 2018</u>
VFD Main Website	1 September 2015	= 182,342
Retail Establishments Letter	13 November 2015	= 10,788
State/Federal VCPR	13 November 2015	= 7,616
GFI # 233 – Common Format	30 November 2015	= 4,505
GFI # 120	January 2016	= 10,710

<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

Since “Hits” as of 14 August 2018

Videos

Overview	18 November 2016	=	8,239
Veterinarian	18 November 2016	=	3,661
Distributors	19 November 2016	=	2,100
Producers	20 November 2016	=	2,079

<https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>

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

Federal Agencies

CVM FDA

Brochures

“Hits” from July 2015

as of 14 August 2018

Producers

17,035

Distributors

Who manufacture

10,439

Who don't

8,114

Veterinarians

15,045

Students

4,897

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:

Fostering Stewardship	1 April 2017	713
Honey Bees	7 August 2017	1,571

<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

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/ct_aast



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 Times Completed by Accredited Veterinarians

Module # 23 –	Since 2012 = 27,695	CY 2018 = 3,761
Module # 29 –	Since 2016 = 8,322	= 2,920
Module # 30 -	Since 2018 = <u>819</u>	= <u>819</u>
Totals	= 36,836	= 7,500

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/ct_aast

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/memorandaofunderstandingmou/s/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:

	<u>Since</u>	<u>As of 31 July 2018</u>
VFD Webpage	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:

<u>Since</u>		<u>As of 31 July 2018</u>
January 2018	=	2,187

Core Stewardship Principles for VFD Animal Feed
 Antimicrobial Stewardship Definition and Core Principles

5. Educate and build expertise

Professional Associations

Since

As of 31 July 2018

Honey Bee

Website **1 July 2017** = **3,921**

Webinar **1 July 2017** = **872**



Core Stewardship Principles for VFD Animal Feed
Antimicrobial Stewardship Definition and Core Principles

5. Educate and build expertise

Professional Associations – AVMA

Since

As of 31 July 2018

Aquaculture

Webinar

1 July 2017

=

207

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
- CVM Program Policy And Procedures Manual Guide 1240.3605, Regulating Animal Foods With Drug Claims at
 - <http://www.fda.gov/downloads/animalveterinary/guidancecompliance/enforcement/policiesproceduresmanual/ucm046883.pdf>
 - Matrix listing to delineate drug vs. food



Core Stewardship Principles and VFD Animal Feed Antimicrobial Stewardship Definition and Core Principles

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.

