

VFD

Veterinary Feed Directive



Agenda

- Background
- FDA regulations
- VFD
- Veterinary Client Patient Relationship (VCPR)
- Minor species

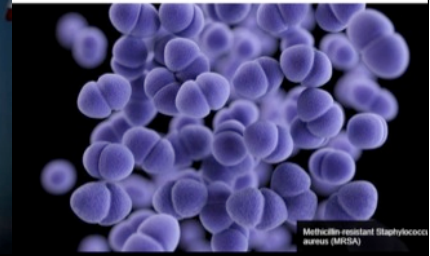


So how did we get here??

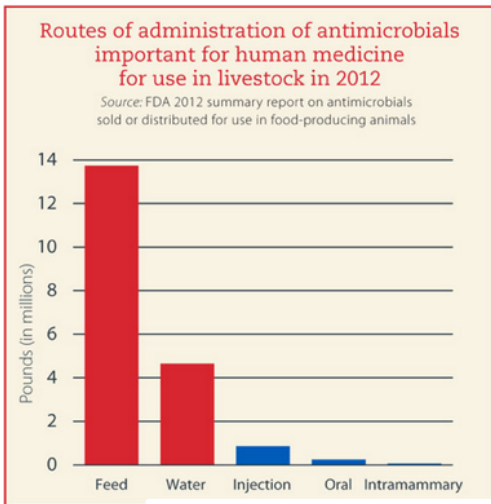


President signs order to fight superbugs

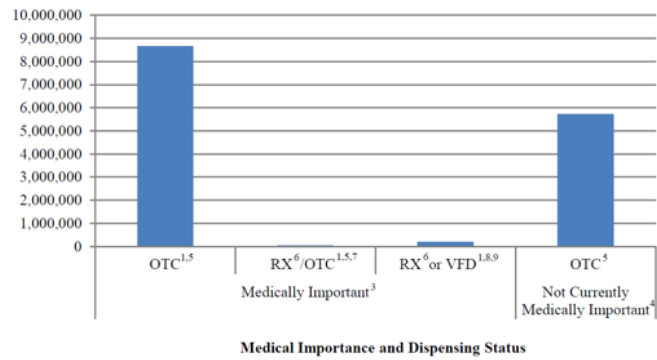
By Sandra Young, CNN
Updated 5:28 PM EDT, Thu September 18, 2014



Antibiotic Usage Reporting – FDA 2012



ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS¹
ACTIVELY MARKETED IN 2012
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND DISPENSING STATUS



95% of all antibiotic usage is in feed and water



FDA Guidance for Industry 152

Finalized 2003

“Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern”

- Discusses the use of antibiotics in herds or flocks for production purposes
- Classified all antibiotics into 2 classes
 - Medically Important for Human Use
 - Non-medically Important for Human Use



Medically Important Antimicrobial Drugs

- | | |
|---|--|
| <ul style="list-style-type: none"> • Critically Important <ul style="list-style-type: none"> – Ceftiofur – Flouroquinolones – Macrolides – Sulfas • Important <ul style="list-style-type: none"> – Everything else | <ul style="list-style-type: none"> • Highly Important <ul style="list-style-type: none"> – Penicillins – Tetracyclines – Phenicols • Not Important <ul style="list-style-type: none"> – Ionophores – Bambermycins – Bacitracin |
|---|--|



FDA Guidance for Industry 209

Released in 2010, Finalized 2012

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

- Specifically addresses use of antibiotics in food producing animals for production or growth-enhancement purposes



FDA Rational

- Misuse and overuse of antimicrobial drugs enables antimicrobial resistant bacteria to increase in numbers
- Human important drugs must be used judiciously in both animal and human medicine to slow the development of resistance.



Key Principles from GFI 209

Principle 1 : *The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health.*



FDA Guidance for Industry 209

Released in 2010, Finalized 2012

- FDA believes the use of medically important antimicrobial drugs in food-producing animals for **production** purposes (e.g., to promote growth or improve feed efficiency) represents an **injudicious (not judicious)** use of these important drugs



FDA Guidance for Industry 209

Released in 2010, Finalized 2012

- FDA considers uses that are associated with the **treatment, control, or prevention of specific diseases**, including administration through feed or water, to be uses that are necessary for assuring the health of food-producing animals



Key Principles from GFI 209

Principle 2: *The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.*



FDA Guidance for Industry 209

Released in 2010, Finalized 2012

- Most of the **feed-use** antimicrobial drugs are currently approved for over-the-counter use in food-producing animals for purposes that include the treatment, control, and prevention of disease as well as for production purposes

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FDA Guidance for Industry 213

Released 2012, Finalized December 2013

- “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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Summary of GFI 213

- Identifies medically important antimicrobials
 - All drugs listed in GFI 152 Appendix
- Describes the process for voluntarily phasing out antibiotics for production purposes
- Discusses the phasing in of veterinary oversight for all therapeutic uses of antibiotics in the feed or water
- Also provides a timeline for implementation (December 2016)



Take Home Message?

- Label indications for production purposes will be removed
 - Voluntary change
 - Effective December 2016



Take Home Message?

- Restrictions on OTC feed-grade or OTC water soluble antibiotics
 - Water soluble products will become Rx
 - Products used in or on feed will become VFD
- DOES NOT APPLY to injectable antibiotics



Take Home Message?

A Veterinary Feed Directive (VFD) will be required to:

- Obtain and use antibiotics that are delivered in the feed
- Obtain and use products that already contain an antibiotic
 - Bagged feeds, mineral blocks, milk replacer, etc.
- **A prescription will be required to:**
 - Obtain and use antibiotics that are delivered in the water



Generic CTC (Chlortetracycline) 100 NADA 48-480	
Generic Name: chlortetracycline hydrochloride granule Dosage Form: FOR ANIMAL USE ONLY	
Calves	
DOSAGE LEVEL	INDICATIONS FOR USE
0.1 mg/lb. body wt daily	Calves (up to 250 lbs.): For an increased rate of body weight gain & improved feed efficiency.
25-70 mg/head/day	Calves (250-400 lbs.) For an increased rate of weight gain and improved feed efficiency
WARNING: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	
Growing Cattle	
DOSAGE LEVEL	INDICATION FOR USE
70mg/head/day	Growing cattle (over 400 lbs.): For increased rate of weight gain, improved feed efficiency & reduction of liver condemnation due to liver abscesses. Zero-Day withdrawal period
WARNING: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	

Increased rate of body weight gain & Improved Feed Efficiency will be removed

Wording might be changed to read:
"For reduction of incidence of liver abscesses in beef cattle associated w/ *Fusobacterium necrophorum* & *Arcanobacterium pyogenes*"

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Affected feed-use antibiotics

Antimicrobial Class	Specific drugs approved for use in feed
Aminoglycosides	Apramycin, Hygromycin B, Neomycin, Streptomycin
Diaminopyrimidines	Ormetoprim
Lincosamides	Lincomycin
Macrolides	Erythromycin, Oleandomycin, Tylosin
Penicillins	Penicillin
Streptogramins	Virginiamycin
Sulfas	Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline
Tetracycline	Chlortetracycline, Oxytetracycline



Affected water-use antibiotics

Antimicrobial Class	Specific drugs approved for use in water
Aminoglycosides	Apramycin, Gentamicin, Neomycin, Spectinomycin, Streptomycin
Lincosamides	Lincomycin
Macrolides	Carbomycin, Erythromycin, <u>Tylosin</u>
Penicillins	Penicillin
Sulfas	Sulfachloropyrazine, Sulfachlorpyridazine, Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline
Tetracycline	Chlortetracycline, Oxytetracycline, Tetracycline



Antibiotics **NOT** affected by Guidance 209/213

- Antibiotics that are already VFD or Rx based:
 - avilamycin, florfenicol, tilmicosin; or Rx - Tylosin.
- Antibiotics that are not medically important:
 - Ionophores (monensin, lasalocid, narasin (Skycis, etc.))
 - Bacitracin (BMD, bacitracin zinc)
 - Bambermycins (Flavomycin, GainPro)
 - Carbadox (Mecadox)
- Other drugs (that are not antibiotics), including:
 - Anthelmintics: Coumaphos, Fenbendazole, Ivermectin
 - Beta agonists: Ractopamine, Zilpaterol
 - Coccidiostats: Clopidol, Decoquinate, Diclazuril



Caveat

- While FDA believes that all medically important antimicrobial new animal drug products should be marketed with the appropriate professional oversight restriction, **at this time** FDA is most concerned with medically important antimicrobial new animal drugs and combination new animal drug products intended for use in or on the feed or water of food-producing animals.



Veterinary Feed Directive

- 1996 Animal Drug Availability Act
- Alternative status for feed medication
- Written directive
- Requires VCPR



Veterinary Feed Directive (VFD)

- An order for utilizing “medically important” antibiotics in animal feed.
 - Functionally works just like a prescription
 - Technically not a prescription
- It requires a VFD from a veterinarian with whom the producer has a valid VCPR.
 - Veterinarian is responsible for filling it out correctly, based on the correct information from the producer.
- Producer (or the veterinarian) will need to get the VFD to the feed mill to manufacture the feed.



Veterinary Feed Directive (VFD)

- New Requirements:
 - VCPR
 - State or Federal
 - Electronic signature and transmittal acceptable
 - Telephone VFDs still not allowed
 - Estimate of tons of feed no longer required
 - Replaced by estimate of number of animals



Extra-Label Drug Use (ELDU)

- Extra-label use of feed additive antibiotics is **illegal**
 - Extra-label use is using a drug at a **dose**, by a **route**, for a **condition or indication**, in a **species**, or for a **duration** not described on the label



Implementation Timeline Summary

- January 1, 2017
- Implementation date for all medically important antimicrobials for use in or on feed to require a VFD



What do you need to do for a VFD

- Working relationship with your veterinarian (VCPR)



Veterinarian-Client-Patient-Relationship (VCPR)

1. A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the **client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;**
2. There is **sufficient knowledge of the animal(s) by the veterinarian** to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
3. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the **veterinarian has recently seen and is personally acquainted** with the keeping and care of the animal(s) by **virtue of examination of the animal(s),** and/or by medically appropriate and **timely visits to the premises** where the animal(s) are kept.



VCPR Clarification

- Veterinarian must be licensed in state where animals reside
- Veterinarian does not need to make diagnosis but responsible for disease diagnosis protocol and training
- Livestock producer/management willing to abide by protocol



Veterinary Feed Directive

Veterinarian: Grant Dewell
Address: 1600 S 16th Street
Ames, IA 50011
Phone: 515-294-7595
Fax or email (optional): _____

Client: XYZ Feedlot
Address: 1234 B Ave
Ames, IA 50011
Phone: 515-123-4567
Fax or email (optional): _____



Drug(s): Tylosin Phosphate Drug Level: 10 g/ton

No substitutions allowed

Duration of Use: Continuously


Species and production class: Beef cattle

Indications for use: Reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*

Caution (if any):

No refills/reorders authorized

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**USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD)
DRUG IN A MANNER OTHER THAN AS DIRECTED
ON THE LABELING (EXTRALABEL USE) IS NOT PERMITTED**


Approximate number of animals: 999

Premises: 234 B Ave, Ames, IA 50011

Other identification (e.g., age, weight) (optional):

Special instructions (if any):

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Affirmation of intent (for combination of VFD drugs) (mark one statement)

- This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.
- This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component:

Drug(s)	Drug Level(s) and Any Special Instructions
Drug(s)_Row_1	

**Affirmation of intent (for combination of VFD drugs) (mark one statement)**


- This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.




Withdrawal time (if any): This VFD must be withdrawn 0 days prior to slaughter

VFD date of issuance (month/day/year): 01/01/2017

VFD expiration date (month/day/year): 06/30/2017

Veterinarian's signature: 

All parties must retain a copy of this VFD for 2 years after the date of issuance

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Producer Responsibilities

- Only use feed containing VFD drug with a valid VFD issued by licensed veterinarian
- Follow VFD/label directions in terms of dose, duration, etc.
- Do not feed VFD feed after expiration date
- Provide a copy VFD order to feed distributor if necessary
- Maintain copy of VFD for 2 years
- Provide VFD orders to FDA on request

FDA Expectations

- Expect reduction in quantity of medically important antibiotics
- Expect Veterinarians to be gatekeeper



Inspections

- FDA beginning VFD inspections “Pilot Project”
- First inspect distributors
 - Will evaluate 3 randomly selected VFD forms
 - Will pick 1 to trace back to veterinarian and producer
- Looking for all the required information, evidence of VCPR, feed records, etc.



Enforcement

- Focus will initially be on education and guidance



Minor Species

- CPG Sec 615.115 Extra-Label Use of Medicated Feeds for Minor Species
- The use or intended use of medicated feeds for treating animals in any manner other than in accordance with the approved labeling causes the drug used in the feed to be adulterated



Minor Species

- Nevertheless, extra-label use of medicated feed for treatment of minor species may be considered when the health of animals is threatened and suffering or death would result from failure to treat the affected animals. In instances of this nature, the agency **will not ordinarily consider regulatory action** against the veterinarian or animal producer provided all of the circumstances listed below exist.



Minor Species

- Only for treatment of minor species
- Drug approved for major species
- Feed approved major species
- Express prior written recommendation veterinarian, oversight, VCPR



Minor Species

- FDA currently reviewing this policy
- Expect a new policy related to ELDU VFD drugs for Minor Species



Minor Species

- Feedmills are unwilling to formulate VFD feed ELDU
- Expect it will still be allowable in the future
- Source?



Thank You

