Using Feed-Grade Antibiotics in Livestock:

What Changes Should We Prepare For?

SDSU Extension

Russ Daly, DVM, MS, DACVPM

Extension Veterinarian
State Public Health Veterinarian

Animal Antibiotics: Currently

Injectable

Oral Bolus

Drinking Water

Feed

iGrow.org

Animal Antibiotics: Currently

Labeled Uses:

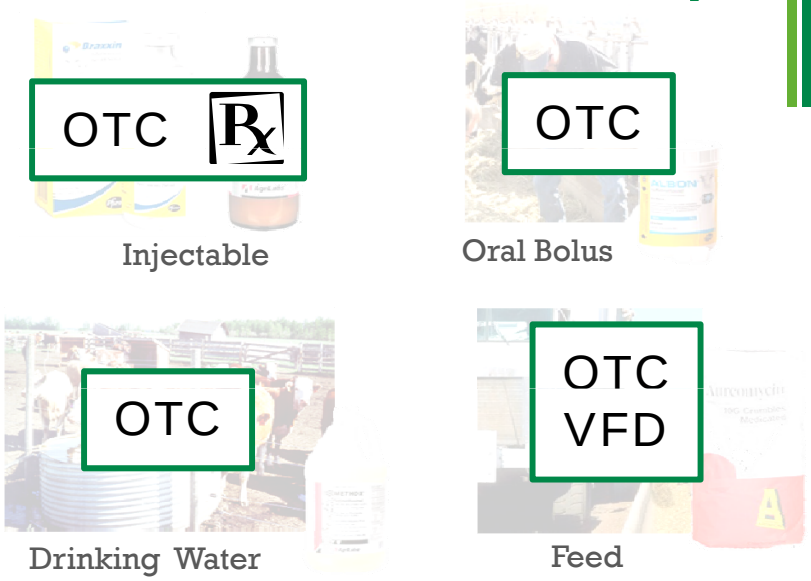
- Treatment of disease
- Control of disease
- Prevention of disease
- Feed efficiency
- Growth promotion

Drinking Water

Feed

iGrow.org

Animal Antibiotics: Currently



OTC Rx

Injectable

OTC

Oral Bolus

OTC

Drinking Water

OTC
VFD

Feed

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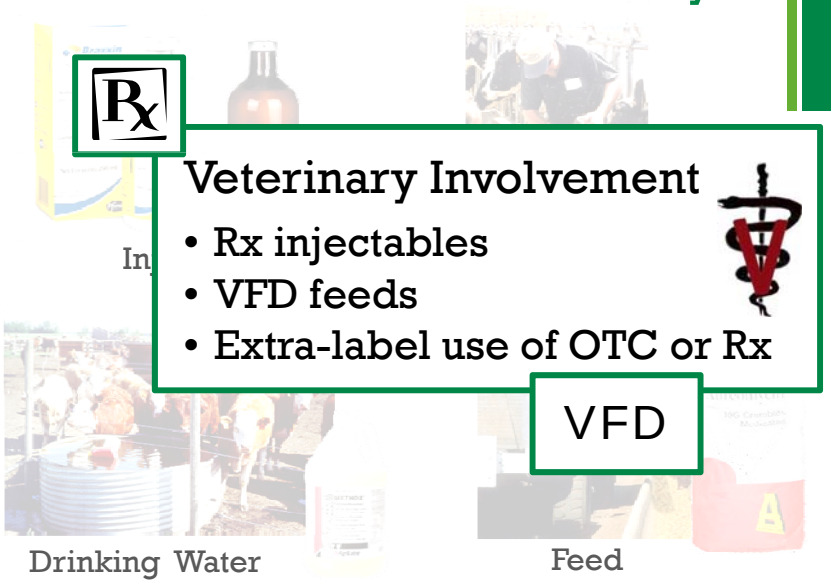
Animal Antibiotics: Currently



Veterinary Involvement

- Rx injectables
- VFD feeds
- Extra-label use of OTC or Rx

VFD

In

Drinking Water

Feed

iGrow.org

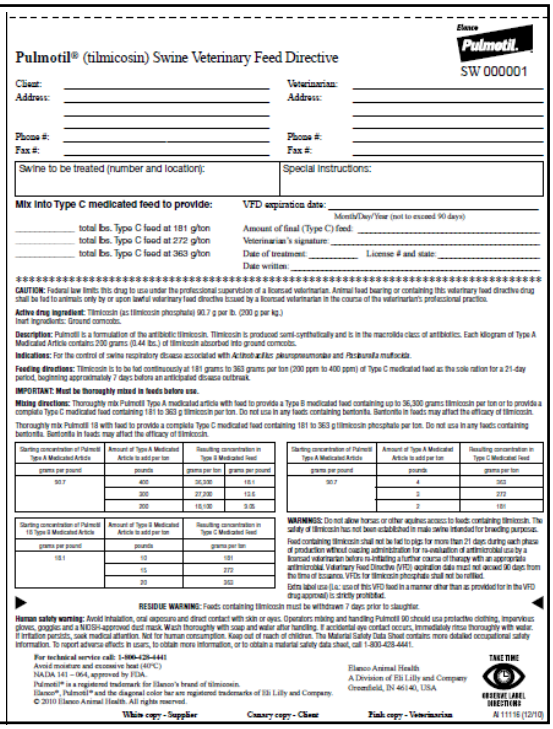
Veterinary Client Patient Relationship (VCPR)

- Veterinarian has assumed responsibility for medical judgments about the animals and the client has agreed to follow the vet's instructions.
- 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 timely visits.
- Veterinarian is available for follow-up in case of adverse reactions or treatment failure

Veterinary Involvement

- Rx injectables
- VFD feeds
- Extra-label use of OTC or Rx

Veterinary Feed Directive



Pulmotil® (tilmicosin) Swine Veterinary Feed Directive

SW 000001

Client: _____ Veterinarian: _____

Address: _____ Address: _____

Phone #: _____ Phone #: _____

Fax #: _____ Fax #: _____

Swine to be treated (number and location):	Special instructions:

Mix into Type C medicated feed to provide:

_____ total lbs. Type C feed at 181 g/ton

_____ total lbs. Type C feed at 272 g/ton

_____ total lbs. Type C feed at 363 g/ton

VFD expiration date: _____ Month/Day/Year (not to exceed 90 days)

Amount of final (Type C) feed: _____

Veterinarian's signature: _____

Date of treatment: _____ License # and state: _____

Date written: _____

CAUTION: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.

Active drug ingredient: Tilmicosin (as tilmicosin phosphate) 90.7 g per lb. (200 g per kg.)
Inert ingredients: Ground corncobs.

Description: Pulmotil is a formulation of the antibiotic tilmicosin. Tilmicosin is produced semi-synthetically and is in the macrolide class of antibiotics. Each kilogram of Type A Medicated Article contains 200 grams (9.44 lbs.) of tilmicosin absorbed into ground corncobs.

Indications: For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

Feeding directions: Tilmicosin is to be fed continuously at 181 grams to 363 grams per ton (200 ppm to 400 ppm) of Type C medicated feed as the sole ration for a 21-day period, beginning approximately 7 days before an anticipated disease outbreak.

IMPORTANT: Must be thoroughly mixed in feeds before use.

Mixing directions: Thoroughly mix Pulmotil Type A medicated article with feed to provide a Type B medicated feed containing up to 36,300 grams tilmicosin per ton or to provide a complete Type C medicated feed containing 181 to 363 g tilmicosin per ton. Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.

Thoroughly mix Pulmotil 18 with feed to provide a complete Type C medicated feed containing 181 to 363 g tilmicosin phosphate per ton. Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.

Starting concentration of Pulmotil Type A Medicated Article	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type B Medicated feed	
grams per pound	pounds	grams per ton	grams per pound
90.7	400	36,300	18.1
	300	27,200	13.6
	200	18,100	9.05

Starting concentration of Pulmotil Type A Medicated Article	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type C Medicated feed
grams per pound	pounds	grams per ton
90.7	4	363
	3	272
	2	181

Starting concentration of Pulmotil 18 Type B Medicated Article	Amount of Type B Medicated Article to add per ton	Resulting concentration in Type C Medicated feed
grams per pound	pounds	grams per ton
18.1	10	181
	15	272
	20	363

WARNINGS: Do not allow horses or other equines access to feeds containing tilmicosin. The safety of tilmicosin has not been established in male swine intended for breeding purposes.

Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for re-evaluation of antimicrobial use by a licensed veterinarian before re-initiating a further course of therapy with an appropriate antimicrobial. Voluntary Feed Directive (VFD) expiration date must not exceed 90 days from the time of issuance. VFDs for tilmicosin phosphate shall not be refilled.

Extra label use (i.e.: use of this VFD feed in a manner other than as provided for in the VFD drug approval) is strictly prohibited.

RESIDUE WARNING: Feeds containing tilmicosin must be withdrawn 7 days prior to slaughter.

Human safety warning: Avoid inhalation, oral exposure and direct contact with skin or eyes. Operators mixing and handling Pulmotil 90 should use protective clothing, impervious gloves, goggles and a NIOSH-approved dust mask. Wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. If irritation persists, seek medical attention. Not for human consumption. Keep out of reach of children. The Material Safety Data Sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain a material safety data sheet, call 1-800-428-4441.

For technical service call: 1-800-428-4441
Avoid moisture and excessive heat (40°C)
NADA 141 – 064, approved by FDA.
Pulmotil® is a registered trademark for Elanco's brand of tilmicosin.
Elanco®, Pulmotil® and the diagonal color bar are registered trademarks of Eli Lilly and Company.
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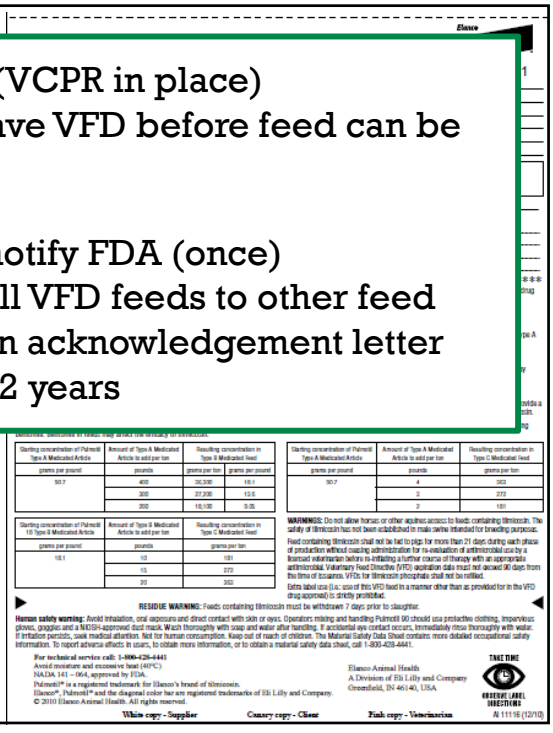
Elanco Animal Health
A Division of Eli Lilly and Company
Greenfield, IN 46140, USA

TAKE TIME
ADHERE LABEL DIRECTIONS

White copy - Supplier Canary copy - Client Pink copy - Veterinarian AI 111 16 (12/10)

Veterinary Feed Directive

- Filled out by vet (VCPR in place)
- Feed mill must have VFD before feed can be distributed
  - Hard copy or fax
- Feed mills must notify FDA (once)
- Feed mills can sell VFD feeds to other feed mills if they get an acknowledgement letter
- Records kept for 2 years



Pulmotil® (tilmicosin) Swine Veterinary Feed Directive

Elanco Pulmotil

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VFD expiration date: _____

Month/Day/Year (not to exceed 90 days)

Amount of final (Type C) feed: _____

Veterinarian's signature: _____

Date of treatment: _____ License # and state: _____

Date written: _____

Veterinary Feed Directive

Animal Antibiotics: Currently

Drinking Water

Feed

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Antibiotic Resistance: "One of Our Most Serious Health Threats"

Estimated minimum number of illnesses and deaths caused by antibiotic resistance*:

At least **2,049,442** illnesses,

23,000 deaths

**bacteria and fungus included in this report*

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Urgent Threats

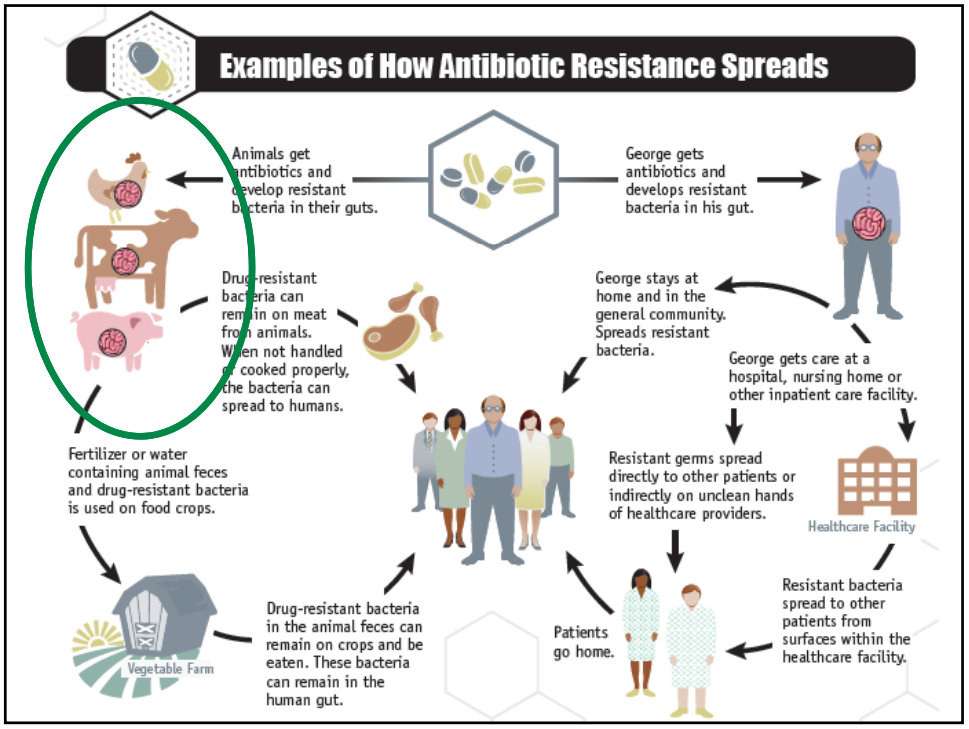
- *Clostridium difficile*
- Carbapenem-resistant Enterobacteriaceae (CRE)
- Drug-resistant *Neisseria gonorrhoeae*

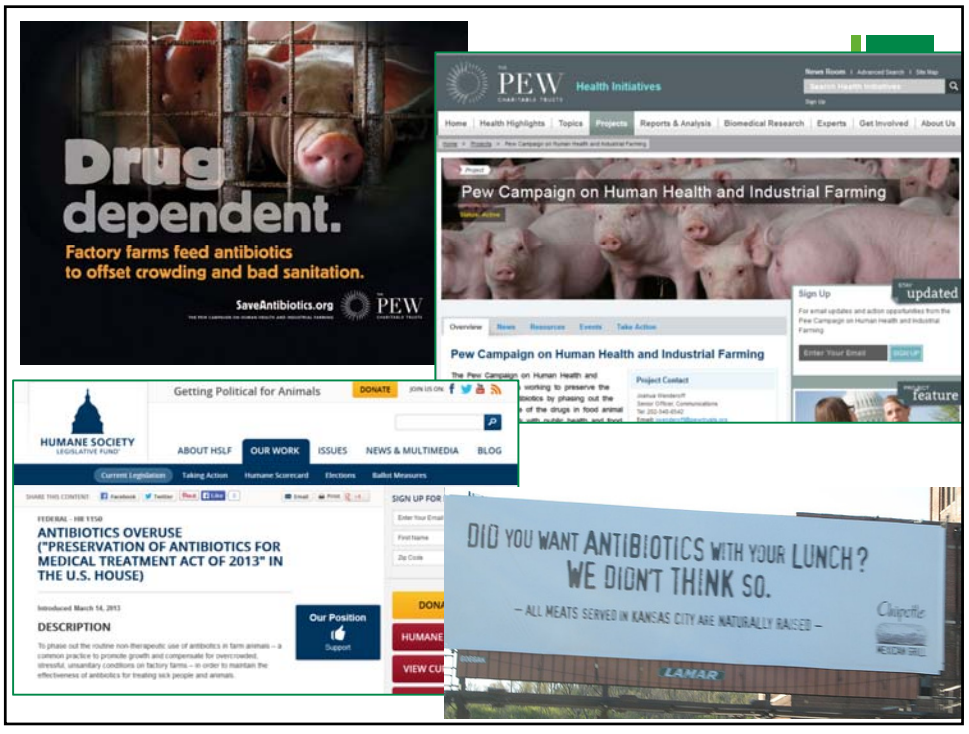
Serious Threats

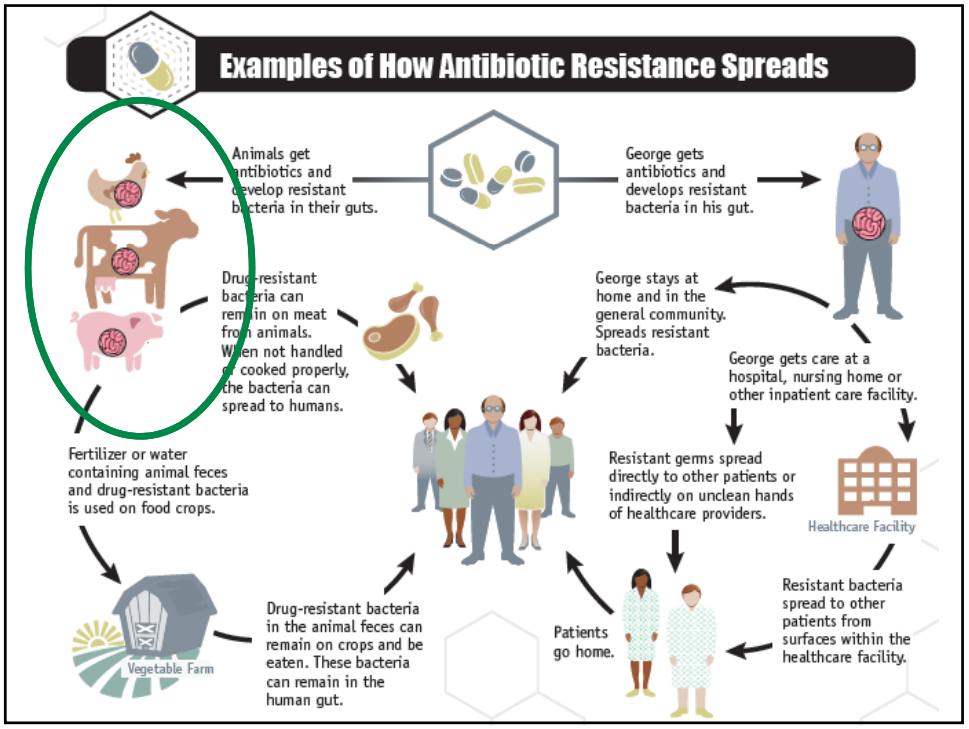
- Multidrug-resistant *Acinetobacter*
- Drug-resistant *Campylobacter*
- Fluconazole-resistant *Candida* (a fungus)
- Extended spectrum β-lactamase producing Enterobacteriaceae (ESBLs)
- Vancomycin-resistant *Enterococcus* (VRE)
- Multidrug-resistant *Pseudomonas aeruginosa*
- Drug-resistant Non-typhoidal *Salmonella*
- Drug-resistant *Salmonella* Typhi
- Drug-resistant *Shigella*
- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Drug-resistant *Streptococcus pneumoniae*
- Drug-resistant tuberculosis

Concerning Threats

- Vancomycin-resistant *Staphylococcus aureus* (VRSA)
- Erythromycin-resistant Group A *Streptococcus*
- Clindamycin-resistant Group B *Streptococcus*

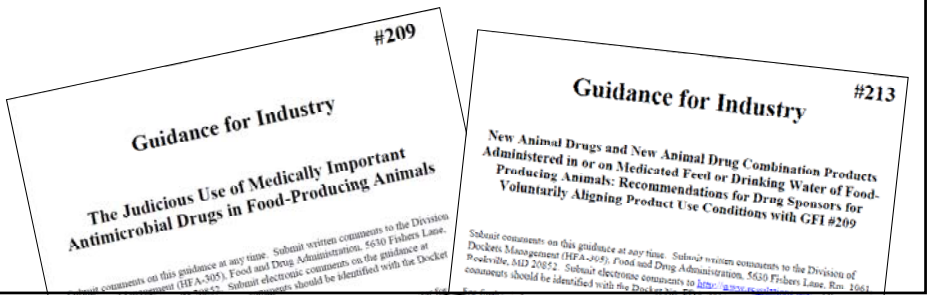

Examples of How Antibiotic Resistance Spreads
Animals get antibiotics and develop resistant bacteria in their guts.
George gets antibiotics and develops resistant bacteria in his gut.
Drug-resistant bacteria can remain on meat from animals. When not handled or cooked properly, the bacteria can spread to humans.
George stays at home and in the general community. Spreads resistant bacteria.
George gets care at a hospital, nursing home or other inpatient care facility.
Fertilizer or water containing animal feces and drug-resistant bacteria is used on food crops.
Resistant germs spread directly to other patients or indirectly on unclean hands of healthcare providers.
Healthcare Facility
Vegetable Farm
Drug-resistant bacteria in the animal feces can remain on crops and be eaten. These bacteria can remain in the human gut.
Patients go home.
Resistant bacteria spread to other patients from surfaces within the healthcare facility.


Drug dependent.
Factory farms feed antibiotics to offset crowding and bad sanitation.
SaveAntibiotics.org
PEW
Health Initiatives
Pew Campaign on Human Health and Industrial Farming
Getting Political for Animals
HUMANE SOCIETY LEGISLATIVE FUND
ABOUT HSLF
OUR WORK
ISSUES
NEWS & MULTIMEDIA
BLOG
ANTIBIOTICS OVERUSE ("PRESERVATION OF ANTIBIOTICS FOR MEDICAL TREATMENT ACT OF 2013" IN THE U.S. HOUSE)
DESCRIPTION
Our Position
DID YOU WANT ANTIBIOTICS WITH YOUR LUNCH? WE DIDN'T THINK SO.
– ALL MEATS SERVED IN KANSAS CITY ARE NATURALLY RAISED –
Chipotle
LAMAR



FDA's Proposals

- Guidance for Industry #209
  - "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals"
- Guidance for Industry #213
  - "Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209"
- Veterinary Feed Directive proposed rule



FDA Guidance for Industry #209

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

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FDA Guidance for Industry #209

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

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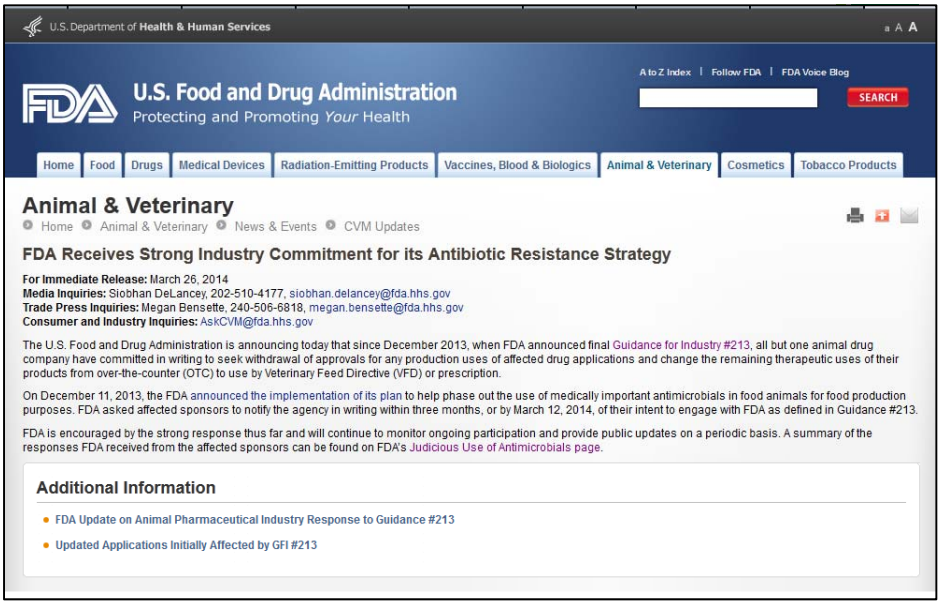
FDA Guidance for Industry #209: Medically Important Antibiotics

Class of antibiotic	Feed-Grade Examples
Aminoglycosides	Neomycin, Streptomycin
Lincosamides	Lincomix®
Macrolides	Pulmotil®
Penicillins	Penicillin, CSP
Streptogramins	Stafac®
Sulfonamides	Sulfamethazine, Aureomix®
Tetracyclines	Aureomycin®, CTC

FDA Guidance for Industry #213

- Final as of December 2013
- For the drug companies
- For "medically important antibiotics"
- Asks companies to voluntarily revise their product labels to remove growth promotion and feed efficiency
- Provides for moving OTC products to Rx or VFD status



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FDA Receives Strong Industry Commitment for its Antibiotic Resistance Strategy

For Immediate Release: March 26, 2014
Media Inquiries: Siobhan DeLancey, 202-510-4177, siobhan.delancey@fda.hhs.gov
Trade Press Inquiries: Megan Bensette, 240-506-6818, megan.bensette@fda.hhs.gov
Consumer and Industry Inquiries: AskCVM@fda.hhs.gov

The U.S. Food and Drug Administration is announcing today that since December 2013, when FDA announced final Guidance for Industry #213, all but one animal drug company have committed in writing to seek withdrawal of approvals for any production uses of affected drug applications and change the remaining therapeutic uses of their products from over-the-counter (OTC) to use by Veterinary Feed Directive (VFD) or prescription.

On December 11, 2013, the FDA announced the implementation of its plan to help phase out the use of medically important antimicrobials in food animals for food production purposes. FDA asked affected sponsors to notify the agency in writing within three months, or by March 12, 2014, of their intent to engage with FDA as defined in Guidance #213.

FDA is encouraged by the strong response thus far and will continue to monitor ongoing participation and provide public updates on a periodic basis. A summary of the responses FDA received from the affected sponsors can be found on FDA's Judicious Use of Antimicrobials page.

Additional Information

- FDA Update on Animal Pharmaceutical Industry Response to Guidance #213
- Updated Applications Initially Affected by GFI #213

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So… What will change?

- Growth promotion uses in feed no longer allowed
  1. Tetracyclines: CTC, Aureomycin, NeoTerra
  2. Stafac (virginiamycin)
- Use of "medically important" feed antibiotics will need a VFD
  - Can only use for treatment, control, prevention
  1. Tetracyclines (CTC, Aureomycin, NeoTerra)
  2. Tylan
  3. Sulfamethazine (Aureomix)
  4. Stafac for liver abscesses
  5. Medicated milk replacers (w/ oxytetracylcine, neomycin…)

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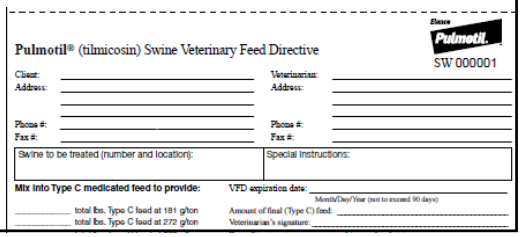
So… What will change?

- Changes to the VFD process
  - Still under comment period
  - No longer need to estimate amount of feed consumed
    - Inclusion rate, animals to feed, duration
  - Expiration dates up to 6 months (maybe longer)
  - Electronic delivery
  - Reduce bookkeeping requirement to 1 year



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Veterinarian's signature: _____

So… What will Change?

- Who defines a valid Veterinary Client Patient Relationship
  - Will be left to each state's regulations or veterinary board
  - Veterinarian must be licensed in state where the animals are
- "Medically important" water medications will move to prescription status

What Won't Change

- Use of non- "medically important" drugs:
  - Ionophores (Bovatec, Rumensin, etc.)
  - Coccidiosis treatments (Corid, Deccox, etc.)
  - Bacitracin (BMD)
- Ability to use the same products currently used for treatment, control, prevention
  - But will need a VFD now
- Injectable medication uses
- Extra-label uses of feed-grade medications
  - Is illegal now, will continue to be illegal

What Won't Change

- Ability for current feed mill operators to supply feed medications
  - VFD documentation and records need to be kept
  - VFD drugs will not automatically need to be handled only by licensed feed mills
- Need for veterinarians to be involved in medication decisions


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