

Stewardship of Antibiotics in Food Producing Animals

Veterinary Feed Directive
Dr. Al Schultz, Vita Plus



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Breaking News – May 25, 2016

**'Nightmare Bacteria' Superbug
Found for First Time in U.S – *NBC
News***

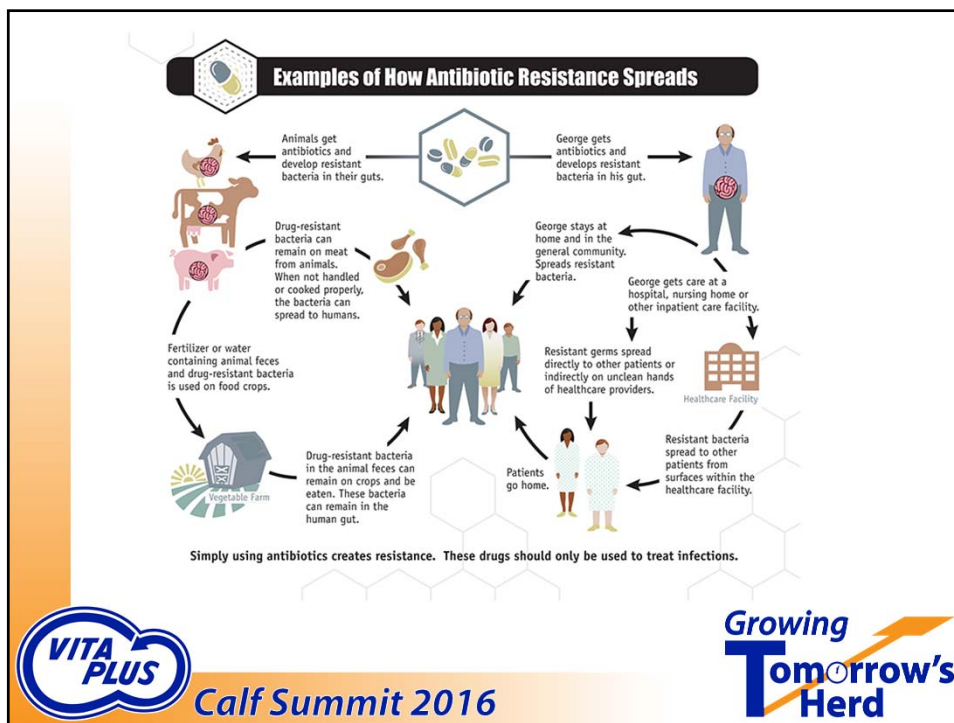
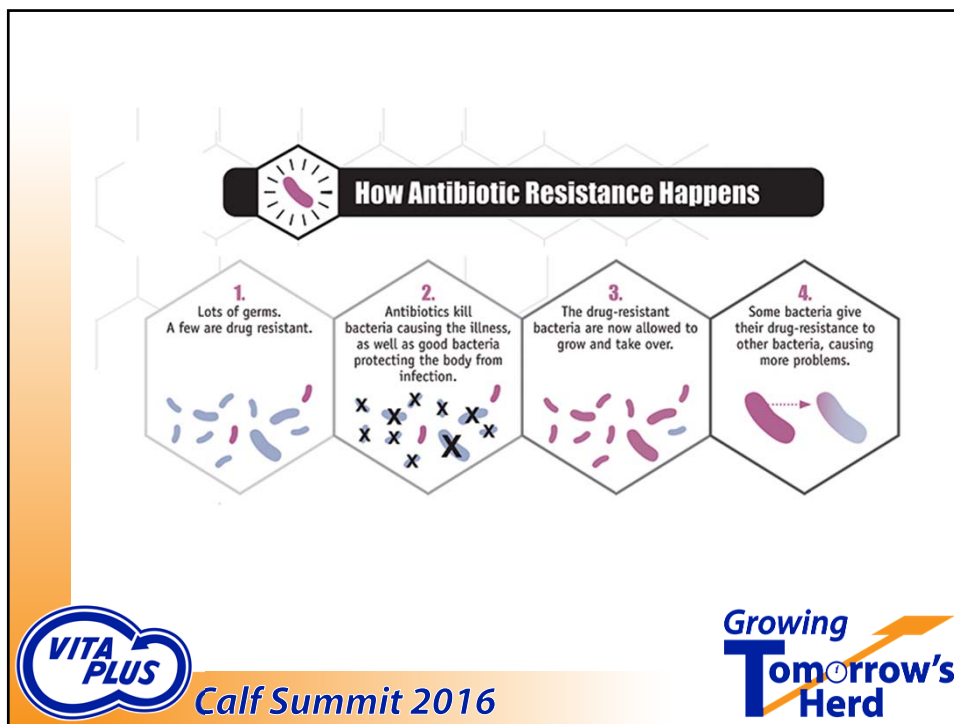
**Woman found to harbor infection
resistant to antibiotic of last
resort – *USA Today***

**The superbug that doctors have been
dreading just reached the U.S. –
*Washington Post***



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Science Says!!!

Several things must happen to transfer antibiotic resistance

- Antibiotic –resistant bacteria must be present in an animal when it leaves the farm
- The bacteria must survive the sanitation steps in processing
- The bacteria must survive the food preparation step (cooking, washing , etc.)
- The bacteria must cause human illness
- The sick patient must receive the same class of antibiotic used on the farm
- The patient must fail to recover due to the resistant infection



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Consumer Attitudes/Perception

You say	They hear
We use antibiotics to be more efficient.	You only care about making money.
We use antibiotics to keep animals healthy.	You HAVE to use antibiotics because of the filthy conditions.
FDA has approved antibiotics as safe after a rigorous review process.	They've been wrong before.
Rules dictate acceptable residue limits	How can we be sure ANY residue is safe.
There is no evidence that antibiotics in animals causes resistance in humans.	Yeah, right! You are using so much, that has to be contributing to the problem.



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All milk
in the grocery store is antibiotic free!



Every tanker load of milk is tested for antibiotics. If antibiotics are found in the load, the entire load is dumped.

Top Chain Restaurant Antibiotics Policies & Sourcing Practices*

Grade	Restaurants
A	Chick-fil-A, Firehouse Subs
B	Chickadee
C	Dunkin' Donuts, McDonald's
F	Arby's, Burger King, Dairy Queen, Domino's, Five Guys, Hardee's, Jack-in-the-Bowl, KFC, Little Caesars, Long John Silver's, Moe's, Oldemark, Outback Steakhouse, Panera Bread, Pardon My Chicken, Pei Wei, Popeyes, Quiznos, Raising Cane's, Sbarro, Sonic Drive-In, Subway, The Habit, The Meltdown, Wendy's, White Castle, Yogen, Zaxby's

* Information in this graphic regarding companies' antibiotic sources and/or meat purchasing practices reflects "best current information" which comes from company press releases or the source's follow-up efforts. Such information is not verified by the source's authors.

McDonald's
Is Making a Serious
CHANGE to Its
CHICKEN



80% OF ALL ANTIBIOTICS
ARE USED ON
FACTORY FARM
ANIMALS







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Status quo on antibiotics in feed is not an option




Preservation of Antibiotics for Medical Treatment Act (PAMTA)
by Rep. Louise Slaughter




OR





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FDA Develops Veterinary Feed Directive over the course of a decade

- Guidance Document #152 – October, 2003
- Guidance Document #209 – April, 2012
- Guidance Document #213 – April, 2012
- VFD codified in CFR – June, 2015
- Guidance Document #120 – June, 2015
- Guidance Document #233 – December, 2015



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Antibiotics (used in calves) divided into two classes

Medically Important *Used in human medicine*

- Chlortetracycline
- Neo-Terramycin
- Oxytetracycline
- Sulfamethazine

Medically Not Important *Not used in human medicine*

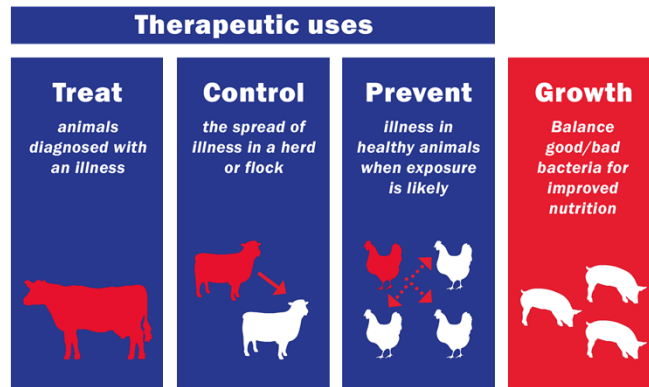
- Bovatec
- Corid
- Deccox
- Gainpro
- Rumensin



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Four Uses of Antibiotics



Growth (or efficiency) will no longer be an option for medically important antibiotics



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What is a veterinarian-client-patient relationship (VCPR)? CFR 530.3 slightly abridged

1. Veterinarian has responsibility for making medical judgements and the client agrees to follow instructions of the veterinarian.
2. Veterinarian has sufficient knowledge of animals to make a general or preliminary diagnosis of the medical condition of the animals.
3. Veterinarian is readily available for follow-up in case of adverse reaction or failure of prescribed therapy. Such can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animals by medically appropriate and timely visits to the premises.



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What is a Veterinary Feed Directive (VFD)

A VFD is a written or electronic license, authorizing a veterinary client to obtain and use a VFD drug for the treatment of that client's animals in accordance within the conditions of the VFD.



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Pulmotil[®] (tilmicosin) Veterinary Feed Directive for use in Cattle

Client: _____ Address: _____ Phone #: _____
 Business or Home _____
 Location of animals: _____

Approximate number of cattle: _____ Special instructions and/or other animal identification (optional): _____

Indication: For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in groups of beef and non-lactating dairy cattle, where active BRD has been diagnosed in at least 10% of the animals in the group.

Dosage: _____ g/ton (566 to 757 g/ton) **Duration:** 14 Days

Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra-label use) is not permitted.

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

To ensure both food safety and responsible use in cattle, the treatment of cattle with this medicated feed is required to be initiated within the first 45 days of the production period. The treatment should not occur concurrent with or following administration of an injectable macrolide, or within 3 days following administration of a non-macrolide injectable BRD therapy.

Use only in cattle fed in confinement for slaughter. Tilmicosin medicated feed treatment has not been evaluated in cattle with severe clinical disease. Cattle with severe clinical illness should be evaluated for individual treatment with an alternative non-macrolide therapy.

The expiration date for a tilmicosin Veterinary Feed Directive (VFD) for cattle must not exceed 45 days from the time of issuance. VFDs for tilmicosin phosphate shall not be refilled.

Complete Type C medicated feeds containing tilmicosin should not be pelleted. Do not use in any feeds containing bentonite, cottonseed meal, or cottonseed hulls. Bentonite, cottonseed meal, or cottonseed hulls in feeds may affect the efficacy of tilmicosin.

RESIDUE WARNING: Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product.

This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk.

This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves.

Combination Feeding with Other Drugs (select one):

☐ 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.

_____(not approved combination)

☐ 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.

VFD Issuance Date: _____ VFD Expiration Date: _____
 Month/Day/Year
 (Not to exceed 45 days from issuance date)

Veterinarian's signature: _____

For technical service call: 1-800-428-4441

NADA 141-064. Approved by the FDA.

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 Indianapolis, IN 46205, USA

White Copy (Original) - Veterinarian Canary Copy - Client Pink Copy - Distributor

What does a VFD look like?



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Expiration vs Duration

- The expiration date defines the period of time for which the authorization to feed the VFD feed is lawful. You cannot feed (even what you might have in your inventory) after the expiration date.
- The duration determines the length of time the VFD feed is allowed to be fed to animals as specified on the product label (for example 5 days for CTC at 10 mg/lb bodyweight).



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VFD Practical Issues

- A veterinarian can ONLY use the approved feed clearance. No extra-label authority.
- Water soluble antibiotics are neither OTC nor VFD – they are strictly veterinary prescription
- A veterinarian can specify generic (chlortetracycline) or brand (Aureomycin). The feed dealer must use branded if VFD is written as such



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VFD Practical Issues

- Injectables are not affected by this rule
- Enforcement primarily at veterinarian and feed supplier level.



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When does this take effect?

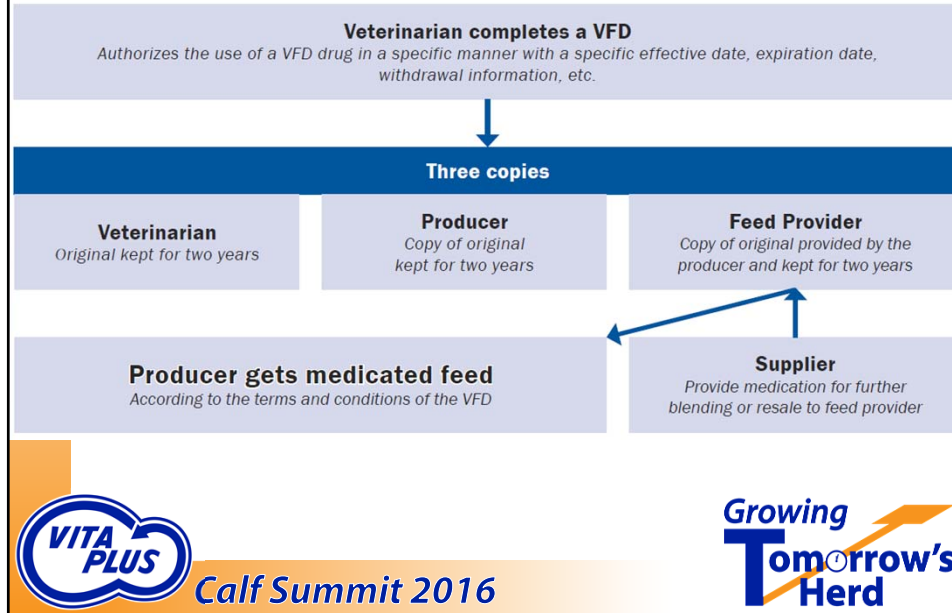
January 1, 2017



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The VFD Process



Let's talk about specific drugs!



Antibiotics used in calf starters that require a VFD

Product	Drug	Dosage	Duration	Slaughter Withdrawal
Aureomycin	Chlortetracycline	10 mg/lb bodyweight/day	5 days	Zero
Chloratet	Chlortetracycline	10 mg/lb bodyweight/day	5 days	10 days
Chlormax	Chlortetracycline	10 mg/lb bodyweight/day	5 days	1 day
Pennchlor	Chlortetracycline	10 mg/lb bodyweight/day	5 days	Zero
Pennox	Oxytetracycline	10 mg/lb bodyweight/day	7-14 days	5 days
Terramycin	Oxytetracycline	10 mg/lb bodyweight/day	7-14 days	5 days
Aureo S 700	Chlortetracycline + Sulfamethazine	350 mg of each drug/hd/day	28 days	7 days

Drugs used in calf starters that are not affected by VFD

Product	Drug	Dosage	Duration	Slaughter Withdrawal
Corid	Amprolium	5 or 10 mg/kg bodyweight/day	21/5 days	1 day
Gainpro	Bambermycin	10-40 mg/hd/day	Continuous	Zero
Deccox *	Decoquinat	0.5 mg/ kg bodyweight/day	>28 days	Zero
Bovatec *	Lasalocid	60-360 mg/hd/day or 1 mg/kg bodyweight/day	Continuous	Zero
Rumensin	Monensin	50-200 mg/hd/day or 0.14-0.42 mg/lb bodyweight/day	Continuous	Zero

* Also available as medicated milk replacer option

What about combinations (with a VFD)

	Corid	Gainpro	Deccox	Bovatec	Rumensin
Aureomycin	No	No	No	YES	No
Chloratet	No	No	No	No	No
Chlormax	No	No	No	No	No
Pennchlor	No	No	No	No	No
Pennox	No	No	No	No	No
Terramycin	No	No	No	No	No
Aureo S-700	No	No	No	No	No
Neo-Terramycin	No	No	No	No	No

Neo-Terra as an additive to milk replacers (yes – BUT)

- Requires a VFD
- Only high level of 10 mg/lb bodyweight of each drug per day for 7-14 days
- If symptoms persist after using for 2-3 days consult a veterinarian
- Treatment should continue for 1-2 days beyond remission of symptoms
- A withdrawal period has not been established in calves



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Transition labeling will start to appear soon

For example

Chlortetracycline Chlormax 50 2016-02—Zoetis.

The following notation was added to the labelling:

Beginning January 1, 2017: This product will require a veterinary feed directive issued by a licensed veterinarian and will be subject to the following restriction: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian." This product will no longer be approved for the indications of: increased rate of weight gain and improved feed efficiency which means the use of this product for these purposes will no longer be legal after that date. 21 CFR 558.6 (a) (6)



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What can a producer do to prepare?

- Put one person in charge of all things VFD related
- Take inventory of what antibiotics are currently used
- Establish a veterinarian-client relationship
- With your veterinarian, review all animal health protocols
- Start a record keeping system
- Communicate with your feed mill



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VFD Application Summary

Client name _____ Business Address _____

Best Contact Name & Phone (cell) number: _____

Date began feeding	Location Description and/or Premise ID	Animals Description and ID	VFD Drug <small>circle how applied</small>	Date finished <small>Duration from label</small>	Withdrawal date <small>calculate from label</small>	Veterinarian	VFD Expiration date	Where Purchased From
			Feed Water					
			Feed Water					
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<http://fyi.uwex.edu/wbic/2016/01/29/new-vfd-veterinary-feed-directive-record-keeping-tools-available/>



Google: UWEX, VFD

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Some Potential Scenarios

- You raise your own calves but also sell feed to others
- You have multiple sites on which you raise calves
- You have multiple sites in different states



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Disclaimer

Some of the small details are still somewhat “fluid” and may change, be interpreted differently, or administrative flexibility applied, before January 1st



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Other Questions?



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