

# **Veterinary Feed Directives (VFD)**

**Understanding the Why the FDA's Changing  
Feed Antibiotic Use Regulations**

**... AND ...**

**What does this mean to Small Ruminant  
Producers & Caregivers?**

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# **When did the FDA really start working with antibiotic resistance issues in livestock?**

- **Two decades ago ...**
- **Drugs like Oxytet, PenG, Tylan and Erythromycin had become less and less effective for treating diseases such as pneumonia.**
- **AMDUCA became law in 1994, gave vet the opportunity to write prescriptions.**



# What came with AMCUCA?

- “Extra Label Drug Use” (ELDU).
- It applied to over the counter (OTC) medications like Penicillin G.
  - Legally only allowed 1CC per 100 lbs (CWT)
  - This is an ineffective dose, but doses higher than that would likely cause a violative drug residue.
  - Causing a violative drug residue is a criminal offense.



# **FDA's next step on dealing with antibiotic resistance concerns**

- **Almost a decade of work between the FDA and Center for Disease Control (CDC) trying to better understand the origin and trends of antibiotic resistance ... AND ... develop a plan.**



# FDA antibiotic resistance potential grid (GFI 152)

## LENGTH OF TIME BACTERIA ARE EXPOSED TO THE ANTIBIOTIC

### ANTIBIOTIC IMPORTANCE

Less than 7 days

7 to 21 days

Over 21 days

#### Critically Important Antibiotics to Humans

Aminoglycosides, (ex: Neomycin)  
 Amphenicols, (ex: Nuflor)  
 b-Lactams, (ex: PenG, Excede)  
 Macrolides, (ex: Tylan, Pulmotil),  
 Quinolones (ex: Baytril, Advocin)

Would allow in livestock if a veterinarian was involved

Would allow in livestock if a veterinarian was involved

Would not allow in livestock

#### Highly Important Antibiotics to Humans

Sulfas (ex: Albon, Sustain),  
 Tetracyclines (ex: Oxytet, CTC),  
 Virginiamycin (ex: V-Max)

Allowed in livestock ONLY for disease treatment, prevention or control

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#### Antibiotic Not Important to Humans

Ionophores (Rumensin, Bovatec),  
 Bambermycin (GainPro)

Allowed in livestock

Allowed in livestock

Allowed in livestock



# **FDA developed an antibiotic resistance potential grid (GFI 152)**

- **In addition to GFI 152 ...**
- **No future approvals for “production purposes”**
- **Production purposes means**
  - **“improved growth or gain” or**
  - **“improved feed efficiency” or**
  - **“improved reproductive efficiency”.**



# Antibiotics Not Classified as “Medically Important”

- **Ionophores:** monensin, lasalocid
- **Flavophospholipol:** bambermycins  
(e.g., Flavomycin®, Gainpro®)
- **Bacitracin**
- **Tiamulin**



# How to reopen the FDA approval for feed usage of antibiotics?

- Approved to be fed ONLY FOR DISEASE
  - » Treatment
  - » Prevention
  - » Control





# **Livestock Producers ... Stuck would get no new feed use antibiotics**

- ... nothing new was going to be available to help manage health problems in their livestock.
- It is important to remember we have very good products to control coccidia ...

**Bovatec Deccox Rumensin**



# NO New Feed Use Antibiotics

- **But no new antibiotics for use in feed would be forthcoming unless the FDA-CVM figured out a mechanism that the antibiotic use WITHOUT jeopardizing the safe guards needed to protect humans ...**  
**=> VFD**

**VFD was the mechanism the FDA-CVM derived to allow the safe guards demanded by those concerned.**



# FDA GFI # 209 (April 2012)

- Outlined the development of “Veterinary Feed Directives” (VFD)
- Mechanism that could be used by the FDA to approve an antibiotic for use in livestock feed to ...
  - “**treat**”, “**prevent**” or “**control**” a “**disease causing bacteria**”
  - in a “**targeted**” group of “**affected animals**”
  - or a group of animals at a “**high risk**” of developing disease caused by a “**specific bacteria**”



# Why would “enthusiastically endorse” FDA’s GFI #213 announcement?

- With “production use” (improved growth, gain, efficiency) labeling gone ...
- Comes opportunity for FDA approval of several new VFD medications.
- Very realistic that others can be approved



**What will the new labels  
looks like? ...**

**How will the wording  
change?**



# Example Of How the Sheep & Goat VFD Label Might Read

## Generic Neomycin 325 Medicated Premix NADA 140-976

Generic Name: neomycin sulfate

Dosage Form: FOR ANIMAL USE ONLY

**Sheep** DOSAGE LEVEL: 10 mg/lb. body weight daily

### INDICATIONS FOR USE

Indications: For treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin.

Limitations: Maximum of 14. Amount consumed will vary depending on animal's consumption and weight. Treatment should continue 24 to 48 hours beyond remission of disease symptoms.

WARNING: Discontinue treatment prior to slaughter 2 days.

**Goats** DOSAGE LEVEL: 10 mg/lb. body weight daily

### INDICATION FOR USE

Indications: For treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin.

Limitations: To provide 10 milligrams of neomycin sulfate per pound of body weight for a maximum of 14. The concentration of neomycin sulfate required in medicated feed must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. Treatment should continue 24 to 48 hours beyond remission of disease symptoms.

WARNING: Discontinue prior to slaughter 3 days. Do not use in female dairy goats 12 months of age or older.

# What's Next?

- While the final VFD rule became final June 6, 2015, feed antibiotics will continue to be available over-the-counter (OTC) products until January 1, 2017.
- After this date, antibiotics for use in feed will only be available as a VFD from a licensed veterinarian that has a valid veterinary client patient relationship (VCPR) with the herd or flock.



# “VPCR” ... *required to issue a VFD*

1. Vet assumed responsibility for making clinical judgments, need for treatment, and the client has agreed to follow the veterinarian's instructions.
2. Veterinarian has sufficient knowledge to initiate preliminary diagnosis. Meaning has recently seen & personally acquainted with keeping & care via exam or medically appropriate & timely visits.
3. The veterinarian is readily available for follow-up evaluation in the event of adverse reactions or failure of the treatment regimen.





# Current sheep and goat disease associated feed antibiotic labels are:

- **Sheep:**
  - Chlortetracycline for control (reduction) of vibronic abortions caused by *Campylobacter fetus*.
  - Neomycin sulfate for treatment and control of colibacillosis caused by *Escherichia coli*
  - Oxytetracycline for treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline.
- **Goats:**
  - Neomycin sulfate for treatment and control of colibacillosis caused by *E. coli*.



# Are there alternatives?

- **Feed is not the only option for delivering appropriate antibiotic therapy to a flock or herd.**
- **The same antibiotics listed above are available as water medications.**
- **Additionally, sulfadimethoxine (Albon) and sulfamethazine (Sulmet) are available for drinking water.**



# Are there alternatives?

- **Dosing of water medications follows the same FDA regulations as injectable medications.**
- **This means you can work with your veterinarian to determine the appropriate medication and dose.**
- **And working the AMDUCA – VCPR your veterinarian can consider ELDU as may be appropriate for your sheep flock or goat herd.**



# **Bottom line ... downside paperwork**

- **The downside ... paper work involved for using VFD medications.**
- **Will learn how to streamline the paperwork.**
- **Already, an enterprising company, Global Vet Link, has made an online method for managing VFD paperwork much easier.**



# Bottom Line ... a decade from now

- If decreased antibiotic resistance ...  
we will all be glad we participated in helping the effort.
- If no change in antibiotic resistance ...  
pressure is reduced on livestock agriculture
- **FOR US ... we likely get a few new feed usage antibiotics that are much more effective than what we currently have available.**



# Recently...

## ***Consumer Reports: Meats Produced Without Antibiotics Harbor Fewer "Superbugs"***

- *November 18, 2015*

## ***The American Academy of Pediatrics Report: Antibiotics in Animal Feed***

- *November 16, 2015*
- **“...practice of adding antibiotics to the feed of healthy livestock to promote growth and prevent disease is not only a global health threat, but is especially dangerous to infants and children.”**



# Summary for Sheep and Goat Producers

- **Establish a VPCR**
- **Limited in options for feed use antibiotics**
  - All will require a VFD
  - None available OTC after Jan 1, 2017
  - No ELDU capabilities
- **Water and injectable antibiotic rules remain the same**

