VFD
Where it is today

Vita Plus Swine Summit | Morton, MN | March 30th, 2016

Dr. J. Tyler Holck, DVM, MS, MBA
Veterinary Feed Directives

- How did we get here?
- Impact
- Requirements
- Streamlining the Work – Electronic VFDs
- FeedLINK® and GlobalVetLINK
- Questions
Mid-afternoon “Wake-up” QUIZ!

- What questions do you have regarding the new VFD ruling?

- What are the critical success factors for your company to implement the new VFD ruling in preparation for January 1, 2017?
HOW DID WE GET HERE?

“Is this really going to happen?”
VFDs – How We Got Here

FDA Guidance #152
- Risk assessment for veterinary drugs creating “potential” resistance issues for human medicine.
- Classified all antibiotics into two classes:
  1) Medically Important for Human Use
  2) Non-medically Important for Human Use
- 2003 (13 years ago)
### Medically Important For Humans

#### Feed Grade Antibiotics (All Species)

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

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VFDs – How We Got Here

► FDA Guidance #209

– Outlined FDA intent regarding:
  • Removing growth promotion uses of medically important antibiotics in food-animal production
  • Veterinarian oversight for remaining therapeutic applications
  • Feed-grade and water-based antibiotics

– 2010 (6 years ago)
Antimicrobial Usage in US Food Animal Production

- Feed: 70%
- Water: 24%
- Injectable: 5%
- Other: 1%
FDA Guidance #213

- Initiated a three-year transition process:
  - Voluntarily remove growth promotion uses from medically important antibiotics
  - Eliminates OTC status of medically important antibiotics
  - Implementation by January 1, 2017
- December 2013 (3 years before implementation)
Final VFD Ruling (June 2015)

- Guidance for Industry #120
- Outlines specific VFD requirements
- No growth promotion claims beginning January 1, 2017
Impact of new VFD rule
Implementation Timeline

- **October 1, 2015**: new requirements for current VFD drugs or any new NADA approvals prior to January 1, 2017
  - Pulmotil
  - Tilmovet
  - Kavault
- **July 2016**: Transition labels may begin
- **December 2016**: Withdrawal of growth promotion claims, prepare January 1 VFDs
- **January 1, 2017**: targeted OTC move to VFD
## Swine Feed Grade Antibiotics

<table>
<thead>
<tr>
<th>Medically Important</th>
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<tbody>
<tr>
<td>Chlortetracycline</td>
</tr>
<tr>
<td>Chlortetracycline/Sulframethazine/Penicillin</td>
</tr>
<tr>
<td>Chlortetracycline/Sulfathiazole/Penicillin</td>
</tr>
<tr>
<td>Lincomycin</td>
</tr>
<tr>
<td>Neomycin/Oxytetracycline</td>
</tr>
<tr>
<td>Oxtetracycline</td>
</tr>
<tr>
<td>Penicillin</td>
</tr>
<tr>
<td>Tylosin</td>
</tr>
<tr>
<td>Tylosin/Sulfamethazine</td>
</tr>
<tr>
<td>Virginiamycin</td>
</tr>
</tbody>
</table>
OTC

Virginiamycin
Tylosin/Sulfamethazine
Tylosin
Penicillin
Oxtetracycline
Neomycin/Oxytetracycline
Lincomycin
Chlortetracycline/Sulfathiazole/Penicillin
Chlortetracycline/Sulfamethazine/Penicillin
Chlortetracycline
Tiamulin
Carbadox
Bambermycin
Bacitracin

VFD

Avilamycin
Florfenicol
Tilmicosin

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OTC to VFD Shift

2012 FDA Estimates
- OTC: 99%
- VFD: 1%

FDA Estimates beginning Jan 2017
- OTC: 39%
- VFD: 61%
### Growth Claims Phased Out

<table>
<thead>
<tr>
<th>Drug*</th>
<th>Manufacturer</th>
<th>Dose</th>
<th>Current Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lincomycin®</td>
<td>Zoetis</td>
<td>20 g/Ton</td>
<td>Increased rate of weight gain in growing-finishing swine</td>
</tr>
<tr>
<td>Tylan®</td>
<td>Elanco</td>
<td>10-20 g/Ton</td>
<td>Increased rate of weight gain in growing-finishing swine</td>
</tr>
<tr>
<td>Stafac®</td>
<td>Phibro</td>
<td>5-10 g/Ton</td>
<td>Increased rate of weight gain and improved feed efficiency</td>
</tr>
</tbody>
</table>
Compounds NOT Affected

- Antibiotics that are not medically important:
  - Ionophores (monensin, lasalocid, narasin (Skycis))
  - Bacitracin (BMD, bacitracin zinc)
  - Bambermycins (Flavomycin)
  - Carbadox (Mecadox)
  - Tiamulin (Denagard)

- Other drugs (not antibiotics), including:
  - Anthelmentics: Coumaphos, Fenbendazole, Ivermectin
  - Beta agonists: Ractopamine, Zilpaterol
  - Coccidiostats: Clopidol, Decoquinate, Diclazuril
Implementation Issues

► Stakeholder understanding of new VFD rules
► Collaboration among all stakeholders
► Increase in number of VFDs
► Communication logistics
► Record-keeping requirements
► Awareness and adoption of electronic (paperless) solution
VFD Requirements

- One Vet
- One Client
- One Feed Distributor (mill or store)
- One or multiple production sites (new)
Veterinary Feed Directive (VFD)

**Key New Requirements:**

- VCPR – by state or default to federal definition
- Electronic signature and transmittal not only acceptable, but encouraged by FDA!
  - Telephone VFDs will still not be allowed
- Drug substitution – must state if not allowed
  - Estimate of tons of feed no longer required, replaced by:
    - Estimate of number of animals
    - Duration of use
VFD Duration of Use

- Time period that feed containing the VFD drug is allowed to be fed
- Established as part of the drug approval, conditional approval, or index listing process (ie. 21 days for Pulmotil)

If VFD expires prior to completing duration of use

Client must request new VFD from their veterinarian
VFD Expiration Date

- Time period for which a VFD is valid
- Either specified by product label – or - a maximum of six months after date of VFD issuance, whichever is shorter
- Veterinarian has discretion to determine if a more limited time period is warranted
- A feed including a VFD drug should NOT be fed after the VFD expiration date
# Current VFD Drugs

<table>
<thead>
<tr>
<th>Current VFD Drugs</th>
<th>Approved for Use in the Following Species</th>
<th>Duration of Use</th>
<th>VFD Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avilamycin (Kavault®)</td>
<td>Swine – reduction of diarrhea – E. coli.</td>
<td>21-42 d</td>
<td>90 d</td>
</tr>
<tr>
<td>Florfenicol (Nuflor®)</td>
<td>Fish – control of mortality (various diseases by fish type)</td>
<td>10 d</td>
<td>15 d</td>
</tr>
<tr>
<td>Tilmicosin (Pulmotil®, Tilmovet®)</td>
<td>Swine – control of SRD</td>
<td>21 d</td>
<td>90 d</td>
</tr>
<tr>
<td></td>
<td>Cattle – control of BRD</td>
<td>14 d</td>
<td>45 d</td>
</tr>
</tbody>
</table>
Combination Drugs

FDA approved label for combination of different drugs in feed whereby at least one of the antibiotics is a VFD drug
- VFD drug = “medically important antibiotic”

Example

- Tiamulin: Non-medically important antibiotic
- Chlortetracycline: Medically important antibiotic (VFD drug)
- VFD drug
Intent Statements

- Depending on the drug label, there will be up to three intent statements from which to select.
Distributors

Distributor: any person who distributes a feed containing a VFD drug to another person

- “Another person” may be another distributor or the client-recipient of the VFD medicated feed

- Two kinds of distributors:
  - Only distributes VFD feed
  - Manufactures and distributes VFD Feed
Distributor Responsibilities

► Must notify the FDA
  – File one-time notice on intent to distribute VFD drugs
  – Ownership, name, address change (within 30 days)

► Fill VFD orders (must contain all required information)

► Retain for two years:
  – All VFD orders (from date of issuance)
  – Receipt and distribution records of all feeds containing VFD drugs
  – The acknowledgement letter (if shipping feed containing VFD drugs to another distributor)
Biopharma Manufacturer

Distributor (Feed mill or store)

Animal Producer

Letter of Acknowledgment

VFD from Client’s Veterinarian

Type A

Type B or C
On-Farm Feed Manufacturing

➢ If producing feed for commerce, must register as distributor
  – Otherwise, will not need to register

➢ VFD required to buy medicated premix (Type B)

➢ No medicated feed in bin after VFD expiration date

➢ VFD required for feed in bins on January 1, 2017
HOW WILL ELECTRONIC VFDS STREAMLINE THE WORK?
Benefits

- Streamline communication
- Reduce (eliminate?!) paper
- Enable compliance
- Electronic storage
- Streamline workflow (integrate with current software)
FeedLINK Communication

- Veterinarian
- Producer
- Feed Distributor

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Sample eVFD

Veterinary Feed Directive (VFD) for Swine

Owner/Client Address
Joe Smith
123 Main
Anza, IA 12345
Phone: 111-222-1234

Animal Locations
See attached page for additional sites.

Feed Distributor
Demonstration Feedmill
123 1st Street
Some Town, IA 55555
Phone: 123-123-1234

Drug Name: Pennchlor 100 G (Chlorotetracycline)
Dosage and Duration: 400 g/l for 14 days.
Species: Swine

Production Date: Approx. Number to be Fed: 3500
Expiry Date: 2016-01-21

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.

COMBINATION FEEDING WITH OTHER DRUGS:
The 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.

INDICATIONS:
For control of respiratory infections (reducing the incidence of abortion and shedding of leukocytes) caused by Leptospira pomona susceptible to chlortetracycline. For reducing the incidence of respiratory infections (reducing the incidence of abortion and shedding of leukocytes) caused by Group 3 Streptococcus susceptible to chlortetracycline. For treatment of bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis and bacterial pneumonia caused by Pasteurella multocida susceptible to chlortetracycline.

WARNING:
Read the warning: 30-day withdrawal period.

CAUTION:
- Feed for not more than 14 days.
- For use in Dry Feeds Only. Not for use in Liquid feed Supplements.
- Federally mandated label containing this Veterinary Feed Directive (VFD) drug to use by or on the order of a licensed veterinarian in the course of the veterinarian's professional practice.

Veterinarian's Signature:
This is a legally binding equivalent of a handwritten signature.

Sample DVM
123 Main
Tedd City, MN 55555
Phone: 123-123-1234

Page 1 of 2

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GVL Electronic VFD Timeline

1996
• Pulmotil® first approved VFD on the market

2005
• GVL launches FeedLINK, the first electronic VFD solution

2013
• Addition of Pulmotil for Cattle and Tilmovet for Swine

2015
• GVL updated FeedLINK to accommodate GFI #120
• Feed Distributor login released

2016
• All transition VFDs labels in FeedLINK, available for January 1, 2017
Creating an eVFD
Creating an eVFD

![Image of eVFD interface](image)

**Animal**

- **Species:** Swine
- **Group ID:**
- **Number to be fed:** 1000
- **Production Class:** Broil-Finish

**Drug**

- **Drug Name:** Pulmotil (Tilmicosin)
- **Effective Date:** 01/13/2016
- **Expiration Date:** 04/12/2016

**Feed Concentrations**

<table>
<thead>
<tr>
<th>Dosage (g/ton)</th>
<th>Duration (days)</th>
<th>Special Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 (181 to 363) g/ton</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>200 (181 to 363) g/ton</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

**Combination Drugs**

- 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.

**Drug Indications**

For the control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae and Pasteurella multocida.
## eVFD Preview

**Owner / Client**

- **Contact**: Robert Q. Holecroft
- **Address**: 1234 Main Street Suite 100 Ames, IA 12345
- **Phone Number**: 555-444-1234
- **Alternate Number**: FAX
- **PIN/LID**: 123457 / NA
- **Email**: test@emaildomain.com
- **MVL Connected**: No

**Animal & Drug Details**

- **Species**: Bovine
- **Group ID**: 1234
- **Approx. # to be Fed**: 1000
- **Production Class**: Cattle in confinement for slaughter

- **Effective Date**: 01/12/2016
- **Expiration Date**: 02/26/2016
- **Drug Sub. Allowed**: Yes

### Drug Indications

- 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. 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.

**Feed Concentrations**

- **Dosage**: 700 g/tom
- **Duration**: 14 days

**Feed Distributor**

- **Address**: Cedar County Coop
  - 906 East 7th St.
  - Suite 56
  - Tipton, IA 52772
- **Phone Number**: 951-555-1234
- **Fax**: No
- **Email**: test2@otherdomain.com

### Combination Feeding with Other Drugs

- **Combination Drug(s)**: Rumensin, Combo ABC, Combo XYZ

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Secure Digital E-Signature
Sample eVFD

Veterinary Feed Directive (VFD) for Swine

Owner/Client Address
Joe Smith
123 Main
Ames, IA 1111
Phone: 111-222-1234

Animal Locations
See attached page for additional sites.

Feed Distributor
Demonstration Feedmill
123 1st Street
Some Town, I 5555
Phone: 123-123-1234

Drug Name: Penicillin 100G (Chlortetracycline)
Dosage and Duration: 400 g/hr for 14 days.
Species: Swine

Product Date: Approx. Number to be Fed: 5600
Effective Date: 2016-01-21
Expiration Date: 2016-07-22

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.

Combination Feeding with other Drugs:
The 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.

Indications:
For control of lepseparalosis (reducing the incidence of abortion and shedding of leptospirosis) caused by Leptospira pomona susceptible to chlortetracycline. For reducing the incidence of leptospirosis (and other diseases) caused by Group S. Serpulinae susceptible to chlortetracycline. For treatment of bacterial enteritis caused by Escherichia coli and Shigella choleraesuis and bacterial pneumonia caused by Pasteurella multocida susceptible to chlortetracycline.

Warnings:
Read the Warning: Zero-day withdrawal period.

Caution:
- Use for not more than 14 days.
- For use in Dry Feeds Only. Not for Use in Liquid feed Supplements.
- Federal law restricts mediated feed containing this Veterinary Feed Directives (VFD) drug to use by or on the order of a licensed veterinarian in the course of the veterinarian's professional practice.

Veterinarian's Signature:
This is a legally binding equivalent of a handwritten signature:

Sample DVM
123 Main
Teal City, MN 5555
Phone: 123-123-1234

I certify, as a licensed veterinarian, that the above information is correct and complete, to the best of my knowledge. I certify that I have a current veterinary client relationship with the owner and/or manager of the animals.
Based upon specific product labels

Only legal, per label options for:

- Species
- Indication of use
- Stage of production
- Dosage
- Duration of use
- VFD expiration
- Approved (legal) combinations
New GVL® Services

► FeedLINK for Feed Distributors
  – Released December 2015
    • VFD Access
    • Storage
    • Easy Retrieval
FeedLINK Communication

- Veterinarian
- Producer
- Feed Distributor
Software integration opportunity

- Feed distributor management software
  - Incorporate GVL eVFDs into software already being used in mills and on farms
  - Manage fulfillment
  - Monitor expirations
  - Integration with Prairie Systems and MetaFarms announced
- Additional integrations in progress
FeedLINK Integration

- Veterinarian
- Producer
- Integration Partners
- Feed Distributor

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Integration Benefits

► Automatically integrate in current software(s)
► Reuse information
► Streamline workflow
► Enable compliance
► Electronic storage
► Convenient for audits (ie. CSIA)
Additional VFD Resources

► FeedLINK Video Tutorial
  – youtu.be/-b5oJgR5DFc

► Pork √-off’s Antibiotic Resource Center
  – pork.org/antibiotics

► US Food and Drug Administration
  – fda.gov/safefeed
  – Guidance for Industry #120
  – 21 CFR 558.6
  – AskCVM@fda.hhs.gov
Production Animal Solutions

- **eVFD**: Electronic Veterinary Feed Directive
- **eScript**: Electronic Veterinary Prescription
- **Diagnostic Database**: Diagnostic Justification
- **eCVI**: Electronic Certificate of Veterinary Inspection

GlobalVetLINK®

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OTC

- Virginiamycin
- Tylosin/Sulfamethazine
- Tylosin
- Penicillin
- Oxtetracycline
- Neomycin/Oxytetracycline
- Lincomycin
- Chlortetracycline/Sulfathiazole/Penicillin
- Chlortetracycline/Sulfamethazine/Penicillin
- Chlortetracycline
- Tiamulin
- Carbadox
- Bambermycin
- Bacitracin

Prescription – water soluble

- Avilamycin
- Florfenicol
- Tilmicosin
ScriptLINK Communication

- Veterinarian
- Producer
- Feed Distributor

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Production Animal Solutions

eVFD
Electronic Veterinary Feed Directive

eScript
Electronic Veterinary Prescription

Diagnostic Database
Diagnostic Justification

eCVI
Electronic Certificate of Veterinary Inspection

Veterinarian
LabLINK HIMS™

- Iowa State University
- University of Minnesota
- South Dakota State University
- Kansas State University
- University of Illinois
- Boehringer Ingelheim
- GeneSeek
Pathogen Flow Summary Report

Charts:

Respiratory Pathogens

1/1/2015 to 6/30/2015 (Months)

% Positive

Case Volume

% Pos. of Mycoplasma
% Pos. of PRRSv
Mycoplasma
PRRSv

Development Version: Not for production use.
## Sensitivity Report

### Sensitivity

<table>
<thead>
<tr>
<th>Antimicrobial</th>
<th>Susceptibility</th>
<th></th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intermediate</td>
<td>Resistant</td>
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<tr>
<td><em>Actibac. pleuropneumoniae</em></td>
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<tr>
<td>Ceftriaxone</td>
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<td>Clindamycin</td>
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Production Animal Solutions

eVFD
Electronic Veterinary Feed Directive

eScript
Electronic Veterinary Prescription

Diagnostic Database
Diagnostic Justification

eCVI
Electronic Certificate of Veterinary Inspection

Veterinarian
Questions

► What questions do you have about the new VFD ruling?

► What are the critical success factors for your company to implement the new VFD ruling in preparation for January 1, 2017?
Acknowledgments:

► Dr. Chris Rademacher, ISU
  – CJRDVM@IASTATE.EDU
► Dr. Jennifer Koeman, NPB
  – JKOEMAN@PORK.ORG
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► Lily Scott, GlobalVetLINK
► Brenda Cowan, GlobalVetLINK
Thank You!

► J. Tyler Holck, DVM, MS, MBA
  – Ph: 515.817.5065
  – Email: tholck@globalvetlink.com