Antibiotic Use in Animal Health

Understanding FDA's final VFD ruling

Montana Nutrition Conference 2016

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Overview

- Consumer Attitudes
- Access to Antibiotics
- Veterinary Feed Directive (VFD) Implementation Timeline
- Final VFD Rules
- Implementing a VFD
- Electronic VFDs
- Impact on Elanco

Consumer Attitudes

Consumer Attitudes

- Antibiotic use is a public health issue
- Important for animal agriculture to:
  - Be proactive & take a leading role
  - Maintain confidence in food supply
  - Build consumer trust

Consumer attitudes*		
48%	**71%**	**53%**
Feel **uncomfortable** about antibiotic use in animal production	Have **"serious or some concerns"** about conventional methods	Frequently **wonder** if the food they buy is safe

* Source: ml&p research for USFRA, 10/11, n=1,400. Accessed: http://feedstuffsfoodlink.com/story-transparency-real-concern-0-106296.

Consumer Attitudes

You say	They hear
We use antibiotics to be more efficient	Because you only care about making money
We use antibiotics to keep animals healthy	You HAVE to use antibiotics because animals are kept in poor conditions
Regulatory agency reviews have approved antibiotics as safe after rigorous review process	We don't know if it's safe for the long term. They've been wrong before
There are rules that dictate maximum residue limits allowed in animals	How can we be sure ANY residue is safe?
There is no evidence that use of antibiotics in animals causes resistance in humans	Yeah, right. We're using so many, that has to be part of the reason

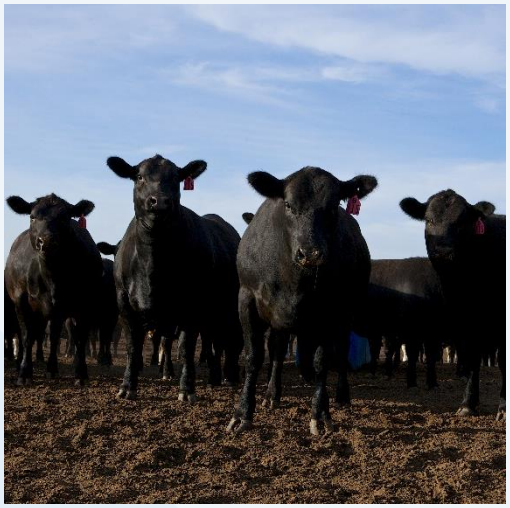
Access to Antibiotics

Access to Antibiotics

- A public health issue
- Access to effective antibiotics

Critical for public health

Vital for livestock & poultry production



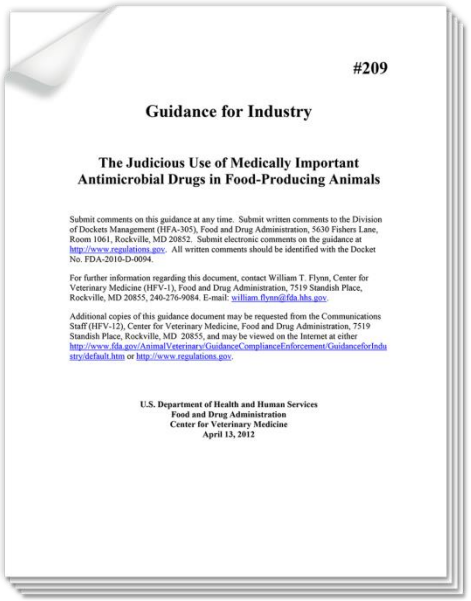
Essential for animal well-being

Access to Antibiotics

- U.S. Food and Drug Administration:
  - Concerned that overuse in animals may reduce effectiveness in humans
  - Is making important changes to antibiotic use in animals
  - Goal is to promote judicious use of antibiotics, protect public health and help curb the development of antimicrobial resistance

Access to Antibiotics

- FDA issued three documents proposing to modify use of medically important antibiotics in food-producing animals



#209

Guidance for Industry

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

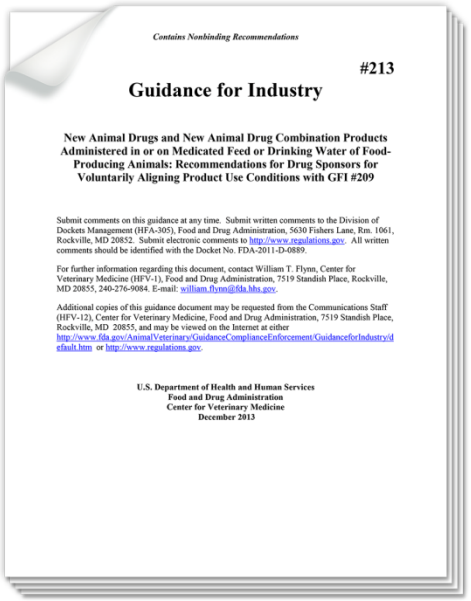
Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments on the guidance at http://www.regulations.gov. All written comments should be identified with the Docket No. FDA-2010-D-0094.

For further information regarding this document, contact William T. Flynn, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9084. E-mail: william.flynn@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
April 13, 2012

Guidance for Industry (GFI) #209



Contains Nonbinding Recommendations

#213

Guidance for Industry

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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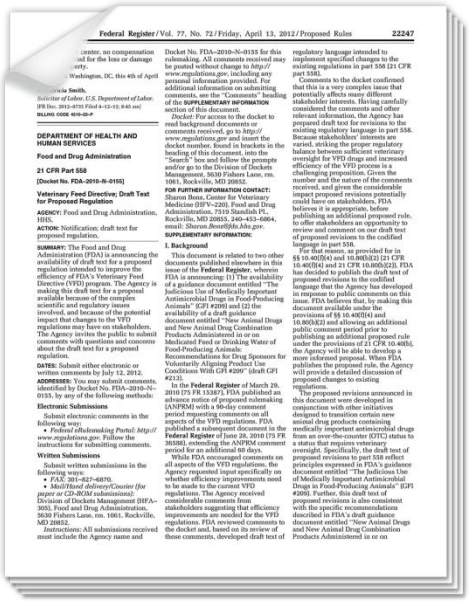
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
December 2013

Guidance for Industry (GFI) #213



Federal Register / Vol. 77, No. 72 / Friday, April 13, 2012 / Proposed Rules 22247

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2010–N–0155]

Veterinary Feed Directive; Draft Text for Proposed Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; draft text for proposed regulation.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft text for a proposed regulation intended to improve the efficiency of FDA's Veterinary Feed Directive (VFD) program. The Agency is making this draft text for a proposal available because of the complex scientific and regulatory issues involved, and because of the potential impact that changes to the VFD regulations may have on stakeholders. The Agency invites the public to submit comments with questions and concerns about the draft text for a proposed regulation.

DATES: Submit either electronic or written comments by July 12, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0155, by any of the following methods:

Electronic Submissions

Written Submissions

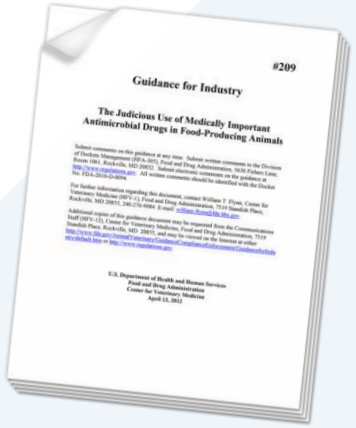
I. Background

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

CFR 558

Guidance for Industry #209


#209

Guidance for Industry

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

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
April 13, 2012

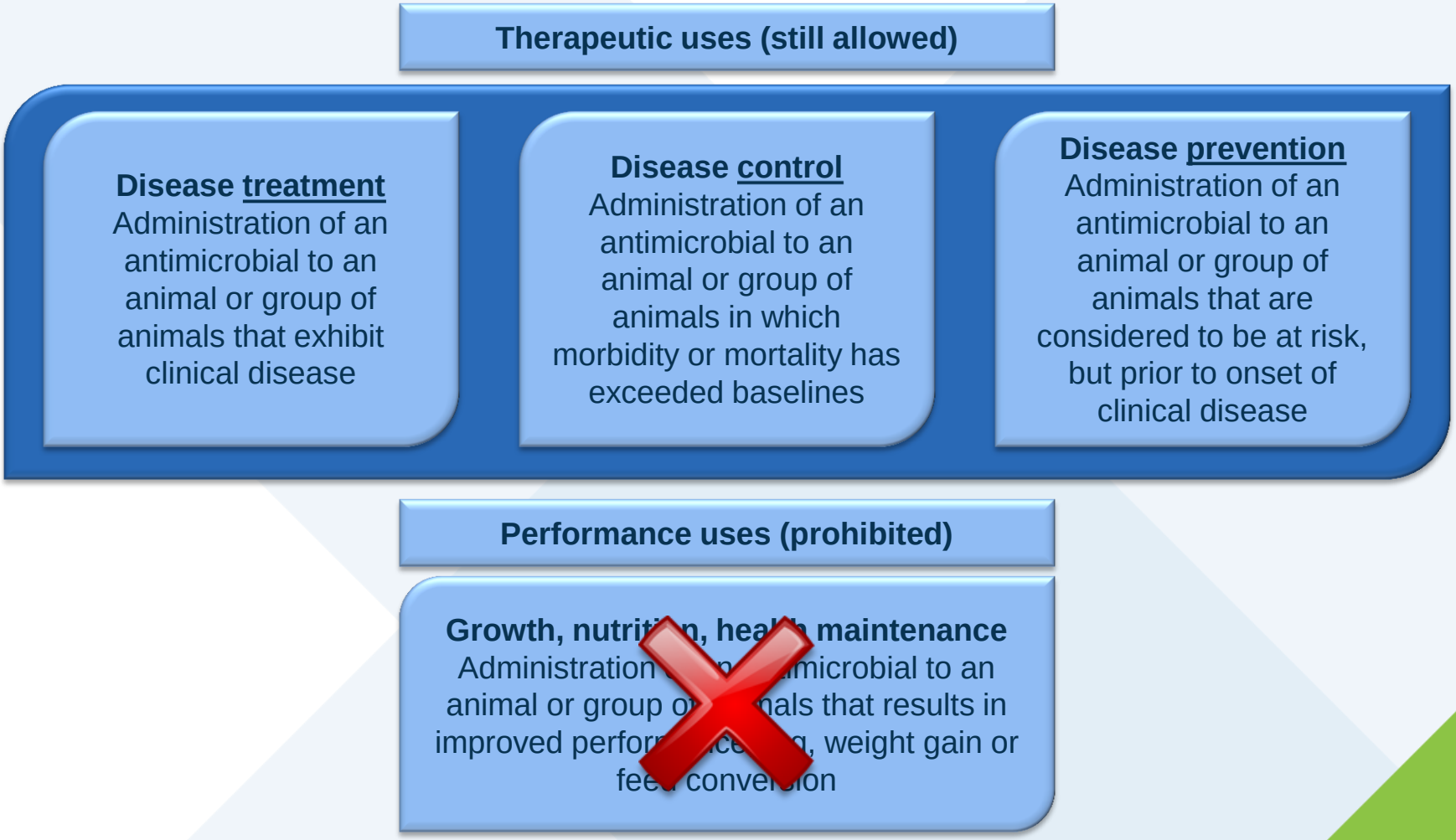
- The “what” component
- Establishes “judicious use” principle
  - Limits shared-class antibiotics to therapeutic purposes
- Key: use of **medically important** antimicrobial drugs in food-producing animals should be limited to:

1. **Uses necessary to assure animal health**
   - Prevention
   - Control
   - Treatment

2. **Uses that include veterinary oversight**
   - **Feed:** OTC to VFD
   - **Water:** Rx *(specified in GFI #213)*

Performance Indications (GFI #209)

- Phases out production indications for certain antibiotics



Products Affected vs. Unaffected as Defined by FDA Guidance 152

Unaffected	Affected
Non-Medically Important Products used exclusively in animals or deemed "non-medically important" if used by both humans & animals: - Ionophores (Rumensin®) - Polypeptides - Carbadox - Bambermycin - Pleuromutilin	**Medically Important** Products deemed "important for human medicine" & used by both animals & humans, such as: - Penicillins - Cephalosporins - Quinolones - Fluoroquinolones - Tetracyclines - Macrolides - Sulfas - Glycopeptides - Others
Production uses — Still allowed Enhance growth or improve feed efficiency	**Production uses —** No longer allowed Enhance growth or improve feed efficiency

Therapeutic uses — still allowed under veterinary supervision

- Treat animals diagnosed with an illness
- Control the spread of illness in a herd
- Prevent illness in healthy animals when exposure is likely

Antibiotics Affected (from GFI #152)

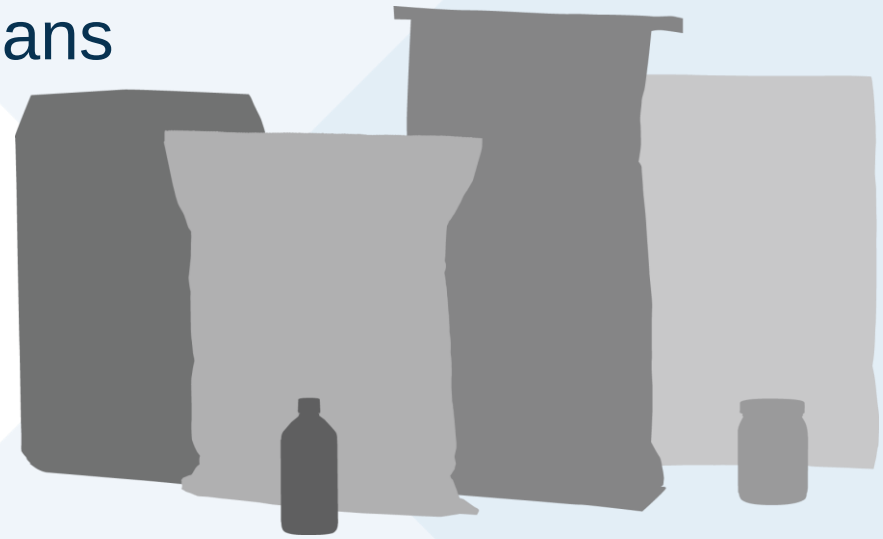
- "Medically important" for human use

Affected		
Penicillins - Penicillin G - Penicillin V	Tetracyclines - Oxytetracyclines - Chlortetracycline (CTC) - Aureomycin®	Clindamycin (Lincosamide class) - Lincomix®
Cephalosporins	Trimethoprim/sulfamethoxazole	Polymyxin B
Carbapenems	Sulfas - Sulmet - ASP, CSP 250	Chloramphenicol
Monobactams	Pyrazinamide	Metronidazole
Quinolones	Glycopeptides	Rifamycins
Fluoroquinolones	Oxazolidinones	Isoniazid
Aminoglycosides - Neomix®	Streptogramins - Stafac®	Macrolides - Tylan® (tylosin) - Pulmotil® (tilmicosin)

Blue = shared feed and/or water

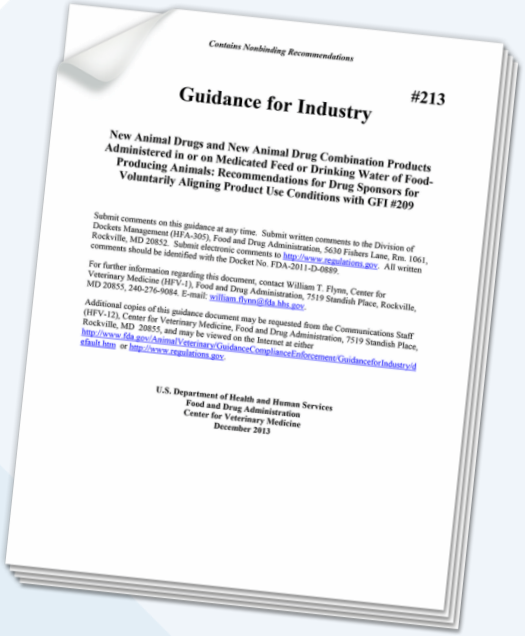
Implications

- Food producers aren't losing all feed-grade antibiotics
- The way they're used will change
- Key phrase is "medically important"
  - Refers to drugs important for therapeutic use in humans



Guidance for Industry #213

- The “how” component
- Recommendations for voluntarily aligning products with GFI #209
- Advises companies on how to revise:
  - Labeling
  - Promotion
- Two options to change product labels
  - Voluntarily remove production indications
  - Seek new therapeutic indications at current doses
- Provides three years to comply (Dec. 2016)



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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
December 2013

21 CFR 558 & 21 CFR 514

- VFD process changes:
  - Strive toward less burdensome process
  - Provide greater flexibility for veterinarians to exercise professional training
  - Streamline FDA administrative procedures

Veterinary Feed Directive

- Existing regulatory framework for veterinary oversight of feed-use drugs (21 CFR 558)
- Designates VFDs as medicated feeds needing veterinary oversight
- Limits use of such products to veterinary oversight
- Requires a written statement (form) issued by a veterinarian
  - Authorizes manufacture & use of feed containing a drug

VFD Modernization

- Over a decade since introduction of VFDs
- Significant expansion of feed grade antibiotics requiring VFDs
- Streamlining current process is critical to facilitate transition of marketing status from OTC to VFD
- Goal: clarify requirements associated with veterinary authority & the use of VFD drugs

VFD Modernization

- GFI #209 assigns VFD status to more feed grade antibiotics
- This shift raised concerns around:
  - Limited experience with VFD process
  - Logistical & administrative burden
  - Access to veterinarians
  - Increased cost (producer, vet, feed mills)
- Draft for comment Dec. 2013
- Final rule June 3, 2015
  - Effective Oct. 1, 2015

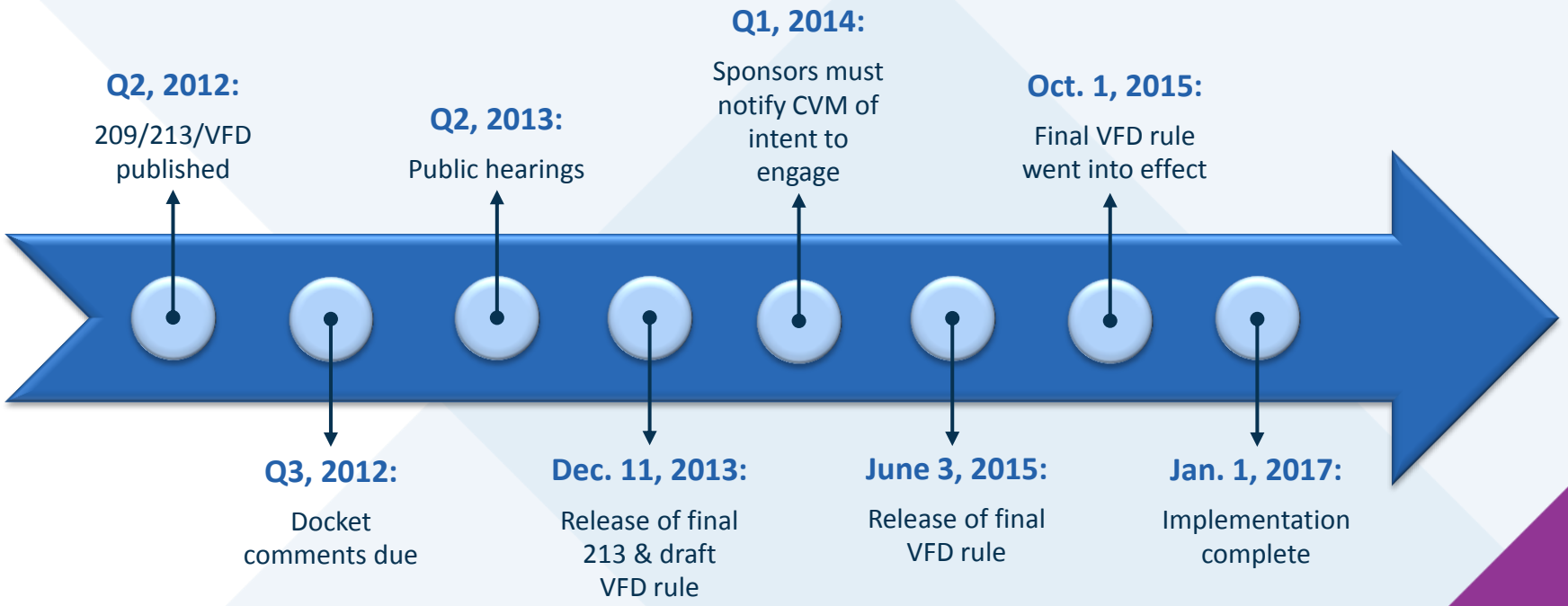
VFD Modernization

- Because of those concerns, FDA modified VFD process
- Goals of modification
  - Improve the efficiency of the VFD program while continuing to protect public health (human & animal health)
  - Striving toward less burdensome process for all
  - Providing greater flexibility to veterinarians
  - Streamlining FDA administrative procedures

VFD Implementation Timing

Compliance Timeline

- FDA pursuing voluntary compliance
- FDA to evaluate progress three years after final publication
  - Guidance for Industry #213 finalized Dec. 2013
  - FDA will consider further actions as warranted



Compliance Timeline

- Voluntary approach:
  - Enables companies to efficiently make transitions
  - Provides time to understand policies
  - Enables companies to vary their own timelines
  - Acknowledges a significant undertaking by affected parties
- Approach **not voluntary** for producers or feed manufacturers once labels have been transitioned

Compliance Timeline

- 26 affected companies
- 100% have confirmed intent to engage with written response to FDA

Final VFD Rules

October 2015

VFD Form Requirements

- The veterinarian's name, address and telephone number
- The client's name, business or home address and telephone number
- The premises at which the animals specified in the VFD are located
- The date of VFD issuance
- The expiration date of the VFD
- The name of the VFD drug(s)
- The species and production class of animals to be fed the VFD feed
- The approximate number of animals to be fed the VFD feed by the expiration date of the VFD (no longer need to include total pounds of feed)
- The indication for which the VFD is issued
- The level of VFD drug in the feed and duration of use
- The withdrawal time, special instructions and cautionary statements necessary for use of the drug in conformance with the approval
- The number of reorders (refills) authorized, if permitted by the drug approval, conditional approval or index listing
- **The statement: "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"**
- An affirmation of intent for combination VFD drugs as described in 21 CFR 558.6(b)(6)
- The veterinarian's electronic or written signature

VFD Record Keeping Requirements

- Maintains record keeping requirement for VFDs for two years for veterinarian, client & distributor
  - Vet now maintains original VFD & sends copy to client & distributor
- Permits electronic storage of VFD records
  - If VFD is transmitted electronically, veterinarian no longer required to send hard copy to distributor
- All creation & storage of electronic forms needs to be 21 CFR 11 compliant
- Prohibits verbal issuance of VFD (e.g., by telephone)

VCPR Requirements

- Any veterinarian issuing a VFD must be licensed to practice veterinary medicine and operate in compliance with appropriate State-defined veterinarian-client-patient relationship (VCPR) requirements
    - In States where the practice requirements do not require that a VFD be issued within the context of a State-defined VCPR, FDA is requiring that the VFD be issued within the context of a Federally-defined valid VCPR, as outlined in 21 CFR 530.3(i)
- VCPR requires that the veterinarian:
    1. Engage with the client to assume responsibility for making medical judgments about animal health and the need for medical treatment
    2. Have sufficient knowledge of the animal by virtue of examination and/or visits to the facility where animal is managed to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s), and
    3. Provide for any necessary follow-up evaluation or care

VFD Product Classification

- Eliminates current automatic classification of VFD products to Category II
  - Access to Type A Concentration Category II products is restricted to licensed feed mills only
  - Change allows VFD products to be Category 1
    - Allows unlicensed feed manufacturers continued access to Type A medicated articles at concentrations currently used
  - As before, distributor must notify FDA before distributing VFD products for the first time
- Veterinarian is required to write the name of the VFD products on the VFD
  - The vet may choose to write the name of a pioneer or generic product name
  - The vet may choose to specify that a substitution of a product is not allowed; if the vet does not specify, the feed manufacturer may choose to use either

Combination Drugs

- Veterinarian must specify whether the VFD drug:
  - May be used in any approved combination in VFD feed
  - May be used in only specific approved combinations in VFD feeds
  - May not be used in any approved combination in VFD feed
- Feed manufacturer may not substitute a generic VFD drug for a pioneer VFD drug in a combination VFD feed if the generic VFD drug is not part of an approved VFD drug

Extra Label Use is Not Permitted

- “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”

Expiration vs. Duration

- The **expiration** date defines the period of time for which the authorization to feed an animal feed containing a VFD drug is lawful
  - The expiration date on the VFD specifies the last day the VFD feed can be fed to the group of animals
  - The vet should use the expiration date that is specified in the label approval (e.g., 45 days for tilmicosin in beef cattle); where such date is not specified, the vet can write a date up to 6 months after date of issuance
- The **duration** determines the length of time the VFD feed is allowed to be fed to the animals, as specified on the product label (e.g., 14 days for tilmicosin in beef cattle)

Specifying Animals & Location

- The veterinarian should enter information about the location of the animals that would allow someone to locate the animals (e.g., address, GPS)
  - The vet may use his/her discretion to enter additional information (e.g., lot, site, pen) & should work with client to determine whether animals remain at the more specific location until the expiration date of the VFD
  - If a VFD is intended to authorize the use of a VFD feed in a group of animals that are located at more than one physical location, it is acceptable to include multiple specified locations for that group to be fed the VFD feed by the expiration date on the VFD, provided 1) they can do so in compliance with professional licensing and 2) the feed is supplied by a single feed manufacturer/distributor

Defining Feed Distributors

- On-farm mixers that manufacture medicated feeds only for use in their own animals are not distributors
- On-farm mixers must be manufacturing VFD feed only for their use in their own animals on their own farm, meaning that the ownership of the feed mill, the animals and the animal production facility must be the same and the on-farm mixer must be the person using the VFD feed
  - If there is a chance an on-farm mixer might distribute to another producer, he/she should be aware they would then be considered a distributor bearing the same notification requirements

Distribution Regulation: Authorized Shipments
(All VFD and/or shipping records must be maintained for two years)

Utilizing a VFD

- Must fill a VFD only if the VFD contains all required information

Utilizing an AOD (one-time notifications)

- **Notice To FDA of Distribution of VFD Feeds** to FDA that you intend to handle/distribute VFD drug-containing medicated feeds
- **Acknowledgement of Distribution Limitations for VFD Feeds** document stating that the purchasers will sell the VFD feeds only to producers with valid VFD orders or to other distributors for whom they have acknowledgement notices
- Maintain documentation

Notice to FDA of Distribution of VFD Feeds

Notice To FDA of Distribution of VFD Feeds

I/We hereby notify the Food & Drug Administration that Vwe have begun distributing VFD feeds.

Signature

Name of responsible party
(please print or type)

Name of Firm or Individual

Business Address

Site address if different from above

City/State/Zip

Date

Send this form to:

Division of Animal Feeds (HFV-226)
Center for Veterinary Medicine
Food & Drug Administration
7500 Standish Place
Rockville, MD 20855
FAX 301/594-1812

Send this form to each of your firm's suppliers of VFD products.

Acknowledgement of Distribution Limitations for VFD Feeds

Acknowledgement Of Distribution Limitations For VFD Feeds

I/we hereby acknowledge that, as required by federal law, I/we shall distribute VFD feeds received by me/us from [name and address of feed supplier] only as follows:

(I) To an animal production facility, if the owner or operator of that facility provides me/us with a copy of a veterinary feed directive (VFD) covering the quantity of feed involved and the animal production facility to which the feed is being distributed; or

(2) To another person for further distribution, if that person provides me/us with a written acknowledgement similar to this acknowledgement.

_____
Signature

_____
Name of Firm or Individual

_____
Business Address

_____
City/State/Zip

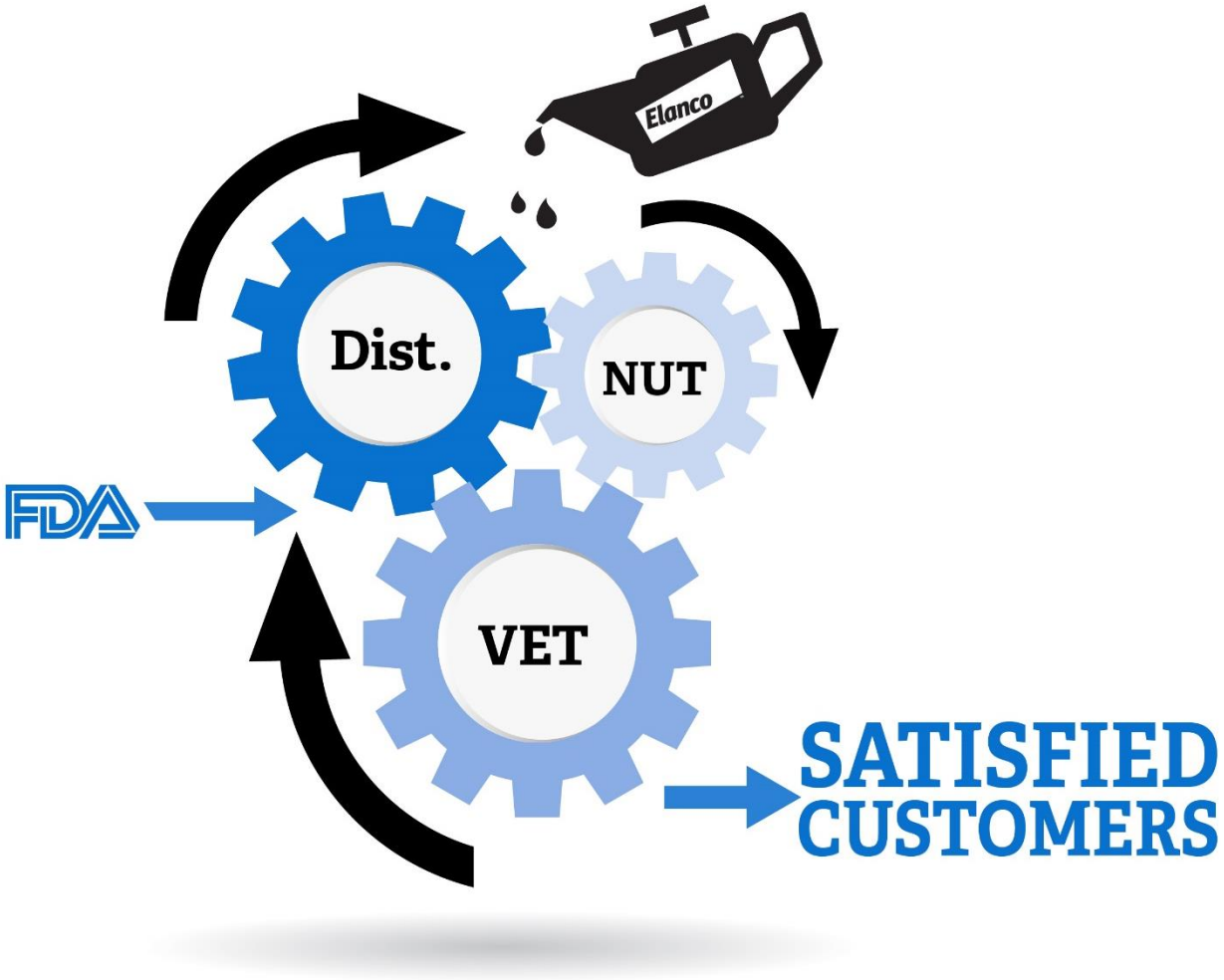
_____
Date

Send this form to each of your firm's suppliers of VFD products.

FDA Enforcement Strategy

- FDA first intends to provide education and training for stakeholders subject to this final rule such as veterinarians, clients (animal producers), feed mill distributors and other distributors
- FDA will then engage in risk-based general surveillance, as well as for-cause inspection assignments
  - FDA intends to use information such as history of VFD use and the volume of VFD feed being produced to focus inspectional resources within the industry based on risk
  - FDA anticipates that it will utilize various sources for obtaining such information including FDA food and drug registration information, feed mill licensing information, the VFD distributor notifications FDA receives, and VFD distribution records maintained by drug sponsors

VFD: Our Cooperation Will Be Crucial For Our Mutual Customers



Implementing a VFD (Cattle)

Pulmotil Cattle VFD Form (Oct. 2015)

Elanco Pulmotil

Pulmotil® (tilmicosin) Veterinary Feed Directive for use in Cattle | Sequential VFD ID Number

Client: _____
Business or Home Address: _____
Phone #: _____

Veterinarian: _____
Address: _____
Phone #: _____

Approximate number of cattle: _____

Location of animals: _____

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 (568 to 757g/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 assure 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.
  _____ (list 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 46285, USA

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White Copy (Original) – Veterinarian **Canary Copy – Client** **Pink Copy – Distributor**

Filling Out a VFD Form (Cattle)

Elanco Pulmotil

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

Sequential VFD ID Number

Client: Business or Home Address: _____

Phone #: _____

Veterinarian: Address: _____

Phone #: _____

Approximate number of cattle: _____

Location of animals: _____

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 (568 to 757g/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.

Requires approx. # of animals & dosage; does NOT require calculation of lbs of feed

Filling Out a VFD Form (Cattle)

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.

_____ (list 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.

Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285, USA

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Must provide approval for any combination drugs

No longer requires vet license number

Caution Statement

- Each product approved under the VFD regulations includes the following caution:

Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

Distribution of VFD form

- Original form must be stored by veterinarian

White Copy (Original) – Veterinarian

Canary Copy – Client

Pink Copy – Distributor

Elanco Pulmotil

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

Sequential VFD ID Number

Client: Business or Home Address:

Phone #:

Veterinarian: Address:

Phone #:

Approximate number of cattle:

Location of animals:

Special instructions and/or other animal identification (optional):

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.

Dosage: _____ g/ton (68 to 757g/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 assure 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 5 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. _____ (list 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.

Elanco Animal Health, A Division of Eli Lilly and Company, Indianapolis, IN 46285, USA

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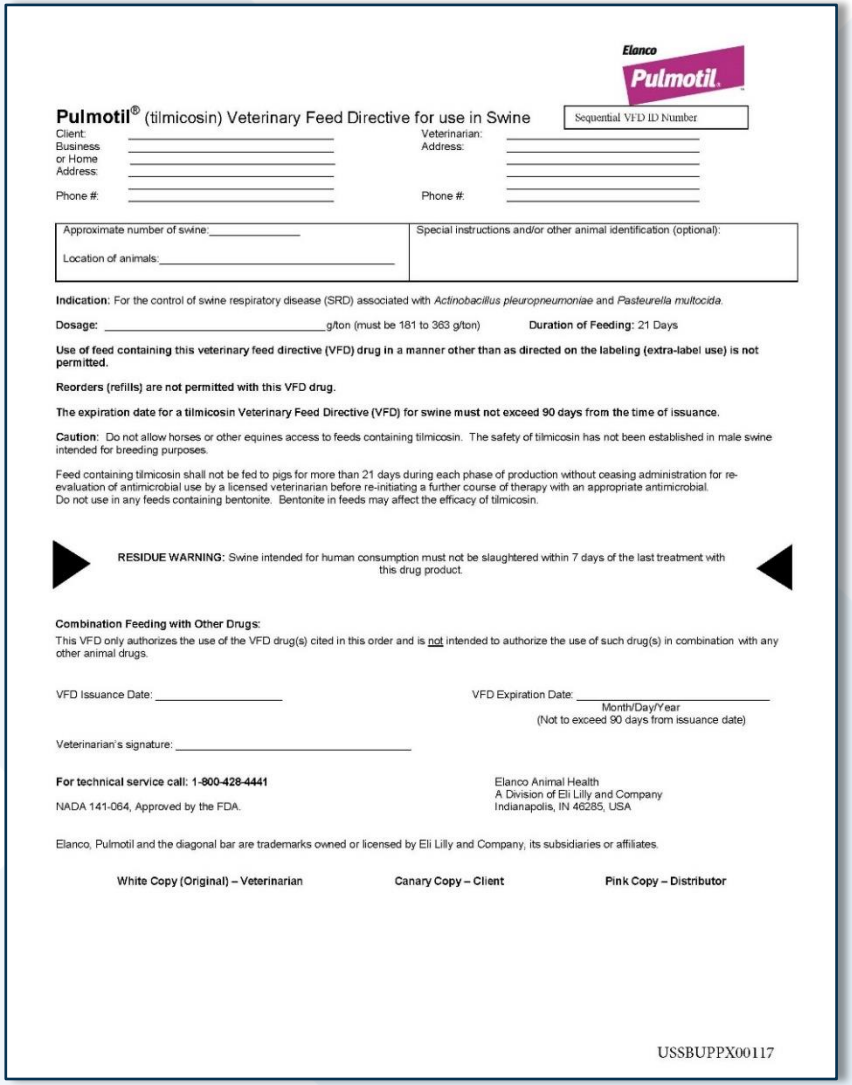
Note: color-coded forms are Elanco-only forms.

Implementing a VFD (Swine)

Pulmotil Swine VFD Form (Oct. 2015)



Elanco Pulmotil

Pulmotil® (tilmicosin) Veterinary Feed Directive for use in Swine

Sequential VFD ID Number

Client: _____
Business or Home Address: _____
Phone #: _____

Veterinarian: _____
Address: _____
Phone #: _____

Approximate number of swine: _____
Location of animals: _____

Special instructions and/or other animal identification (optional):

Indication: For the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

Dosage: _____ g/ton (must be 181 to 363 g/ton) **Duration of Feeding:** 21 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.

Reorders (refills) are not permitted with this VFD drug.

The expiration date for a tilmicosin Veterinary Feed Directive (VFD) for swine must not exceed 90 days from the time of issuance.

Caution: 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. Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.

RESIDUE WARNING: Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this drug product.

Combination Feeding with Other 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.

VFD Issuance Date: _____

VFD Expiration Date: _____
Month/Day/Year
(Not to exceed 90 days from issuance date)

Veterinarian's signature: _____

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

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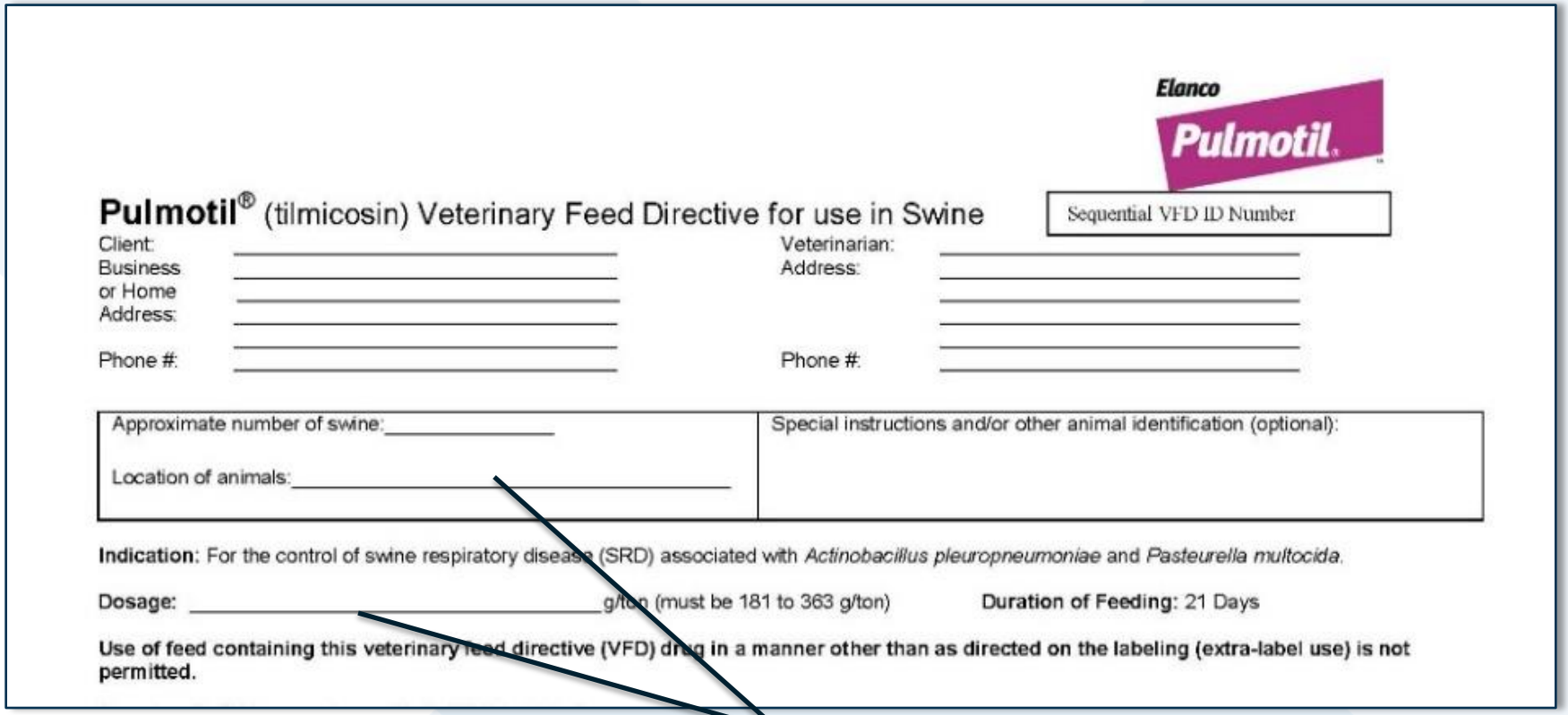
USSBUPPX00117

Filling Out a VFD Form (Swine)



Elanco Pulmotil

Pulmotil® (tilmicosin) Veterinary Feed Directive for use in Swine

Sequential VFD ID Number

Client: _____
Business or Home Address: _____
_____
Phone #: _____

Veterinarian: _____
Address: _____
_____
_____
Phone #: _____

Approximate number of swine: _____

Location of animals: _____

Special instructions and/or other animal identification (optional):

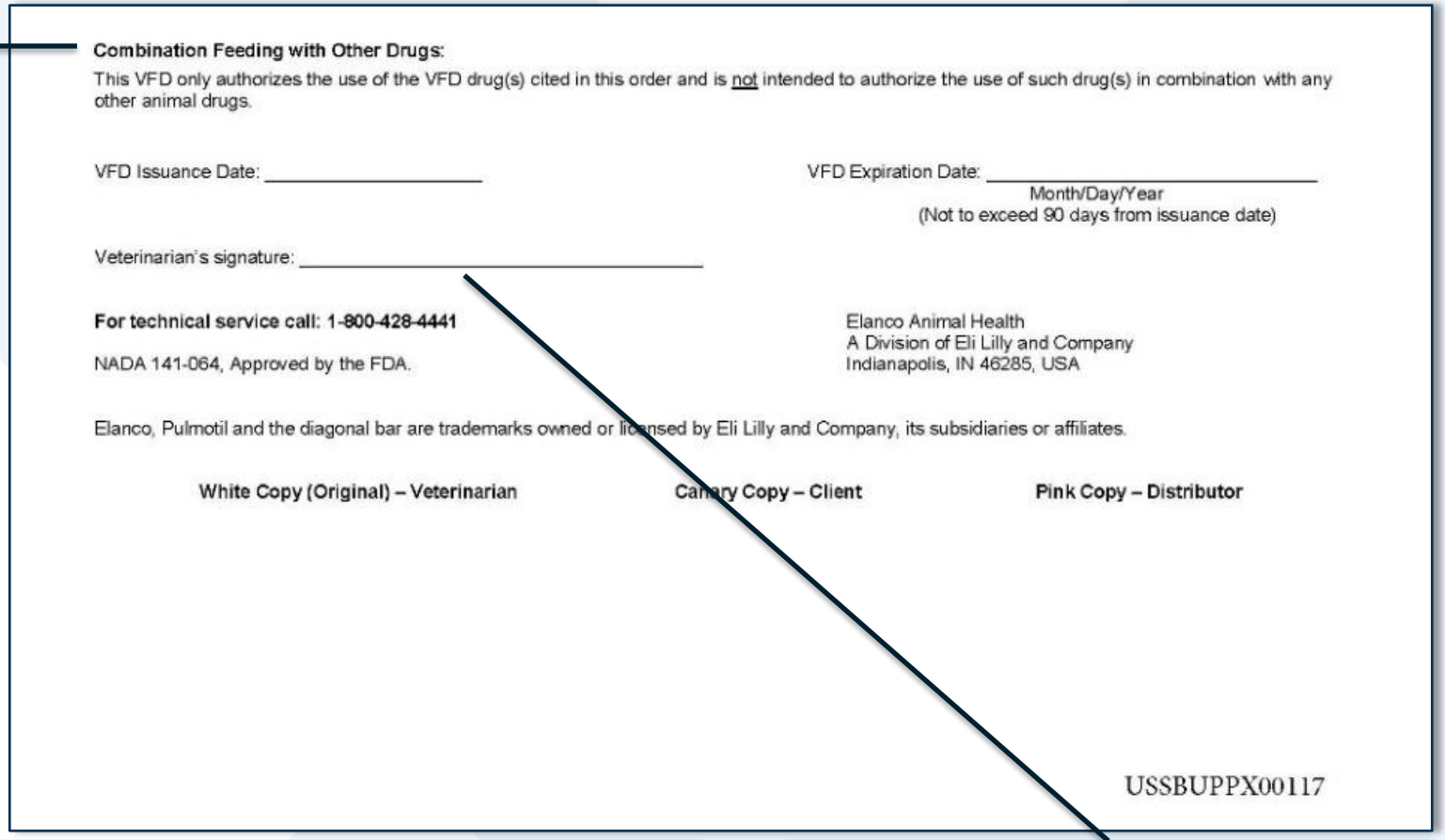
Indication: For the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

Dosage: _____ g/ton (must be 181 to 363 g/ton) **Duration of Feeding:** 21 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.

Requires approx. # of animals & dosage; does NOT require calculation of lbs of feed

Filling Out a VFD Form (Swine)



Combination Feeding with Other 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.

VFD Issuance Date: _____

VFD Expiration Date: _____
Month/Day/Year
(Not to exceed 90 days from issuance date)

Veterinarian's signature: _____

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

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Must provide approval for any combination drugs

No longer requires vet license number

Caution Statement

- Each product approved under the VFD regulations includes the following caution:

Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

Distribution of VFD form

- Original form must be stored by veterinarian

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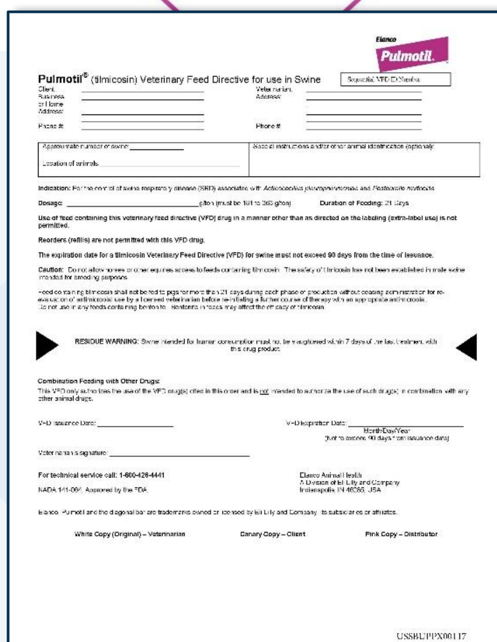

Pulmotil® (tilmicosin) Veterinary Feed Directive for use in Swine

Client
Business or Home Address:
Phone #

Veterinarian
Address:
Phone #

Approximate number of swine: ____
Location of animals: ____
Special instructions and/or other animal identification (optional):

Dosage: ____ g/ton (must be 181 to 363 g/ton) **Duration of Feeding:** 21 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.

Reorders (refills) are not permitted with this VFD drug.

The expiration date for a tilmicosin Veterinary Feed Directive (VFD) for swine must not exceed 90 days from the time of issuance.

RESIDUE WARNING: Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this drug product.

Combination Feeding with Other 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.

VFD Issuance Date: ____
VFD Expiration Date: ____ Month/Day/Year (Not to exceed 90 days from issuance date)

Veterinarian's signature: ____

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

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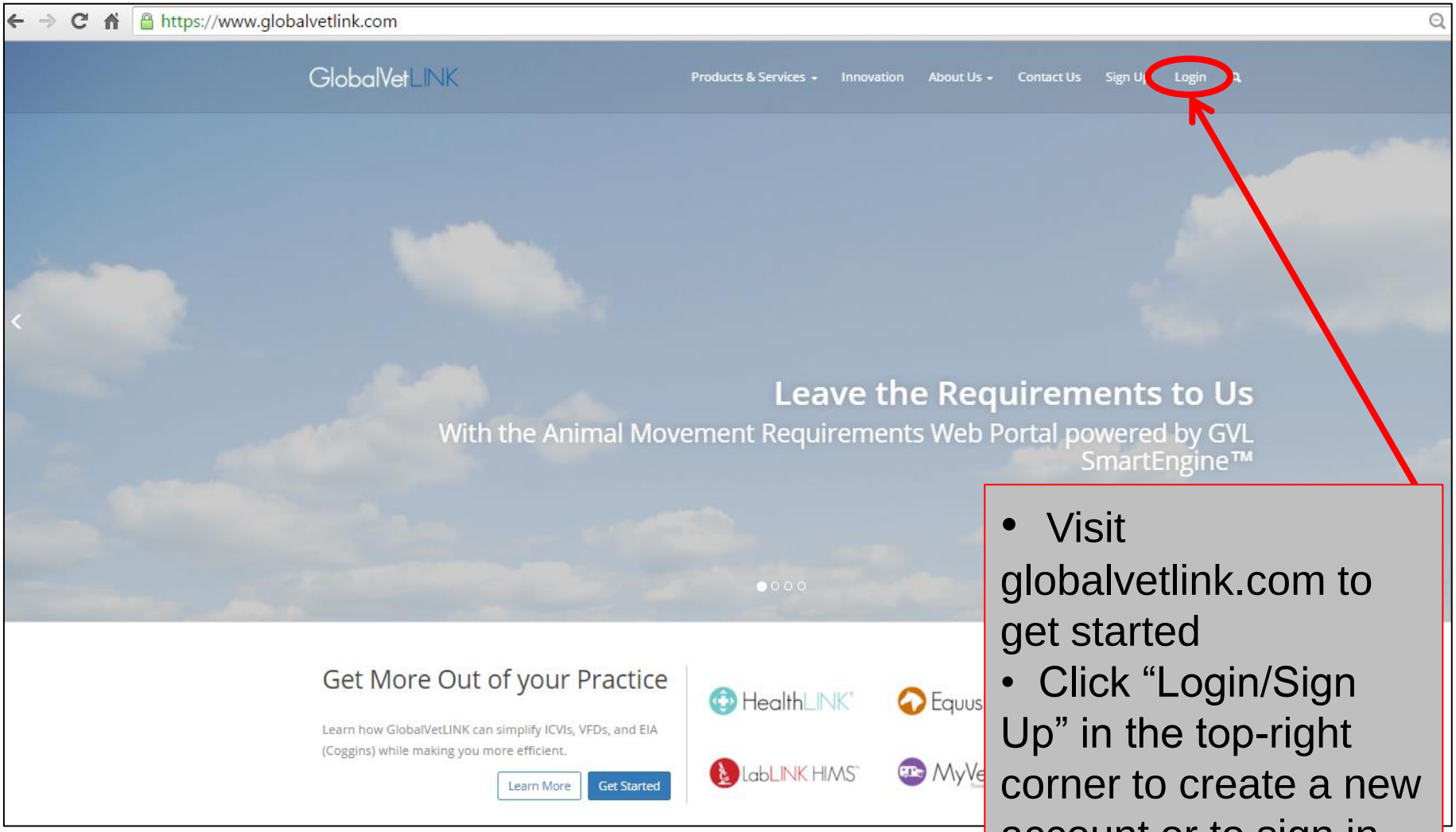
Note: color-coded forms are Elanco-only forms.

Electronic VFDs

FeedLINK Features — eVFD

- Ease the burden of paperwork
  - Spend less time creating VFDs and reduce manual inaccuracies by creating electronic VFD prescriptions
- Provide a reliable source of documentation
  - Maintain VFD compliancy easily with a secure, web-based software solution
  - FeedLINK retains veterinarians' eVFDs for the required two-year period
- Enhance communication with stakeholders
  - Automatically send VFDs to feed suppliers and producers upon creation
  - Renew VFD orders in seconds with an email notification linking to the pre-populated VFD
- 21 CFR Part 11 Compliant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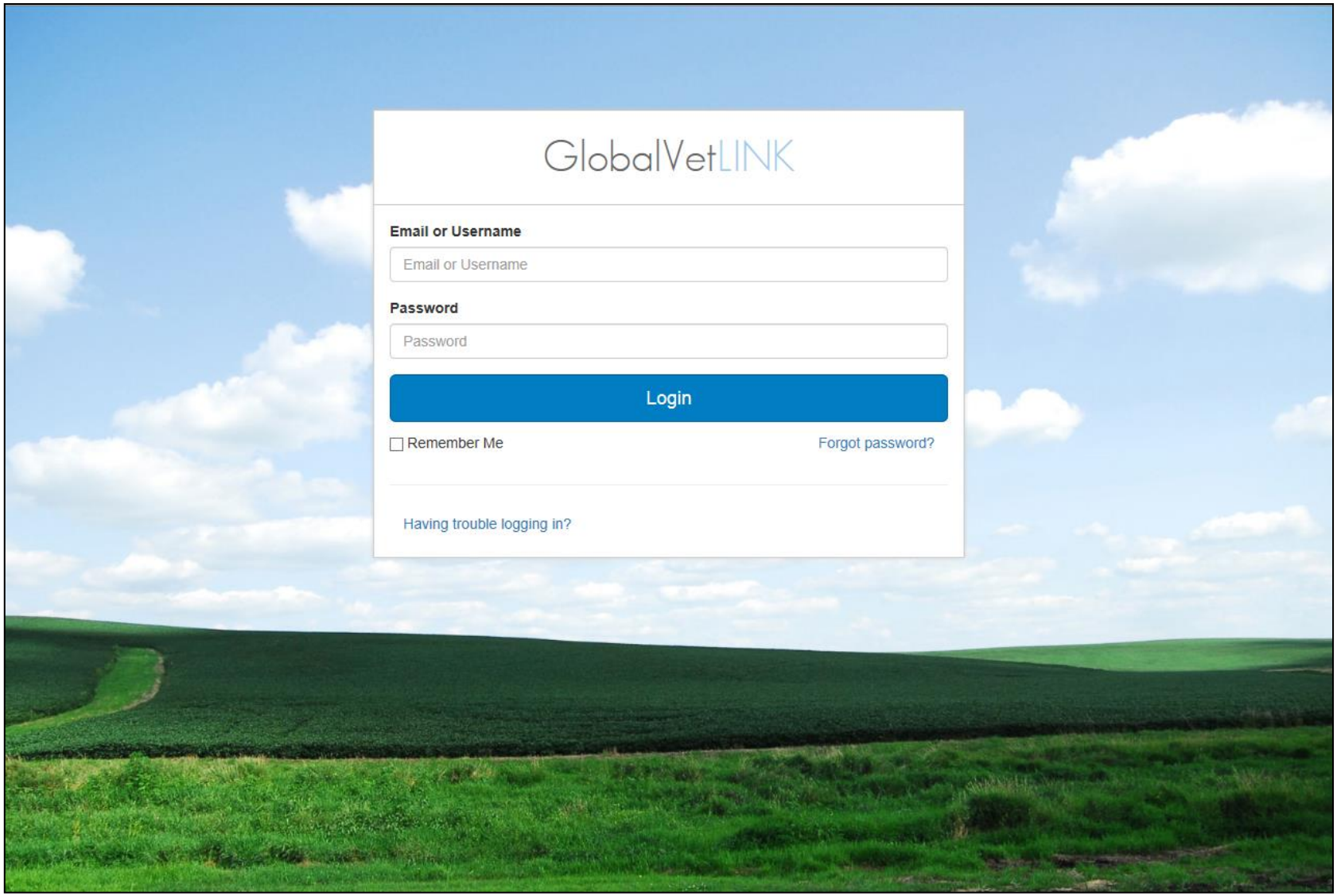
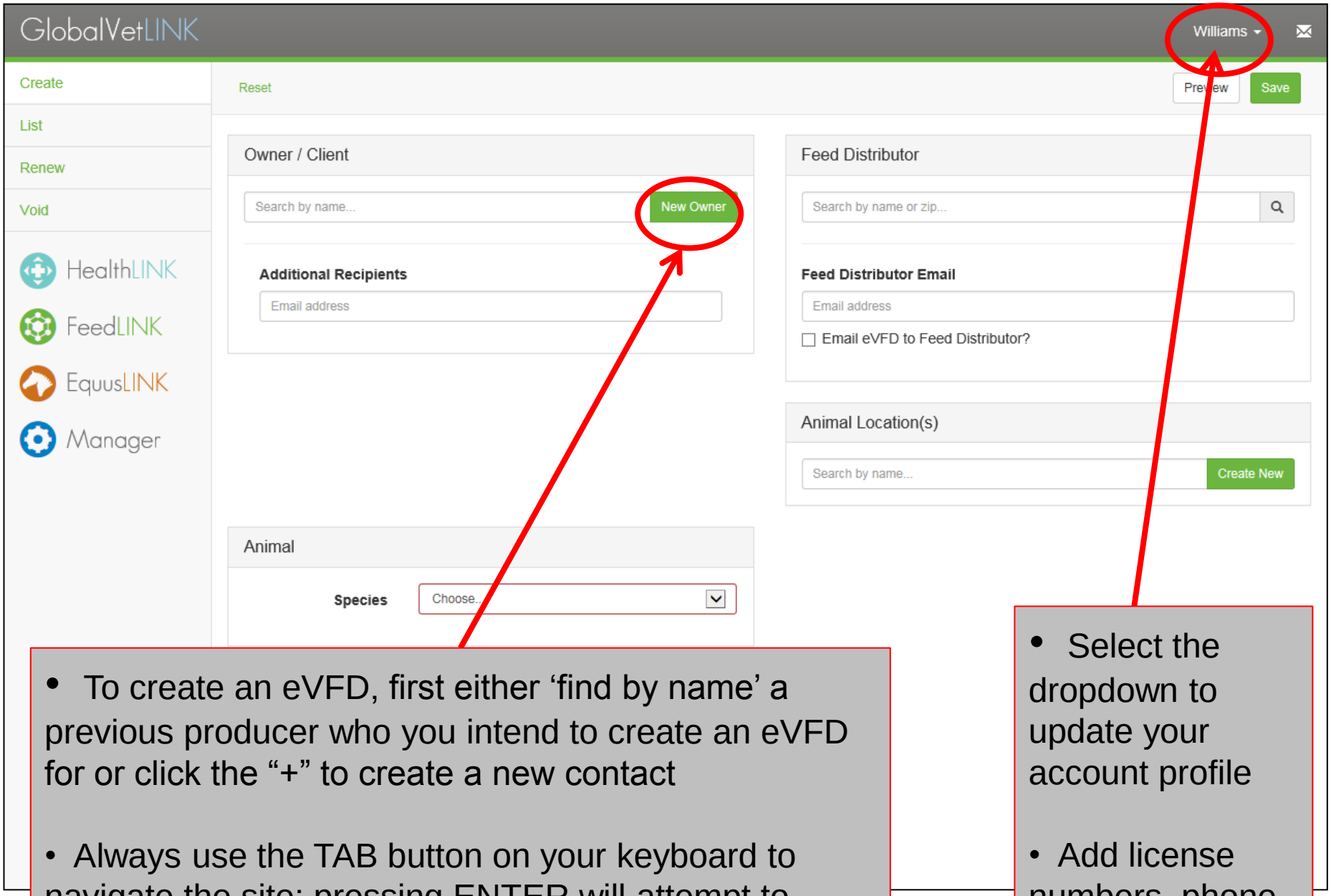
With the Animal Movement Requirements Web Portal powered by GVL SmartEngine™
Get More Out of your Practice
Learn how GlobalVetLINK can simplify ICVIs, VFDs, and EIA (Coggins) while making you more efficient.
Learn More
Get Started
HealthLINK
Equus
LabLINK HIMS
MyVe
• Visit globalvetlink.com to get started
• Click “Login/Sign Up” in the top-right corner to create a new account or to sign in


GlobalVetLINK
Email or Username
Email or Username
Password
Password
Login
Remember Me
Forgot password?
Having trouble logging in?



- To create an eVFD, first either 'find by name' a previous producer who you intend to create an eVFD for or click the "+" to create a new contact

- Always use the TAB button on your keyboard to navigate the site; pressing ENTER will attempt to submit an incomplete eVFD

- Select the dropdown to update your account profile

- Add license numbers, phone numbers, etc.

Contact GlobalVetLINK

- Sales team: (515) 817-5703
  - For training and sales support with new clients
- Technical support: (515) 817-5704
  - To set up accounts, add feed suppliers or other technical system support
- Monday-Friday, 8 a.m.-5 p.m. (CST)

www.globalvetlink.com

Additional eVFD Resources

- RxExpress
  - Customer Service: 888-633-4030 or 720-837-4278
  - www.newplanettek.com

- AGDATA
  - Phil Lawler, 502-857-0103, Phil.Lawler@agdata.net

Impact on Elanco

Impact on Elanco

- Elanco publicly supports FDA initiatives:
  - Aligns with Elanco global antibiotic policy
  - Expedites VFD modernization
  - Protects long-term access
  - Helps support public health
- Elanco will support initiatives via:
  - Resources
  - Leadership
  - Commitment

Impact on Elanco

- In USA, Tylan® premix & Hygromix® use:
  - Will be under the VFD process/require veterinarian oversight
  - Transition labels for Tylan will be placed on bags beginning in May 2016 & will be effective beyond Jan. 1, 2017
- Hygromix:
  - Moves to VFD status but claims would remain
- Tylan Soluble (tylosin tartrate):
  - Moved to a prescription status

Impact on Elanco

- Tylan premix for **swine**
  - Claims for weight gain & feed efficiency withdrawn
  - Claims for swine dysentery & ileitis remain (requires VFD)
- Tylan premix for **cattle***
  - Claim for reduction of liver abscesses remains (requires VFD)
- Tylan premix for **poultry**
  - High-dose use for CRD remains
  - Lower-dose use (most common) for weight gain & feed efficiency withdrawn (effectively eliminates Tylan use in poultry)

*See slide 68 for complete indications.

Impact on Elanco

- Pulmotil (tilmicosin)
  - Continues to be a VFD product
  - First VFD product for use in swine (1996) & beef (2011)

Impact on Elanco

- Ionophores remain unaffected

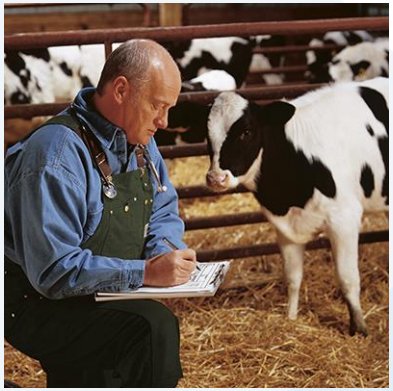
Elanco's Position

- For medically important antimicrobials, Elanco supports:
  - The responsible use for therapeutic purposes with veterinarian oversight
  - Voluntarily narrowing use to therapeutic uses only
  - No longer promoting use for performance purposes
  - Transitioning label indications to therapeutic uses only

Elanco's Position

- Invest in innovation

Pursue advances & treatments that lessen reliance on antibiotics



Seek new therapeutic indications for treatment, control & prevention of diseases

Support use of antimicrobials used only in animals for growth & performance (where permitted)

Provide services that help verify & validate responsible product use

Elanco's "Rules of Engagement"

Subject	Policy highlights
Internal governance	Provide oversight by global antimicrobials team
Product registrations	Seek therapeutic indications for all antimicrobial classes
	Support use of animal-only products for growth/ performance
New product development	Support existing products
	Pursue appropriate extended uses
	Seek new platforms for animal care
Professional oversight	Support oversight of antibiotic use by veterinarians
Risk-based assessment	Review products, resistance monitoring, data, research, etc., to protect human & animal health
Partnerships	Collaborate with industry groups & leaders

The labels contain complete use information, including cautions and warnings.
Always read, understand and follow the label and use directions.

How to use Tylan®* premix for swine	
For control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*:	**Recommendation:**
Feed Tylan at 100 g/ton for at least 3 weeks, followed by 40 g/ton to market weight. *** No withdrawal required when fed according to label directions**	Begin feeding Tylan at 12-15 weeks of age or 3 weeks prior to seroconversion,[1,2] because gross or microscopic lesions appear well in advance of seroconversion/disease.

How to use Tylan®* premix for poultry

- To aid in the control of chronic respiratory disease associated with *Mycoplasma gallisepticum* in broilers
  - Tylan 40 per ton of Type C Feed: 20 to 25 lbs.
  - Tylosin per ton of Type C Feed: 800 to 1,000 g*
- To aid in the control of chronic respiratory disease associated with *Mycoplasma gallisepticum* in replacement chickens
  - 1,000 g/ton
- Feed continuously as the sole ration
- **Tylan requires a 5-day withdrawal period before slaughter when fed at 800 to 1,000 g/ton.**

How to use Tylan® premix for beef cattle

- For reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*:
  - Feed tylosin continuously at 8-10 g/ton (90% DM) to deliver 60-90 mg/hd/d.

*** No withdrawal required when fed according to label directions.**

Pulmotil® directions for use for cattle

- **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:** Feed continuously for a single, 14-day period at 568 to 757 g/ton of tilmicosin (100% DM basis) in a Type C medicated feed as the sole ration to provide 12.5 mg/kg of body weight/day.

Pulmotil® directions for use for swine

- **For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*,** feed continuously at 181–363 g/ton for a 21-day period, beginning approximately 7 days before an anticipated outbreak.

Cattle — Important Safety Information

- **CAUTION:** Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.
- Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment.
- To assure both food safety and responsible use, treatment must 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.
- VFD expiration date must not exceed 45 days from the time of issuance. VFDs shall not be refilled.
- Use only in cattle fed in confinement for slaughter.
- Cattle with severe clinical illness should be evaluated for individual treatment with an alternative non-macrolide therapy.
- Do not use in female dairy cattle 20 months of age or older or in veal calves.
- Safety has not been established for cattle intended for breeding.
- Do not allow horses or other equines access to feeds containing tilmicosin.

Swine — Important Safety Information

- **CAUTION:** Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.
- Swine intended for human consumption must not be slaughtered within 7 days of the last treatment.
- Do not feed more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before re-initiating a further course of therapy with an appropriate antimicrobial.
- VFD expiration date must not exceed 90 days from the time of issuance. VFDs shall not be refilled.
- Safety has not been established in male swine intended for breeding.
- Do not allow horses or other equines access to feeds containing tilmicosin.

The labels contain complete use information, including cautions and warnings.
Always read, understand and follow the label and use directions.

Elanco™ AF1300

Tylan® Soluble™

Tylosin Tartrate

Equivalent to **100 g (3.53 oz)** tylosin base

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

For oral use in chickens, turkeys, swine, and honey bees.

Macrolide Antibiotic, NADA 13-076, approved by FDA

Indications

Chickens: For the control of mortality caused by necrotic enteritis (**NE**) associated with *Clostridium perfringens* in broiler chickens. As an aid in the treatment of chronic respiratory disease (**CRD**) associated with *Mycoplasma gallisepticum* in broiler and replacement chickens. For the control of CRD associated with *Mycoplasma gallisepticum* at the time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* in broiler chickens.

Turkeys: For the reduction in severity of effects of infectious sinusitis associated with *Mycoplasma gallisepticum*.

Swine: For the treatment and control of swine dysentery (**SD**) associated with *Brachyspira hyodysenteriae*. For the treatment and control of SD associated with *Brachyspira hyodysenteriae* when followed immediately by Tylan Type A medicated article in feed.
For the control of porcine proliferative enteropathies (**PPE**, ileitis) associated with *Lawsonia intracellularis* when followed immediately by Tylan Type A medicated article in feed.

Honey Bees: For the control of American Foulbrood (*Paenibacillus larvae*).

Ingredients

Tylosin (as tylosin tartrate) ..... 100 g

Dosage and Administration

Dosages:

Chickens:

NE indication: 851 to 1,419 mg/gallon (225 to 375 ppm) in drinking water.

CRD indications: 2,000 mg/gallon (528 ppm) in drinking water.

Turkeys: 2,000 mg/gallon (528 ppm) in drinking water.

Swine: 250 mg/gallon (66 ppm) in drinking water.

Honey Bees: 200 mg/colony in confectioners/powdered sugar.

Mixing Directions for Medicated Drinking Water:

Always add the water to the powder. Do not pour the powder into the water. Prepare a fresh Tylan Soluble solution every three days. When mixing and handling tylosin, use protective clothing and impervious gloves. If using a water medicating pump see table below, otherwise mix as follows:
To assure thorough dissolution, first place the contents of one jar in a mixing container and add one gallon of water (3785 mL) to the powder to make a concentrated solution. To make medicated drinking water containing 250 mg/gallon (66 ppm), mix this concentrated solution with water to make 400 gallons (1514 liters) of medicated drinking water. To make medicated drinking water containing 851 to 1,419 mg/gallon (225 to 375 ppm), mix this concentrated solution with water to make from 117 gallons + 51 ounces (444 liters) to 70 gallons + 64 ounces (267 liters) of medicated drinking water, respectively. To make medicated drinking water containing 2,000 mg/gallon (528 ppm), mix this concentrated solution with water to make 50 gallons (189 liters) of medicated drinking water.

Mixing Directions for Water Medicating Pump (1:128 inclusion)*:

Desired Concentration in Drinking water	Jars of Tylan Soluble	Volume of Water to Make Stock Solution
250 mg/gallon (66 ppm)	1	3 gallons + 13 ounces
851 mg/gallon (225 ppm)	5	4 gallons + 77 ounces
1,419 mg/gallon (375 ppm)	9	5 gallons + 0 ounces
2,000 mg/gallon (528 ppm)	10	3 gallons + 115 ounces

*This table applies only if the water medicating pump is set to deliver 1 ounce of stock solution per gallon of drinking water.

Mixing Directions for use in Honey Bees: Mix 200 mg tylosin in 20 g confectioners/powdered sugar. Use immediately.

Directions for Use

Chickens: NE indication: Administer medicated drinking water for a single five day period in broiler chickens. To assure all birds receive the intended medication, only medicated water should be available. These practices should be followed to assure both food safety and responsible antimicrobial drug use in chickens: 1) Use in flocks exhibiting signs of a necrotic enteritis outbreak, for example, increased mortality and lesions characteristic of necrotic enteritis upon necropsy; 2) Administer the full dose and dosing regimen once medication is initiated; 3) Use of Tylan Soluble or another macrolide is not advised if additional therapy is needed beyond the original course of medication. **CRD indications:** Administer medicated drinking water for three days; however, medicated water may be administered for one to five days depending upon severity of infection. Treated chickens must consume enough medicated water to provide 50 mg per pound of body weight per day. Only medicated water should be available to the birds.
Turkeys: Administer medicated drinking water for three days; however, medicated water may be administered for two to five days depending upon severity of infection. Treated turkeys must consume enough medicated water to provide 60 mg per pound of body weight per day. Only medicated water should be available to the birds.
Swine: SD indication: Administer medicated drinking water for 3 to 10 days, depending upon severity of infection. Alternatively, administer medicated drinking water for 3 to 10 days, followed by 40 to 100 g tylosin per ton of complete feed (Type C medicated feed manufactured from Tylan Type A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with Tylan Soluble. **PPE indication:** Administer medicated drinking water for 3 to 10 days, followed by 40 to 100 g of tylosin per ton of complete feed (Type C medicated feed manufactured from Tylan A medicated article) for 2 to 6 weeks. Only medicated water should be available to swine while medicating with Tylan Soluble.
Honey Bee Colonies: Administer three treatments of medicated confectioners sugar once weekly for 3 weeks. The 200 mg dose is applied (dusted) over the top bars of the brood chamber.

Warnings

User Safety Warnings: Not for Human Use. Keep Out of Reach of Children. Avoid contact with human skin. Exposure to tylosin may cause a rash.

Residue Warnings: Chickens must not be slaughtered for food within 24 hours after treatment. Do not use in layers producing eggs for human consumption.
Turkeys must not be slaughtered for food within five days after treatment.
Swine must not be slaughtered for food within 48 hours after treatment.
Honey bees: The drug should be fed early in the spring or fall and consumed by the bees before the main honey flow begins, to avoid contamination of production honey. Complete treatments at least 4 weeks prior to main honey flow.

Manufactured For:
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285, USA
Product of the United Kingdom

Store at or below 25°C (77°F)
Excursions Permitted to 40°C (104°F)
Avoid Moisture.

Restricted Drug (California) – Use Only as Directed.

To report suspected adverse events, for technical assistance, or to obtain a Material Safety Data Sheet (MSDS), call 1-800-428-4441.

AF1300 YL087766AMX W1b

Antibiotic Use in Animal Health

Understanding FDA's final VFD ruling

QUESTIONS?