Current Antibiotic Issues and Overview of the New Veterinary Feed Directive (VFD)

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Beef Technical Consultant

Grain & Feed Industry Conference

1/13/16

WHY

WE DO

WHAT WE DO

FULL VALUE BEEF™

Elanco

Elanco Trusted Solutions

Overview

- Consumer attitudes
- Access to antibiotics
- 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.

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.

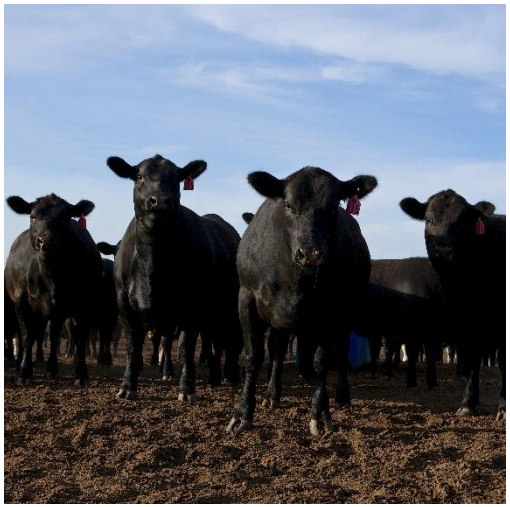
Access to Antibiotics

Access to Antibiotics

- A public health issue
- Access to effective antibiotics:

Critical for public health

Vital for livestock & poultry production



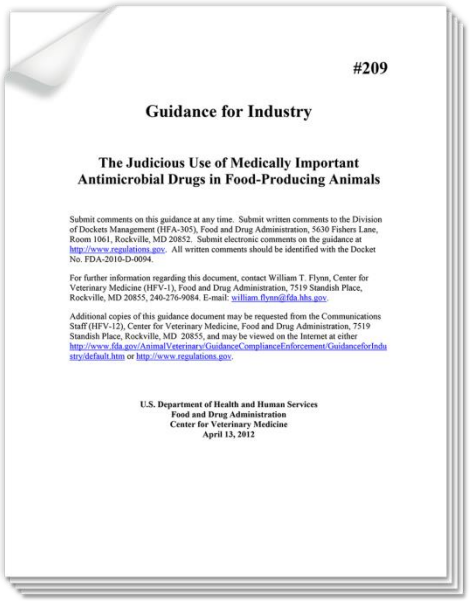
Essential for animal well-being

Access to Antibiotics

- U.S. Food and Drug Administration:
  - Concerned 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 issues 3 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

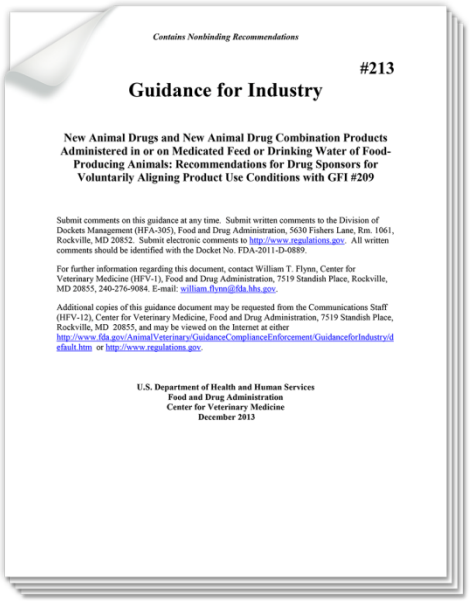
Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments on the guidance at http://www.regulations.gov. All written comments should 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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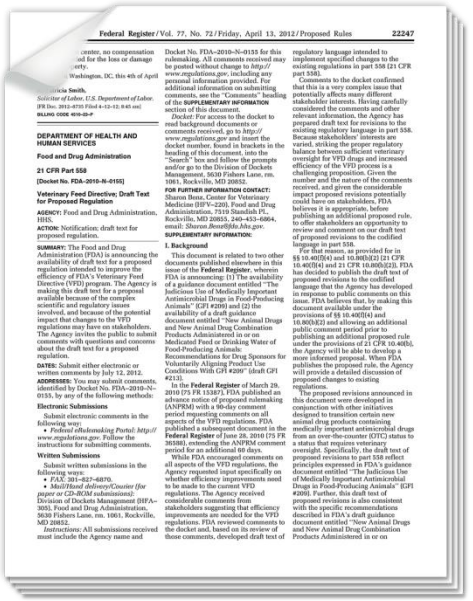
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
December 2013

Guidance for Industry (GFI) #213



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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

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FOR FURTHER INFORMATION CONTACT: Sharon Benz, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6864, email: *Sharon.Benz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This document is related to two other documents published elsewhere in this issue of the **Federal Register**, wherein FDA is announcing: (1) The availability of a guidance document entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (GFI #209) and (2) the availability of a draft guidance document entitled "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" (draft GFI #213).

In the **Federal Register** of March 29, 2010 (75 FR 15337), FDA published an advance notice of proposed rulemaking (ANPRM) with a 90-day comment period requesting comments on all aspects of the VFD regulations. FDA published a subsequent document in the **Federal Register** of June 28, 2010 (75 FR 36588), extending the ANPRM comment period for an additional 60 days.

While FDA encouraged comments on all aspects of the VFD regulations, the Agency requested input specifically on whether efficiency improvements need to be made to the current VFD regulations. The Agency received considerable comments from stakeholders suggesting that efficiency improvements are needed for the VFD regulations. FDA reviewed comments to the docket and, based on its review of those comments, developed draft text of regulatory language intended to implement specified changes to the existing regulations in part 558 (21 CFR part 558).

Comments to the docket confirmed that this is a very complex issue that potentially affects many different stakeholder interests. Having carefully considered the comments and other relevant information, the Agency has prepared draft text for revisions to the existing regulatory language in part 558. Because stakeholders' interests are varied, striking the proper regulatory balance between sufficient veterinary oversight for VFD drugs and increased efficiency of the VFD process is a challenging proposition. Given the number and the nature of the comments received, and given the considerable impact proposed revisions potentially could have on stakeholders, FDA believes it is appropriate, before publishing an additional proposed rule, to offer stakeholders an opportunity to review and comment on our draft text of proposed revisions to the codified language in part 558.

For that reason, as provided for in §§ 10.40(f)(4) and 10.80(b)(2) [21 CFR 10.40(f)(4) and 21 CFR 10.80(b)(2)], FDA has decided to publish the draft text of proposed revisions to the codified language that the Agency has developed in response to public comments on this issue. FDA believes that, by making this document available under the provisions of §§ 10.40(f)(4) and 10.80(b)(2) and allowing an additional public comment period prior to publishing an additional proposed rule under the provisions of 21 CFR 10.40(f)(5), the Agency will be able to develop a more informed proposal. When FDA publishes the proposed rule, the Agency will provide a detailed discussion of proposed changes to existing regulations.

The proposed revisions announced in this document were developed in conjunction with other initiatives designed to transition certain new animal drug products containing medically important antimicrobial drugs from an over-the-counter (OTC) status to a status that requires veterinary oversight. Specifically, the draft text of proposed revisions to part 558 reflect principles expressed in FDA's guidance document entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (GFI #209). Further, this draft text of proposed revisions is also consistent with the specific recommendations described in FDA's draft guidance document entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on

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

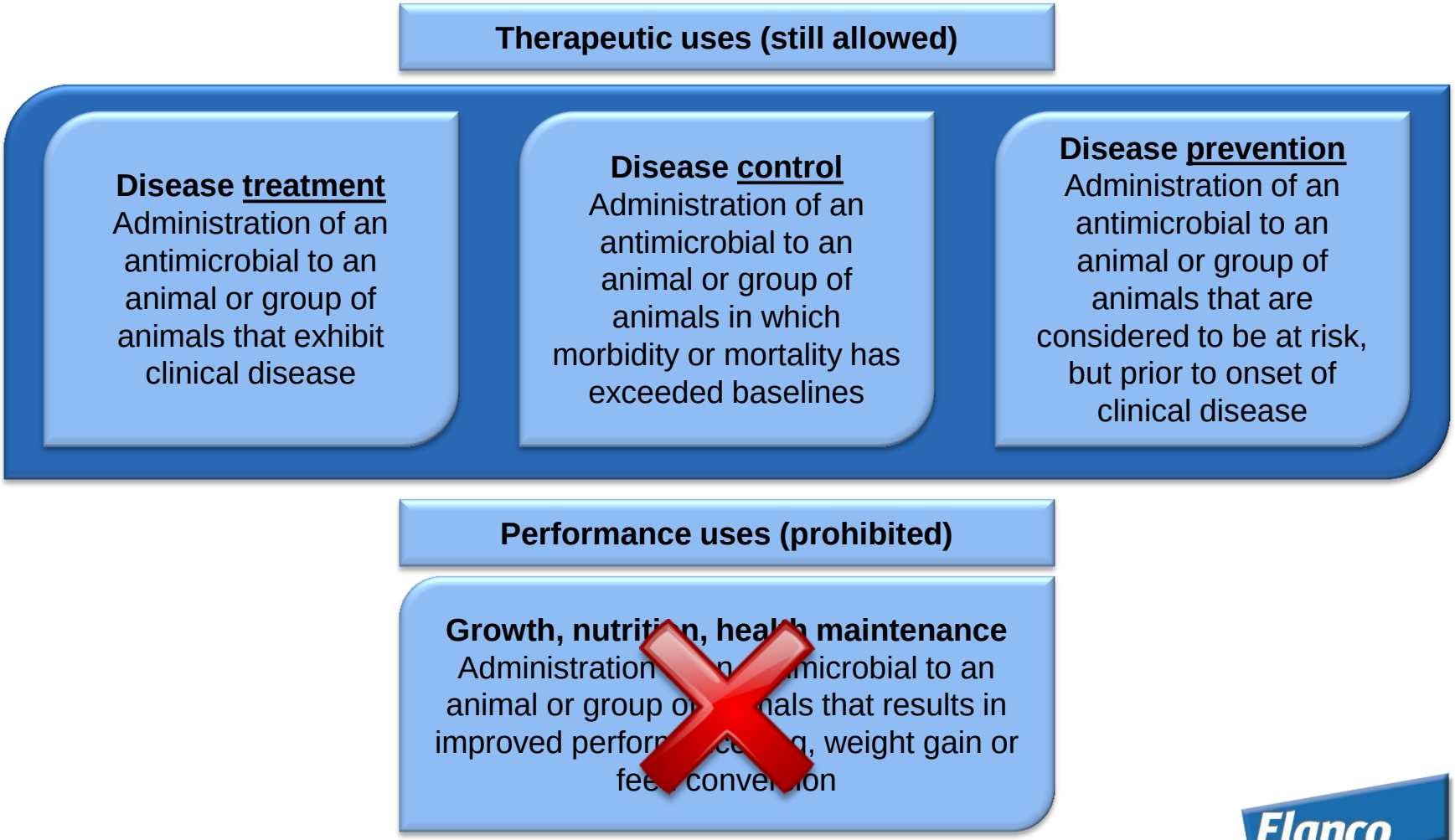
- The “what” component
- Establishes “judicious use” principle
  - Limits shared-class antibiotics to therapeutic purposes
- Key: Use of **medically important** antimicrobial drugs in food-producing animals should be limited to:

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 performance indications for certain antibiotics



Products Affected vs. Unaffected as Defined by FDA Guidance 152

Unaffected	Affected
Non-Medically Important Products used exclusively in 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

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

Production uses — Still allowed Enhance growth or improve feed efficiency	**Production uses —** No longer allowed Enhance growth or improve feed efficiency

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)

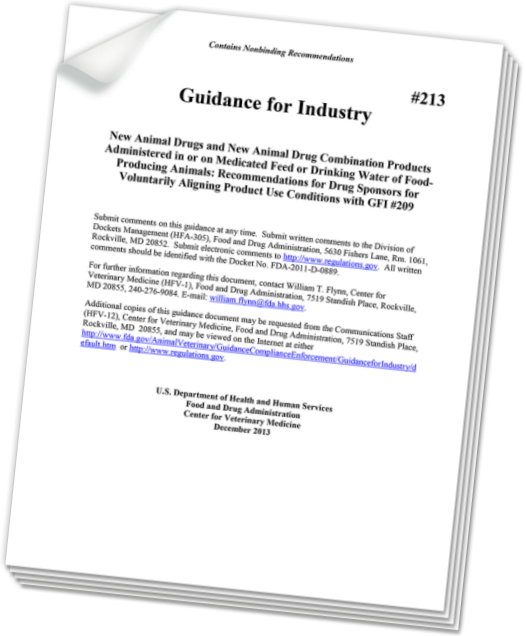
Blue = shared feed and/or water

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
- 2 options to change product labels
  - Voluntarily remove production indications
  - Seek new therapeutic indications at current doses
- Provides 3 years to comply (Dec. 2016)



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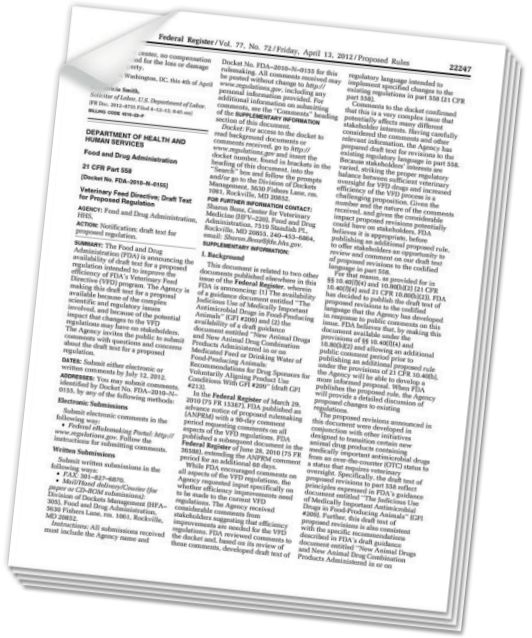
Food and Drug Administration
Center for Veterinary Medicine
December 2013

21 CFR 558

- Proposes changes to VFD process
  - Strives toward less burdensome process
  - Provides greater flexibility for veterinarians to exercise professional training
  - Streamlines FDA administrative procedures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Veterinary Feed Directive (VFD)

- 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

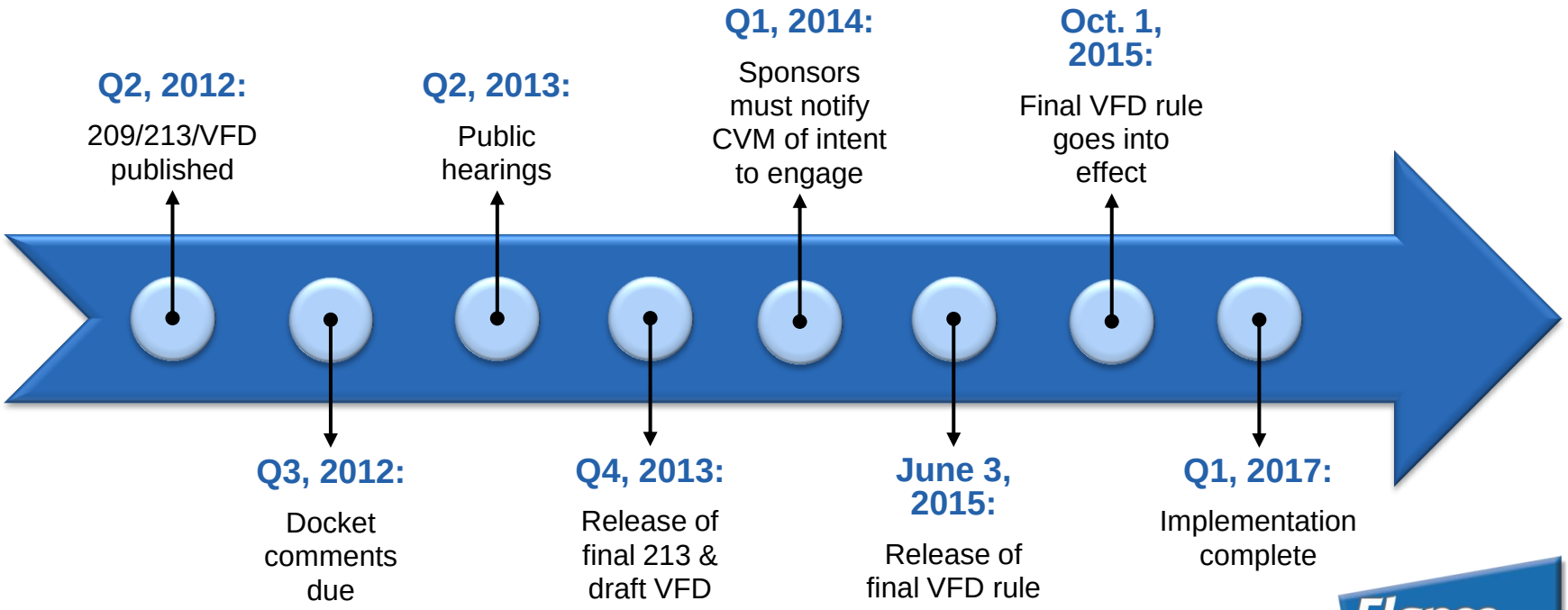
VFD Modernization

- 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 3 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 manufacturing once labels have been transitioned

Compliance Timeline

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

Final VFD Rules

June 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 (extralabel 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 Recordkeeping Requirements

- Maintains record keeping requirement for VFDs for 2 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 be licensed to practice veterinary medicine and operate in compliance with appropriate State-defined veterinarian-client-patient relationship 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
- 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 on 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 only manufacture medicated feeds for use in their own animals are not distributors
- On-farm mixers must only be manufacturing VFD feed 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 an on-farm mixer distributes to another producer, that mixer will be considered a distributor

Distribution Regulation

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

Notice To FDA of Distribution of VFD Feeds

I/we hereby notify the Food and Drug Administration that I/we have begun distributing VFD feeds.

_____
Signature

_____
Name of firm or individual

_____

_____

_____
Business Address

_____
Date

This notice should be sent to: Center for Veterinary Medicine (HFV-226)
7500 Standish Place
Rockville, MD 20855

Acknowledgment of Distribution 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 shipper)

As follows:

1. To an animal production facility, if the owner or operator of that facility provides me/us with a copy of a veterinary feed directive 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 acknowledgment similar to this acknowledgment.

_____
Signature

_____
Name of firm or individual

_____

_____
Street Address

_____
Date

3. By signing this Acknowledgment of Distribution I/we affirm that I/we have notified FDA of our intent to distribute VFD medications.

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

Implementing a VFD (Cattle)

Current Pulmotil Cattle VFD Form

Elanco Pulmotil

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

Client: _____ Veterinarian: _____

Address: _____ Address: _____

_____ _____

_____ _____

Phone #: _____ Phone #: _____

Fax #: _____ Fax #: _____

Cattle to be treated (number and location):	Special Instructions:

Mix into Type C Medicated Feed to Provide:

_____total lbs Type C Complete feed at _____ g/ton

Type C complete feed range of 568 to 757 g/ton

_____total lbs Type C Complete feed at _____g/ton

Type C complete feed range of 568 to 757 g/ton

VFD Expiration Date: _____

Month/Day/Year (not to exceed 45 day

Amount of final (Type C) feed: _____

Veterinarian's signature: _____

Date:_____ License # and State _____

CAUTION: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. Extra label use, (i.e., use of this VFD feed in a manner other than as provided for in the VFD drug approval) is strictly prohibited.

Active Drug Ingredient: tilmicosin (as tilmicosin phosphate) 90.7 g per lb (200 g per kg)
Inert Ingredients: ground corncobs.

Description: Pulmotil is a formulation of the antibiotic tilmicosin. Tilmicosin is produced semi-synthetically and is in the macrolide class of antibiotics. Each kilogram of Type A Medicated Article contains 200 grams (0.44 lbs) of tilmicosin adsorbed onto ground corncobs.

Indications:
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.

Feeding Instructions:
Cattle (Complete Feed): This tilmicosin feed is to be fed continuously for a single, 14-day period at 568 grams to 757 grams (626 ppm to 834 ppm) per ton of Type C medicated feed as the sole ration to provide 12.5 mg tilmicosin/kg/head/day.

IMPORTANT: Must be thoroughly mixed in feeds before use.

Mixing Instructions:
For incorporation into Cattle Feeds (Complete Feed): Thoroughly mix Pulmotil Type A medicated article with feed to provide a complete Type C medicated feed containing 568 to 757 grams tilmicosin per ton. Complete Type C medicated feeds should not be pelleted.

Starting concentration of Pulmotil Type A Medicated Article	Amount of Type A Medicated Article to add per ton	Resulting concentration in Type C Medicated Feed
grams per pound	pounds	grams per ton
90.7	8.35	757
	6.26	568

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.

Use of antibacterial drugs in the absence of a susceptible bacterial infection is unlikely to provide benefit to treated animals and may increase the risk of the development of drug-resistant pathogenic bacteria. 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

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.

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.

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.

WARNINGS:

RESIDUE WARNING: Cattle: 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.

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

For technical service call: 1-800-428-4441
Store at less than or equal to 25°C (77°F). Excursions to 40°C (104°F) are acceptable. Avoid excessive moisture. Elanco Animal Health
NADA 141 - 084, Approved by the FDA. A Division of Eli Lilly and Company
PULMOTIL® is a registered trademark of Eli Lilly and Company Indianapolis, IN 46285, USA

White Copy – Supplier Canary Copy – Client Pink Copy – Veterinarian

*VFD form expected to change in late 2015.

Also to be included:
- Indication
- Withdrawal time, special instructions & cautionary statements

Elanco Pulmotil

083251

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

Client: _____ Veterinarian: _____

Address: _____ Address: _____

_____ _____

_____ _____

Phone #: _____ Phone #: _____

Fax #: _____ Fax #: _____

Cattle to be treated (number and location):

Will require approx. # of animals

Special Instructions:

Mix into Type C Medicated Feed to Provide:

VFD Expiration Date: _____
Month/Day/Year (not to exceed 45 days)

_____ total lbs Type C Complete feed at _____ g/ton

Type C co[illegible]d range of 568 to 757 g/ton (100% Dry Matter Basis)

No longer requires calculation of lbs of feed; will require approx. # of animals

[illegible]al (Type C) feed: _____

Complete this additional line to adjust the amount of tilmicosin included in Type C Complete feed during the 14 day administration period

signature: _____

_____ total lbs Type C Complete feed

Type C co[illegible]d range of 568 to 757 g/ton (100% Dry Matter Basis)

[illegible] License # and State _____

No longer requires license # & state

☐ Initial this box if you would like to use this VFD order to authorize the feeding of this tilmicosin medicated animal feed in an FDA approved combination of tilmicosin with other drug(s). If so, you are required to provide the information on the other drug(s) in such drug combination in the following table.

Drug (Ingredient)	Drug Level or Any Special Instructions	Initial

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 — Veterinarian

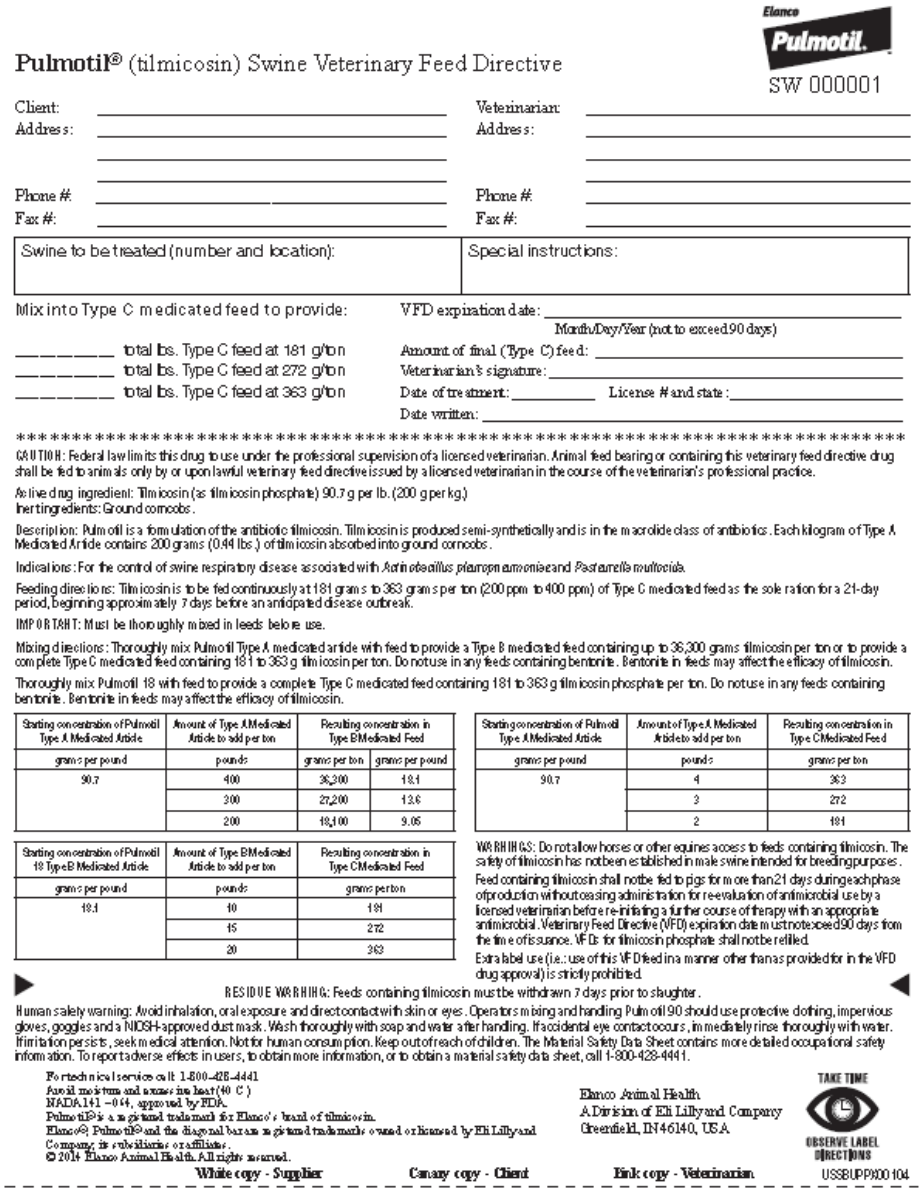
Canary Copy — Client

Pink Copy — Supplier

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

Implementing a VFD (Swine)

Current Pulmotil Swine VFD Form



Pulmotil® (tilmicosin) Swine Veterinary Feed Directive

Elanco Pulmotil

SW 000001

Client: _____ Veterinarian: _____

Address: _____ Address: _____

_____ _____

_____ _____

Phone #: _____ Phone #: _____

Fax #: _____ Fax #: _____

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

Mix into Type C medicated feed to provide:

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

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

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

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

Amount of final (Type C) feed: _____

Veterinarian's signature: _____

Date of treatment: _____ License # and state: _____

Date written: _____

****

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

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

Description: Pulmotil is a formulation of the antibiotic tilmicosin. Tilmicosin is produced semi-synthetically and is in the macrolide class of antibiotics. Each kilogram of Type A Medicated Article contains 200 grams (0.44 lbs.) of tilmicosin absorbed into ground corncobs.

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

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

IMPORTANT: Must be thoroughly mixed in feeds before use.

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

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

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

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

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

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

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

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

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

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

For technical services call: 1-800-428-4441
Avoid moisture and excessive heat (40 C)
NADA 141 –044, approved by FDA.
Pulmotil® is a registered trademark for Elanco's brand of tilmicosin.
Elanco®, Pulmotil® and the diagonal bar are registered trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.
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Elanco Animal Health
A Division of Eli Lilly and Company
Greenfield, IN 46140, USA

TAKE TIME
OBSERVE LABEL DIRECTIONS

White copy - Supplier Canary copy - Client Pink copy - Veterinarian

USSBUPP00104

*VFD form expected to change in late 2015.

Pulmotil® (tilmicosin) Swine Veterinary Feed Directive

Elanco Pulmotil

SW 000001

Client: _____ Veterinarian: _____

Address: _____ Address: _____

_____ _____

_____ _____

Phone #: _____ Phone #: _____

Fax #: _____ Fax #: _____

Swine to be treated (number and location):

Will requiire approx. # of animals

Special instructions:

Expiration date length dependent on product label

Mix into Type C medicated feed to provide:

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

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

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

VFD expiration date: _____

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

Amount of final (Type C) feed: _____

Veterinarian's signature: _____

Date of treatment: _____ License # and state: _____

Date written: _____

No longer requires calculation of lbs of feed; will require approx. # of animals

No longer requires license # & state

Also to be included:

- Name of VFD drug
- Indication
- Level of VFD drug in feed & duration
- Withdrawal time, special instructions & cautionary statements
- Affirmation of intent for combination drugs

Elanco

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.

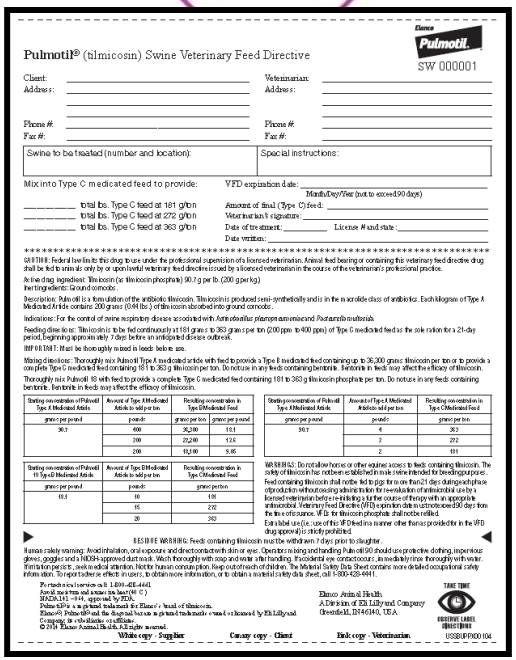
Distribution of VFD form

- Original form must be stored by veterinarian

White Copy — Veterinarian

Canary Copy — Client

Pink Copy — Supplier



Pulmotil® (tilmicosin) Swine Veterinary Feed Directive

Elanco Pulmotil

SW 000001

Client: _____ Veterinarian: _____

Address: _____ Address: _____

_____ _____

Phone #: _____ Phone #: _____

Fax #: _____ Fax #: _____

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

Mix into Type C medicated feed to provide:

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

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

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

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

Amount of final (Type C) feed: _____

Veterinarian's signature: _____

Date of treatment: _____ License # and state: _____

Date written: _____

****

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

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

Inert ingredients: Ground corncobs.

Description: Pulmotil is a formulation of the antibiotic tilmicosin. Tilmicosin is produced semi-synthetically and is in the macrolide class of antibiotics. Each kilogram of Type A Medicated Article contains 200 grams (0.44 lbs.) of tilmicosin absorbed into ground corncobs.

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

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

IMPORTANT: Must be thoroughly mixed in feeds before use.

Mixing directions: Thoroughly mix Pulmotil Type A medicated article with feed to provide a Type B medicated feed containing up to 36,200 grams tilmicosin per ton or to provide a complete Type C medicated feed containing 181 to 363 g tilmicosin per ton. Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.

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

Starting concentration of Pulmotil Type A Medicated Article:	Amount of Type A Medicated Article to add per ton:	Resulting concentration in Type C Medicated Feed:	
grams per pound	pounds	grams per ton	grams per pound
90.7	400	36,280	18.1
	300	27,210	13.6
	200	18,140	9.05

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

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

WARNINGS: Do not allow horses or other equines access to feeds containing tilmicosin. The safety of tilmicosin has not been established in male swine intended for breeding purpose. Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without obtaining administration for re-evaluation of antimicrobial use by a licensed veterinarian before re-initiating a further course of therapy with an appropriate antimicrobial. Veterinary Feed Directive (VFD) expiration date is not to exceed 90 days from the time of issuance. VFD for tilmicosin phosphate shall not be refilled.

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

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

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

For technical service call 1-800-428-4441

Approved as a veterinary feed directive drug (VFD).

NADA 141 –144, approved by FDA.

Pulmotil® is a registered trademark for Elanco's brand of tilmicosin.

Elanco®, Pulmotil® and the diagonal bar are registered trademarks owned or licensed by Eli Lilly and Company or its affiliates.

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TAKE TIME DIRECTIVE LABEL DIRECTIONS

Elanco Animal Health
A Division of Eli Lilly and Company
Greenfield, IN 46140, USA

USSWPP000104

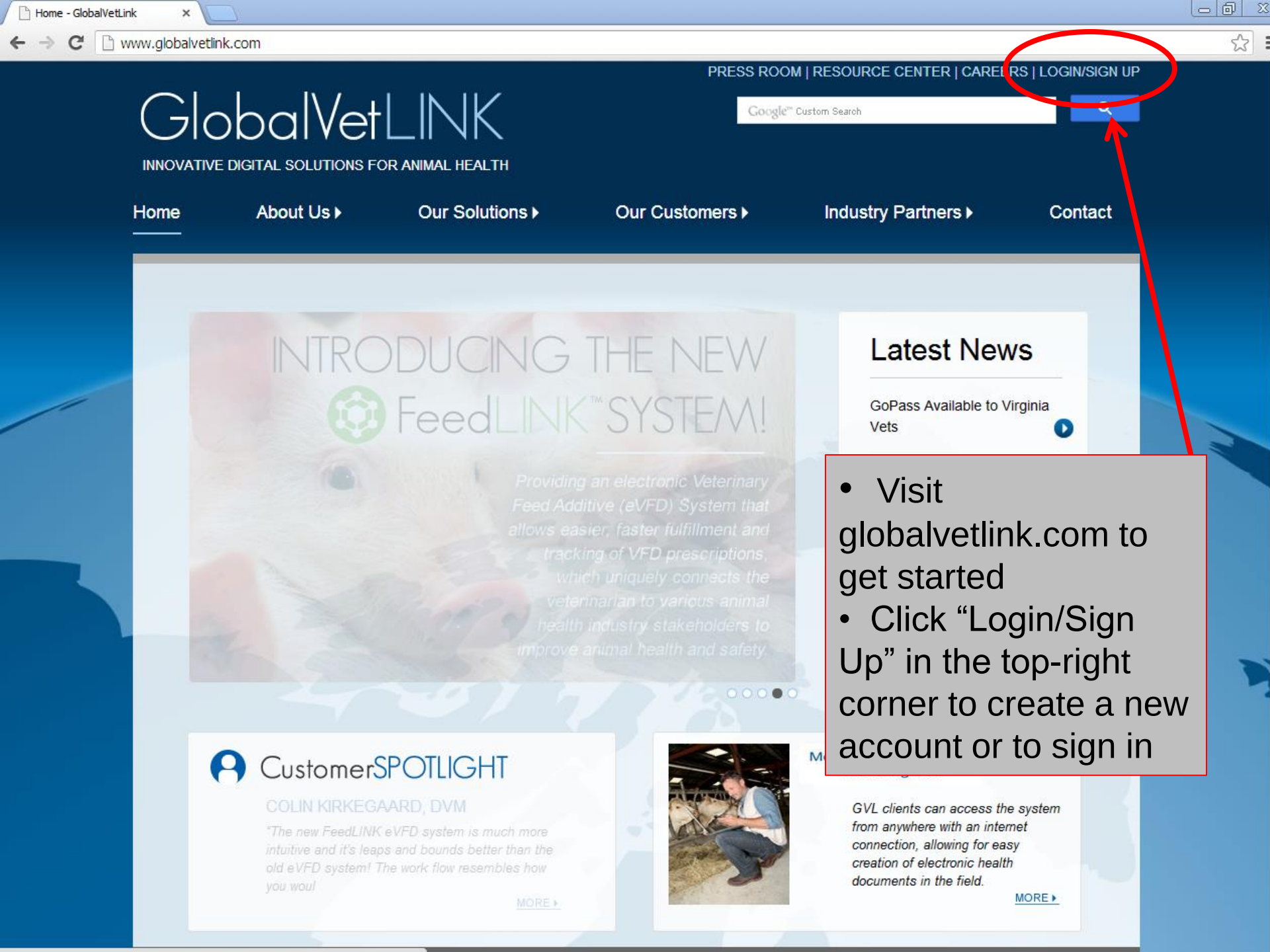
White copy - Supplier Canary copy - Client Pink copy - Veterinarian

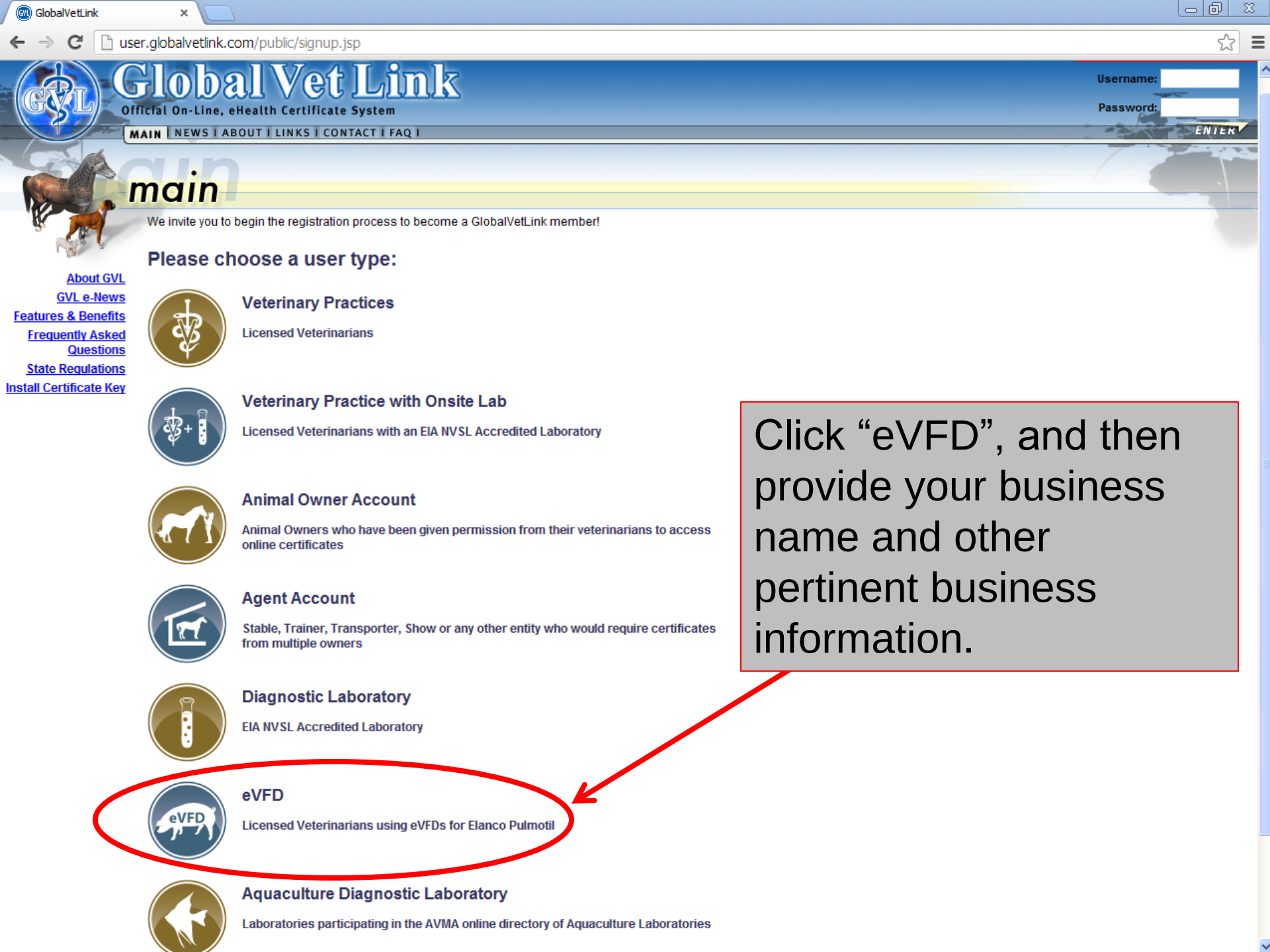
Note: color-coded forms are Elanco-only forms.

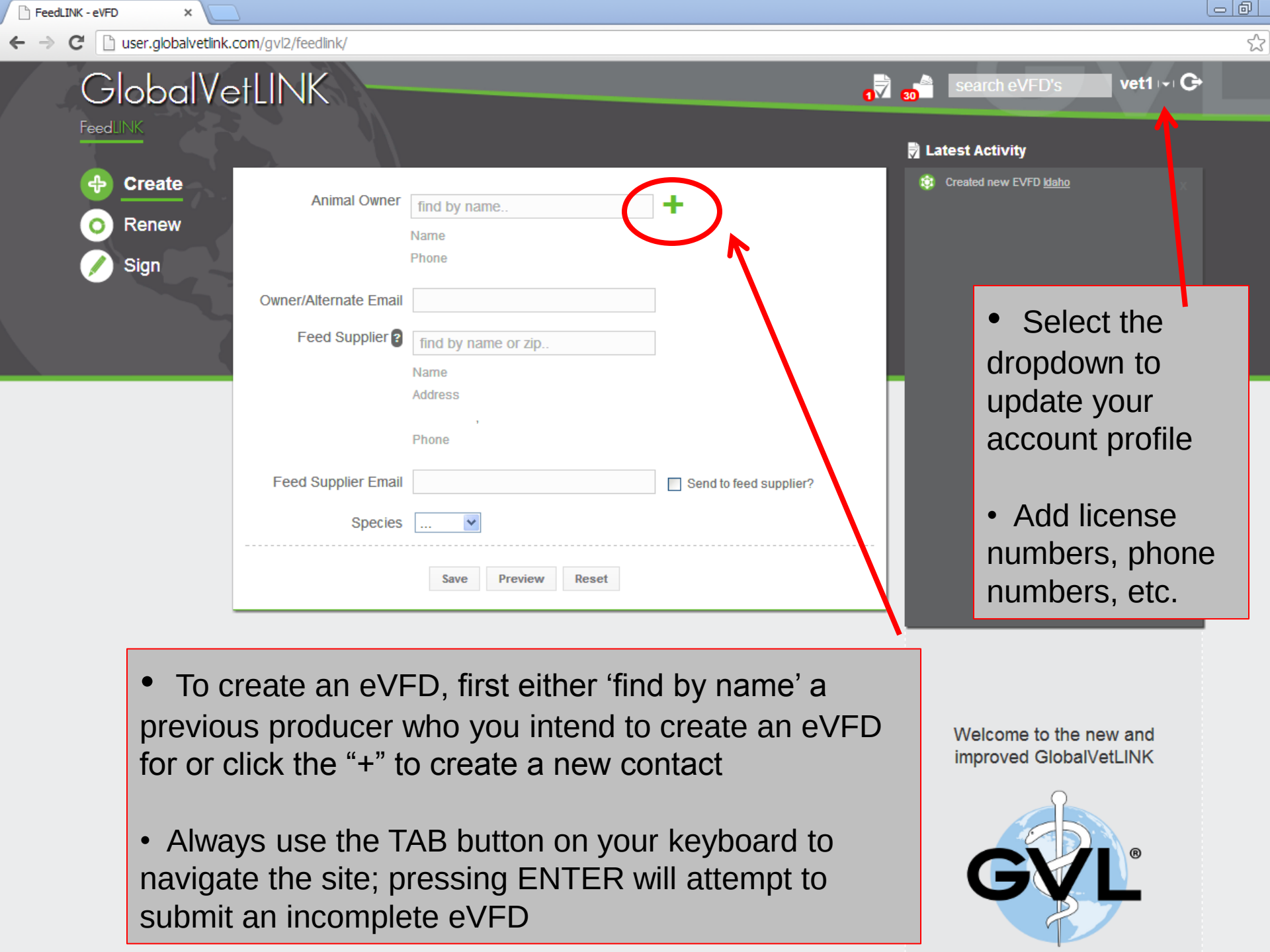
Electronic VFDs

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


Home - GlobalVetLink
www.globalvetlink.com
PRESS ROOM | RESOURCE CENTER | CAREERS | LOGIN/SIGN UP
GlobalVetLINK
INNOVATIVE DIGITAL SOLUTIONS FOR ANIMAL HEALTH
Google™ Custom Search
Home
About Us
Our Solutions
Our Customers
Industry Partners
Contact
INTRODUCING THE NEW FeedLINK™ SYSTEM!
Providing an electronic Veterinary Feed Additive (eVFD) System that allows easier, faster fulfillment and tracking of VFD prescriptions, which uniquely connects the veterinarian to various animal health industry stakeholders to improve animal health and safety
Latest News
GoPass Available to Virginia Vets
CustomerSPOTLIGHT
COLIN KIRKEGAARD, DVM
"The new FeedLINK eVFD system is much more intuitive and it's leaps and bounds better than the old eVFD system! The work flow resembles how you woul
MORE
GVL clients can access the system from anywhere with an internet connection, allowing for easy creation of electronic health documents in the field.
MORE
• 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
user.globalvetlink.com/public/signup.jsp
Global Vet Link
Official On-Line, eHealth Certificate System
Username:
Password:
ENTER
MAIN | NEWS | ABOUT | LINKS | CONTACT | FAQ |
main
We invite you to begin the registration process to become a GlobalVetLink member!
Please choose a user type:
About GVL
GVL e-News
Features & Benefits
Frequently Asked Questions
State Regulations
Install Certificate Key
Veterinary Practices
Licensed Veterinarians
Veterinary Practice with Onsite Lab
Licensed Veterinarians with an EIA NVSL Accredited Laboratory
Animal Owner Account
Animal Owners who have been given permission from their veterinarians to access online certificates
Agent Account
Stable, Trainer, Transporter, Show or any other entity who would require certificates from multiple owners
Diagnostic Laboratory
EIA NVSL Accredited Laboratory
eVFD
Licensed Veterinarians using eVFDs for Elanco Pulmotil
Aquaculture Diagnostic Laboratory
Laboratories participating in the AVMA online directory of Aquaculture Laboratories
Click “eVFD”, and then provide your business name and other pertinent business information.


FeedLINK - eVFD
user.globalvetlink.com/gvl2/feedlink/
GlobalVetLINK
FeedLINK
search eVFD's
vet1
Create
Renew
Sign
Latest Activity
Created new EVFD Idaho
Animal Owner
find by name..
Name
Phone
Owner/Alternate Email
Feed Supplier
find by name or zip..
Name
Address
Phone
Feed Supplier Email
Send to feed supplier?
Species
...
Save
Preview
Reset
• Select the dropdown to update your account profile
• Add license numbers, phone numbers, etc.
• 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
Welcome to the new and improved GlobalVetLINK
GVL

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

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
- Hygromix:
  - Moves to VFD status but claims would remain
- Tylan Soluble (tylosin tartrate):
  - Moved to a prescription status

Impact on Elanco

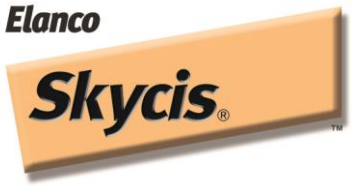
- Tylan® premix for **swine**
  - Claims for weight gain & feed efficiency withdrawn
  - Claims for swine dysentery & ileitis remain (requires VFD)
- Tylan premix for **cattle**
  - Claim for reduction of liver abscesses remains (requires VFD)

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 8-Point Antibiotic Stewardship Plan

Act with responsibility globally

Act with responsibility globally—not just according to U.S. regulation—by working with food producers and retailers to provide training and encourage policies that reduce shared-class antibiotic use and increase veterinarian oversight.

Cease marketing of growth promotion

Cease marketing of growth promotion uses for shared-class antibiotics and complete full regulatory change to end growth promotion use of shared-class antibiotics globally by the end of 2016.

Eliminate continuous antibiotic use

Help customers eliminate continuous use of shared-class antibiotics for therapy purposes by providing an alternative.

Eliminate over-the-counter sales

Eliminate over-the-counter sales of shared-class antibiotics globally—including injectable products—where veterinarian oversight exists.

Eliminate concurrent use

Eliminate concurrent use of shared-class antibiotics to treat the same disease.

Support veterinary oversight

Support veterinary oversight and responsible use, including helping build infrastructure globally.

Develop new animal-only antibiotics

Develop new animal-only antibiotics. No animal should ever be treated with a shared-class antibiotic if an animal-only option exists. Animal- only antibiotics optimize animal welfare without compromising human use antibiotics.

Create alternatives

Elanco commits to invest two-thirds of our food animal research budget to quickly evaluate 25 candidates and deliver 10 viable non-antibiotic development projects that address diseases where there are few, or no, alternatives to shared-class antibiotics. (Respiratory disease and enteric disease in cattle, swine and poultry and mastitis in cattle.)

Background

- Antibiotic resistance is a complex issue and the solutions to addressing it are equally complex.
- In 2013, Elanco announced it's Antibiotic Policy, which outlines our global approach to the responsible use of antibiotics and to help preserve effectiveness of antibiotics for human and animal health.
- Since 2013, Elanco has been leading efforts, including shaping public policy for the responsible use of antibiotics in partnership with stakeholders across the globe.
- Elanco's 8-Point Antibiotic Stewardship Plan aligns with our Global Antibiotic Policy and further outlines our commitment to this issue.

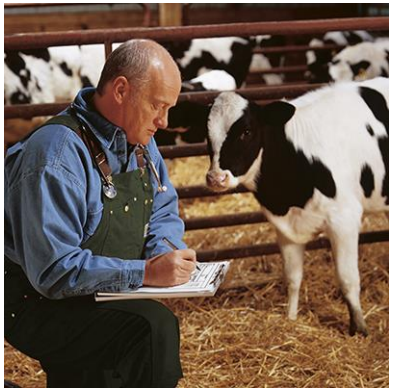
Elanco's Position

- 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

How to use Tylan®* premix for swine

For ileitis control:	Recommendation:
Feed Tylan at 100 g/ton for at least 3 weeks, followed by 40 g/ton to market weight.	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.

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

How to use Tylan® premix for poultry

- For increased rate of weight gain and improved feed efficiency in broilers (indication to be withdrawn), feed Tylan at
  - Tylan 40 per ton of Type C Feed: 0.1 to 1.25 lbs.
  - Tylosin per ton of Type C Feed: 4 to 50 g
- Feed continuously as the sole ration
- 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
- Tylan requires a 5-day withdrawal period before slaughter when fed at 800 to 1,000 g/ton.

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

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.

Hygromix® directions for use

- For use as an aid in the control of parasite infections in chickens associated with *Ascaris galli*, *Heterakis gallinae* and *Capillaria obsignata*.
- Mix 1.0-1.5 lbs. Hygromix 8 per ton of Type C medicated feed for 8-12 g of hygromycin B per ton.
- Feeds containing Hygromix must be withdrawn 3 days prior to slaughter.

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

Pulmotil® directions for use for cattle

- **Feeds containing tilmicosin must be withdrawn 28 days prior to slaughter.**
- **CAUTION:** Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.
- **For the control of Bovine Respiratory Disease (BRD) 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/hd/d.

Pulmotil® directions for use for swine

- Feeds containing tilmicosin must be withdrawn 7 days prior to slaughter.
- **CAUTION:** Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.
- 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.

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.

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