




Veterinary Feed Directives (VFD's)

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Michigan Department of Agriculture & Rural Development

Veterinary Feed Directive (VFD)

- Enacted in 1996, Animal Drug Availability Act
- Serves as an alternative to prescription (Rx) feed
- Directs that feed containing VFD drug(s) may only be distributed to animal producers under a veterinarian's supervision and written order

- Prior to 2017, only four VFD drugs
  - Tilmicosin (Pulmitol, Tilmovet – swine, beef)
  - Florfenicol (Aquaflor and Nuflor – fish, swine)
  - Avilamycin (Kavault – swine, chicken)
  - Tylvalosin (Aivlosin – swine)

Veterinary Feed Directive (VFD)

- January 1, 2017 deadline
- FDA is moving to eliminate the use of certain drugs (i.e. antibiotics) for production purposes
- Bring remaining therapeutic uses under the supervision of a licensed veterinarian
  - Ensure these drugs are used judiciously and only when appropriate for specific animal health claims
- Part of FDA's overall strategy to ensure judicious use of medically important antimicrobials in food-producing animals

VFD language in MI Feed Law

Michigan Feed Law (P.A. 120 of 1975, as amended)

Sec. 8. A commercial feed or material …shall be considered to be adulterated if any of the following conditions exist:

> (r) It contains a drug defined as a veterinary feed directive in 21 CFR 558.3 and does not conform to the requirements of 21 CFR 558

Sec. 13. A person manufacturing or distributing commercial feed shall comply with all of the following:

> (b) The requirements in 21 CFR 558.6 for a veterinary feed directive drug as defined in 21 CFR 558.3.

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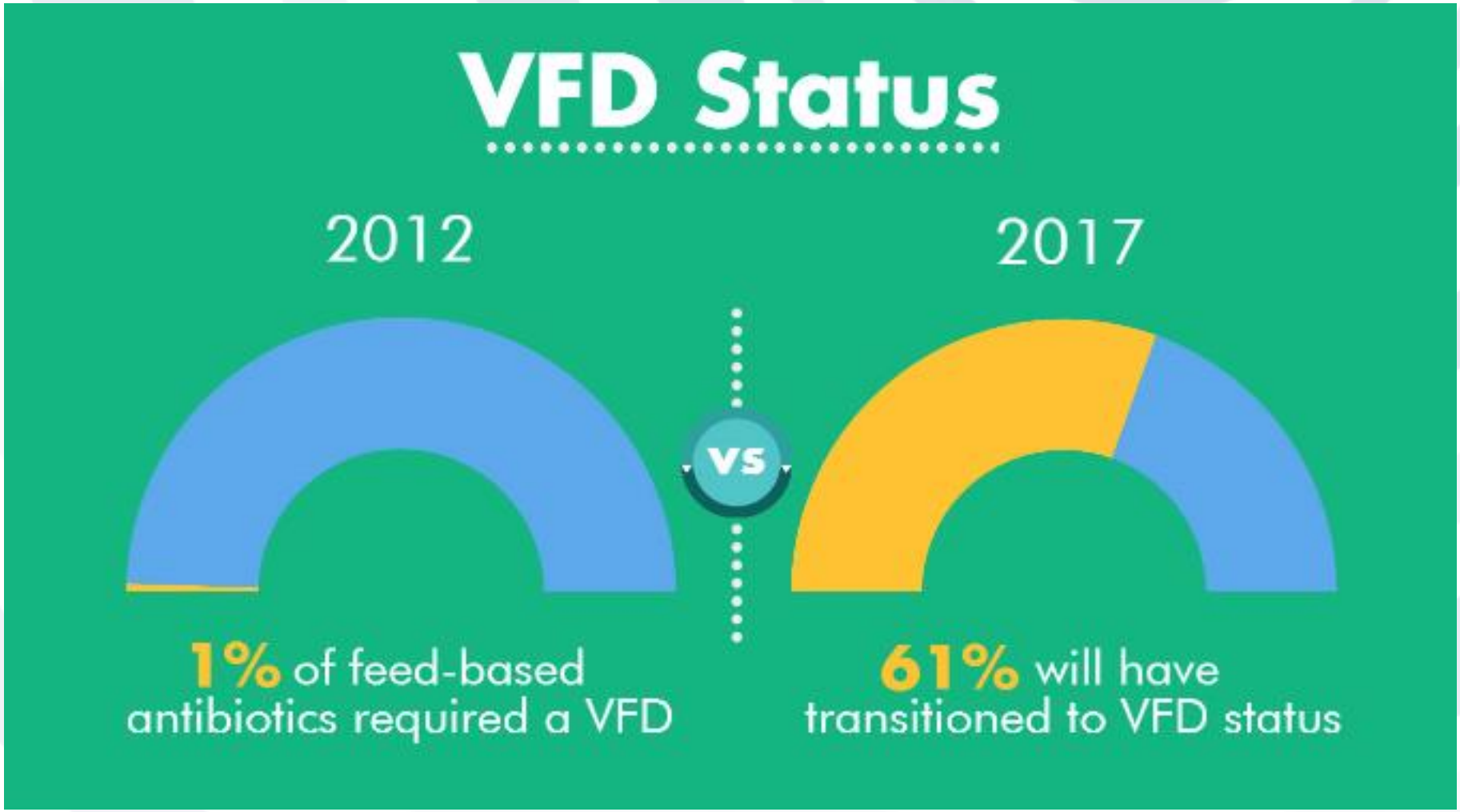
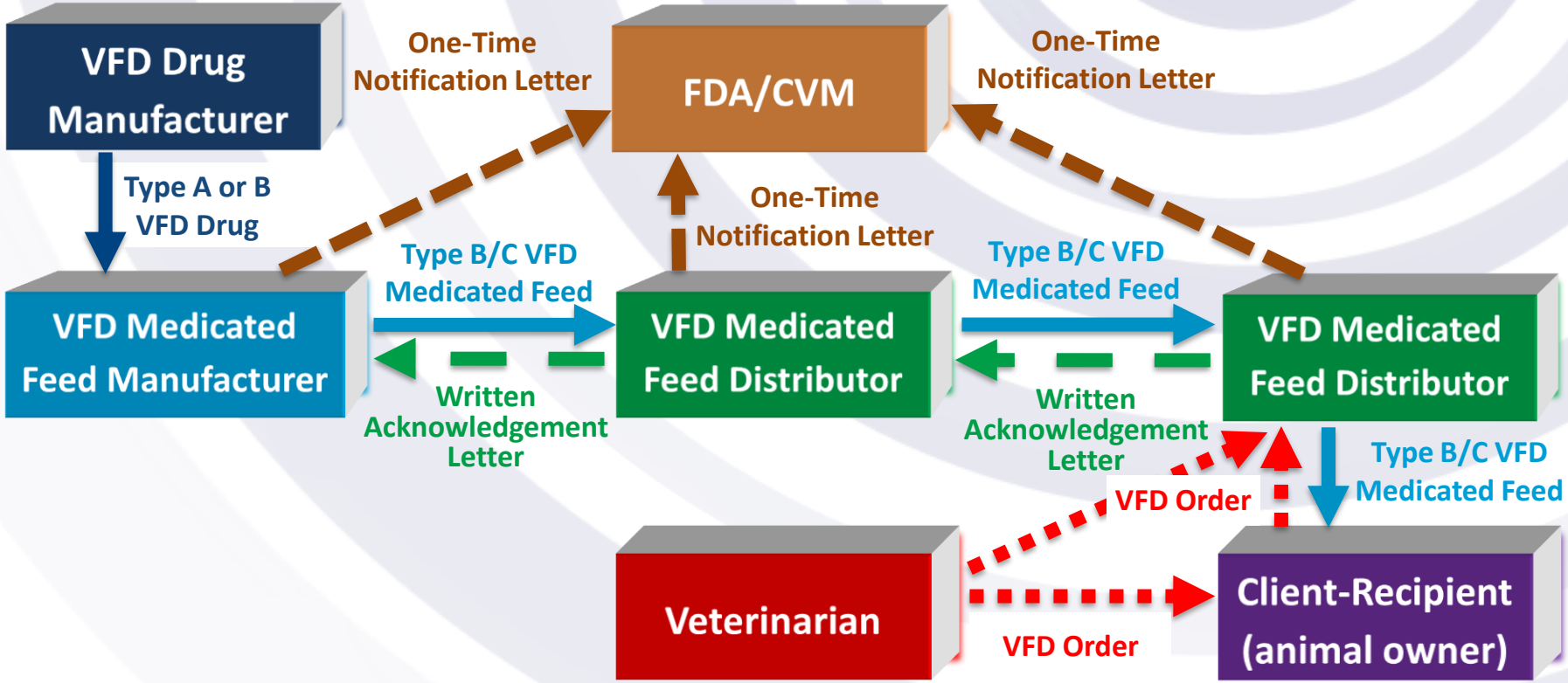
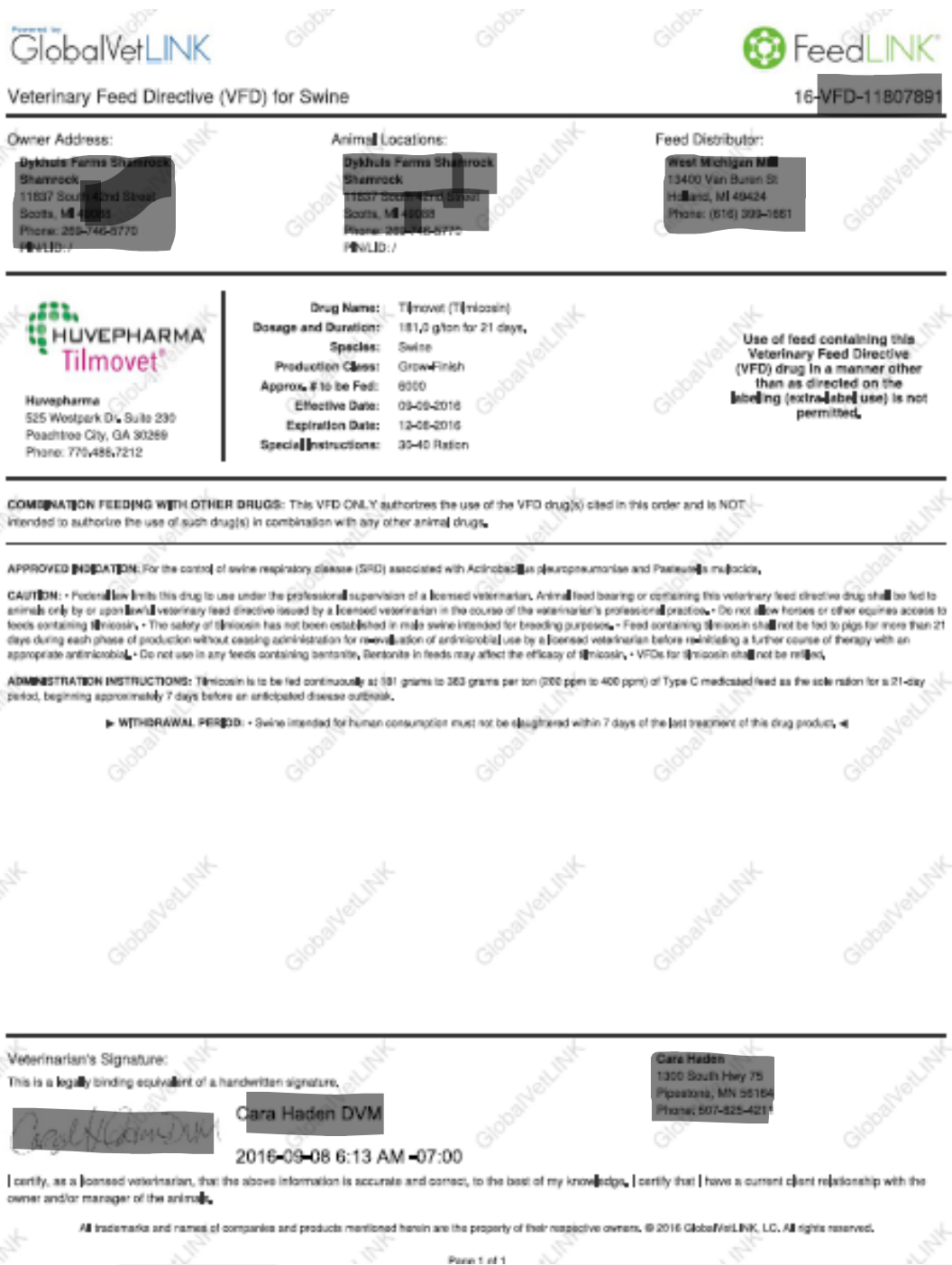


Example VFD Feed Distribution Schematic





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Veterinary Feed Directive (VFD) for Swine

16-VFD-11807891

Owner Address:

Dykhuis Farms Shamrock
Shamrock
11837 South 42nd Street
Scotts, MI 49088
Phone: 269-746-5770
PIN/LID: /

Animal Locations:

Dykhuis Farms Shamrock
Shamrock
11837 South 42nd Street
Scotts, MI 49088
Phone: 269-746-5770
PIN/LID: /

Feed Distributor:

West Michigan Mill
13400 Van Buren St
Holland, MI 49424
Phone: (616) 393-1651

HUVEPHARMA
Tilmovet®

Huvepharma
525 Westpark Dr. Suite 230
Peachtree City, GA 30269
Phone: 770.486.7212

Drug Name: Tilmovet (Tilmicosin)
Dosage and Duration: 181.0 g/ton for 21 days.
Species: Swine
Production Class: Grow-Finish
Approx. # to be Fed: 6000
Effective Date: 09-08-2016
Expiration Date: 12-06-2016
Special Instructions: 30-40 Ration

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

COMBINATION FEEDING WITH OTHER DRUGS: 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.

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

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. • 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 reevaluation of antimicrobial use by a licensed veterinarian before reinitiating 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. • VFDs for tilmicosin shall not be refilled.

ADMINISTRATION INSTRUCTIONS: 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.

► **WITHDRAWAL PERIOD:** • Swine intended for human consumption must not be slaughtered within 7 days of the last treatment of this drug product. ◄

Veterinarian's Signature:

This is a legally binding equivalent of a handwritten signature.

Cara Haden DVM

2016-09-08 6:13 AM -07:00

Cara Haden
1300 South Hwy 75
Pipestone, MN 56164
Phone: 507-825-4211

I certify, as a licensed veterinarian, that the above information is accurate and correct, to the best of my knowledge. I certify that I have a current client relationship with the owner and/or manager of the animals.

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Issues:

- Duration Of Use
- Refills
- Extra Label Use (Minor Species)

Compliance Data

Summary Assessment of Veterinary Feed Directive Compliance Activities Conducted in Fiscal Years 2016 – 2018

https://www.fda.gov/media/130382/download

Table 1: VFD Final Inspection Classification Summary

District Decision	Fiscal Year 2016	Fiscal Year 2017	Fiscal Year 2018	Total
No Action Indicated (NAI)	54	130	230	**414**
Voluntary Action Indicated (VAI)	3	0	38	**41**
Official Action Indicated (OAI)	0	0	1+	**1**
Total	57	130	269	**456**

+ Refer to the *Enforcement Strategy* below for details on enforcement action taken

Compliance Data

Summary Assessment of Veterinary Feed Directive Compliance Activities Conducted in Fiscal Years 2016 – 2018

https://www.fda.gov/media/130382/download

Finding	Fiscal Year 2016	Fiscal Year 2017	Fiscal Year 2018
Distributors who manufacture VFD feed: Labels and formulas matched the VFD reviewed	96.6% (28)	87.2% (34)	91.0% (304)

Table 6: Inspectional Findings: Caution Statement Requirement for VFD Feed Labels

Finding	Fiscal Year 2016	Fiscal Year 2017	Fiscal Year 2018
Distributor's VFD feed labels contained the VFD caution statement	89.3% (25)	74.4% (29)	77.2% (250)

Compliance Data

Table 9: Inspectional Findings: Specific Information to be Included on the VFD

Finding	Fiscal Year 2016	Fiscal Year 2017	Fiscal Year 2018
VFDs included the withdrawal time, special instructions, and/or cautionary statements	100% (75)	97.9% (182)	95.3% (653)

Table 10: Inspectional Findings: VFD Requirements for Clients (Animal Producers)

Finding	Fiscal Year 2016	Fiscal Year 2017	Fiscal Year 2018
Client did not feed VFD feed beyond the expiration date on the VFD	91.7% (11)	75% (15)	100% (9)
Client fed VFD feed to the animals authorized on the VFD (number, species, and/or production class)	100% (12)	90.0% (27)	100% (19)
Client fed VFD feed for the duration identified on the VFD	100% (12)	89.3% (25)	100% (18)
Client complied with the special instructions on the VFD	100% (8)	91.3% (21)	100% (15)

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Veterinary Feed Directive

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Basic information about the Veterinary Feed Directive:

Historically, the Food and Drug Administration (FDA), who regulates the use of medicine in animals, has allowed select antibiotics used in or on animal feeds to be available to producers over-the-counter and without the direct supervision of a licensed veterinarian. In 1999, the Animal Drug Availability Act (ADAA) of 1996 implemented a new category of drugs called veterinary feed directive (VFD). The VFD category is a part of the FDA's overall directive to ensure the judicious use of human medically important antibiotics. Recently, the VFD category was expanded to include medically important antibiotics fed to animals and is defined in FDA Guidance Document #213. The revised VFD policy puts into place important control factors that dictate the appropriate use of feed-grade antibiotics.

In the past they have allowed antibiotics to have label claims for therapeutic (prevention, control, treatment) reasons, growth promotant and feed efficiency. As a part of judicious use strategy, the FDA has aligned with drug sponsors to voluntarily revise label claims, removing growth promotant and feed efficiency. Since these products cannot be used extra-label, and the removal of label claims will discontinue their use for non-therapeutic purposes. This action will

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Questions?

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