



# Farm Scene

## The Veterinary Feed Directive (VFD) and Related Information for Livestock Producers

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The Animal Drug Availability Act of 1996 (ADAA) established a new category of drugs, veterinary feed directive (VFD) drugs. The revised Veterinary Feed Directive rule that goes into effect October 1, 2015 addresses the use of drugs in feeds for livestock. Current focus is on antimicrobials that are considered *medically-important* (human medicine applications).

### ***What does the VFD rule and associated guidance do?***

The VFD rule and associated FDA Guidance documents - *(1). ends the use of medically-important antimicrobials to enhance livestock performance,*

*(2). transitions many of the feed medications that are currently available "over-the-counter" into the VFD drug category,*

*(3). places the use of VFD animal drugs in or on animal feed under the professional supervision of a licensed veterinarian,*

*(4). requires producers to obtain written VFD orders from a licensed veterinarian to purchase and utilize the VFD antimicrobials on or in feed.*

### ***When does the VFD rule become effective?***

This rule becomes *effective October 1, 2015*. All changes associated with medically important antimicrobials that are now available over-the-counter must be implemented *by January 1, 2017*.

### ***What are VFD Drugs?***

VFD drugs are FDA-approved for use in animal feeds under veterinarian supervision and under written VFD orders. Current focus is on antimicrobials delivered in feeds that are deemed to be medically-important. This does not preclude a broadened approach in the future. The label for the additive, or the label for the medicated feed item containing the additives, must state whether the additive is a VFD drug or not.

As of September 2015 there are three VFD drugs - florfenicol (Nuflor - swine; Aquaflor - aquaculture), avilamycin (Kavault; swine), and tilmicosin (Pulmotil; swine, beef, dairy).

*By January 1, 2017, all medically-important antimicrobials intended for use in feed that are currently available "over-the-counter" will become VFD drugs.* Additives such as lasalocid (Bovatec-cattle, Avatec-poultry), monensin (Rumensin-cattle, Coban-poultry), bacitracin, bambarmycins (Flavomycin - swine, Gainpro - cattle), and amprolium are not "medically-important" and will not fall under the VFD unless they are used in combination with a VFD drug.

### ***Producers need written authorization from a licensed veterinarian***

Use of VFD drugs now falls under the supervision of licensed veterinarians. *Producers must receive signed and written (not verbal) authorization from a licensed veterinarian to purchase and utilize VFD antimicrobials on and in feed.* This authorization is referred to as a VFD Order.

The members of Texas A&M AgriLife will provide equal opportunities in programs and activities, education, and employment to all persons regardless of race, color, sex, religion, national origin, age, disability, genetic information, veteran status, sexual orientation or gender identity and will strive to achieve full and equal employment opportunity throughout Texas A&M AgriLife.

### ***An established Veterinarian-Client-Patient Relationship (VCPR) is required***

*To write the VFD order, the licensed veterinarian must have an established veterinarian-client-patient relationship (VCPR) with the producer. Based on the Texas Veterinary Licensing Act, a valid VCPR is present if:*

- (1).** The veterinarian assumes responsibility for medical judgments regarding the health of the livestock, and the client (the owner or caretaker of the livestock), agrees to follow the veterinarian's instructions.
- (2).** The veterinarian possesses *sufficient knowledge* of the livestock to initiate a general or preliminary diagnosis of the medical condition of the livestock. *Sufficient knowledge* exists if the veterinarian has recently seen, or is personally acquainted with, the keeping and care of the livestock as a result of (a) examining the animal, or (b) making medically appropriate and timely visits to the premises where the livestock are kept. A veterinarian-client-patient relationship *may not* be established solely by telephone or electronic means.
- (3).** The veterinarian is readily available to provide follow-up medical care in the event of an adverse reaction, or failure of the regimen of therapy.

### ***Steps to obtain a VFD Order***

- (1).** Contact your veterinarian with whom you have a valid VCPR. If a producer does not have a valid VCPR with an appropriate veterinarian, then the preliminary step is to establish a VCPR.
- (2).** The veterinarian determines whether conditions warrant use of a VFD drug or feed.
- (3).** If warranted, the veterinarian issues a written and signed VFD order containing information specified by regulations. Verbal orders are not allowed but electronic orders are acceptable. Incomplete and unsigned orders are invalid and cannot be filled.
- (4).** The veterinarian retains a copy of the VFD order and gives the completed, signed original and a copy to the client.
- (5).** The client keeps the copy and gives the original signed VFD to the feed mill/feed distributor supplying the VFD feed. The VFD order allows the feed to be released to the client.
- (6).** Depending on the specific VFD drug, and the conditions outlined by the veterinarian, separate VFD orders may be required for different groups of livestock and, new VFD orders may be required to extend the treatment duration (depends on "refill" specifications).

### ***Information required on a lawful VFD order***

Veterinarian's name, address, and telephone number

Client's name, business or home address, and telephone number

Premises where the livestock specified in the VFD are located

Date the VFD was issued

Expiration date of the VFD (this is the date the VFD is no longer valid and use of the VFD feed is illegal)

Name of the VFD drug(s) in the order

Species and production class of livestock to receive the VFD feed

Approximate number of livestock to receive the VFD feed by the expiration date

Health indication for which the VFD was issued

Concentration of VFD drug in the feed Duration of use (length of time the livestock will receive the treatment)

Withdrawal time, special instructions, and cautionary statements necessary for use of the drug to conform with the approval

Number of reorders (refills) authorized, if permitted

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";

Veterinarian's electronic or written signature

### ***Optional information on the VFD order***

More specific description of the location (i.e. pen, barn, pasture or other)

Approximate age range of the animals

Approximate weight range of the animals Any other information the veterinarian deems appropriate to identify the animals involved

### ***Basic Producer Responsibilities***

Establish a VCPR with an appropriate veterinarian.

Contact your veterinarian for consultation and guidance.

Follow your veterinarian's recommendations. Administer the VFD medicated feed according to the directions on the VFD order.

Keep copies of your VFD orders for at least two years.

Provide your VFD order copies for FDA inspectors to copy and review, if requested.

## **Drugs Transitioning from Over-the-counter (OTC) to Veterinary Feed Directive (VFD) Status**

Upon completion of their voluntary transition from OTC to VFD, **all** feed uses of the following drugs, alone **and** in a combination, will require a VFD as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the drug application:

### ***Drugs Transitioning From OTC to VFD Status***

<b>Established drug name</b>	<b>Examples of proprietary drug names(s)<sup>§</sup></b>
chlortetracycline (CTC)	Aureomycin, CLTC, CTC, Chloratet, Chlorachel, ChlorMax, Chlortetracycline, Deracin, Inchlor, Pennchlor, Pfichlor
chlortetracycline/sulfamethazine*	Aureo S, Aureomix S, Pennchlor S
chlortetracycline/sulfamethazine/penicillin*	Aureomix 500, Chlorachel/Pfichlor SP, Pennchlor SP, ChlorMax SP
hygromycin B	Hygromix
lincomycin	Lincormix
oxytetracycline (OTC)	TM, OXTC, Oxytetracycline, Pennox, Terramycin
oxytetracycline/neomycin*	Neo-Oxy, Neo-Terramycin
penicillin*	Penicillin, Penicillin G Procaine
slfadimethoxine/ormetoprim*	Rofenaid, Romet
tylosin	Tylan, Tylosin, Tylovet
tylsoin'sulfamethazine*	Tylan Sulfa G, Tylan Plus Sulfa G, Tylosin Plus Sulfamethazine
virginiamycin	Stafac, Virginiamycin, V-Max

**NOTE:** apramycin, erythromycin, neomycin (alone), oleandomycin<sup>+</sup>, sulfamerazine, and sulfaquinoxaline are also approved for use in feed and are expected to transition to VFD status, but are not marketed at this time. If they return to the market after January 1, 2017, they will require a VFD.

<sup>§</sup>Type A medicated articles used to manufacture medicated feed, all products may not be marketed at this time.

\*Fixed-ratio, combination drug

+Currently only approved for production uses

### ***Current VFD Drugs***

<b>Established drug name</b>	<b>Proprietary drug name(s)s</b>
Avilamycin	Kavault
Florfenicol	Aquaflor, Nuflor
Tilmicosin	Pulmotil, Tilmove

§Type A medicated articles used to manufacture medicated feed

This information is up-to-date as of January 19, 2016. As the industry transitions, CVM anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates;

<http://www.fda.gov/Animal/Veterinary/DevelopmentApprovalProcess/ucm071807.htm>

## **Drugs Transitioning from Over-the-Counter (OTC) to Prescription (Rx) Status**

Upon completion of their voluntary transition from OTC to Rx, all uses of the following drugs will require a prescription from a veterinarian as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the drug application:

### ***Water Soluble Drugs Transitioning From OTC to Rx Status***

<b>Established drug name</b>	<b>Examples of proprietary drug name(s)</b>
Chlortetracycline	Aureomycin, Aureomycin, Chlora-Cycline, Chloronex, chlortetracycline, Chlortetracycline Bisulfate, Chlortet-Soluble-O, CTC, Fermycin, Pennchlor
Erythromycin	Gallimycin
Gentamicin	Garacin, Gen-Gard, GentaMed, Fentocin, Gentoral
Lincomycin	Linco, Lincomed, Lincomix, Lincomycin, Lincomycin Hydrochloride, Lincosol, Linxmed-SP
Lincomycin/spectinomycin*	Lincomycin S, Lincomycin-Spectinomycin, L-S, SpecLinx
Neomycin	Biosol Liquid, Neo, Neomed, Neomix, Neomycin, Neomycin Liquid, Neomycin Sulfate, Neo-Sol, Neosol, Neosol-Oral, Neovet
Oxytetracycline	Agrimycin, Citratet, Medamycin, Oxymarine, Oxymycin, Oxy-Sol, Oxytet, Oxytetracycline, Oxytetracycline HCL, Oxy WS, Pennox, Terramycin, Terra-Vet, Travet-CA, Tetroxy, Tetroxy Aquatic, Tetroxy HCA
Penicillin	Han-Pen, Penaque Col-G, Penicillin G Potassium, R-Pen, Solu-Pen
Spectinomycin	Spectam
Sulfadimethoxine	Agribon, Albon, Di-Methox, SDM, Sulfabiotic, Sulfadimethoxine, Sulfadived, Sulfamed-G, Sulforal, Sulfasol
Sulfamethazine	SMZ-Med, Sulfa, Sulmet
Sulfaquinoxaline	S.Q. Solution, Sulfa-Nox, Sulfaquinoxaline Sodium, Sulfaquinoxaline Solubilized, Sul-Q-Nox, Sulquin
Tetracycline	Duramycin, Polyotic, Solu/Tet, Solu-Tet, Supercycline, Terra-Vet, Tet, Tetra-Bac, Tetracycline, Tetracycline Hydrochloride, Tetramed,

NOTE: apramycin, carbomycin/oxytetracycline\*, chlortetracycline/sulfamethazine\*, streptomycin, sulfachloropyrazine, sulfachlorpyridazine, and sulfamerazine/sulfamethazine/sulfaquinoxaline\* are expected to transition to Rx status, but are not marketed at this time. If they return to the market after January 1, 2017, they will require a prescription from a veterinarian.

\*Fixed-ratio, combination drug

### ***Current Rx Water Soluble Drugs***

Established drug name	Examples of proprietary drug names
Tylosin	Tylan, Tylomed, Tylosin Tartrate, Tylovet

This information is up-to date as of January 19, 2016. As the industry transitions, CVM anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates:

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm>.