TEXAS A&M AGRILIFE EXTENSION

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 - florfenical (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, bambermycins (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.

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

Information required on a lawful VFD order (cont'd)
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 (extralabel 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

Established drug name	Examples of proprietary drug name(s)[$]
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/Pficlor SP, Pennchlor SP, ChlorMax SP
hygromycin B	Hygromix
lincomycin	Lincomix
oxytetracycline (OTC)	TM, OXTC, Oxytetracycline, Pennox, Terramycin
oxytetracycline/neomycin*	Neo-Oxy, Neo-Terramycin
penicillin[+]	Penicillin, Penicillin G Procaine
sulfadimethoxine/ormetoprim*	Rofenaid, Romet
tylosin	Tylan, Tylosin, Tylovet
tylosin/sulfamethazine*	Tylan Sulfa G, Tylan Plus Sulfa G, Tylosin Plus Sulfamethazine
virginiamycin	Stafac, Virginiamycin, V-Max

Note: apramycin, erythromycin, neomycin (alone), oleandomycin[+], 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.

[$]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

Established drug name	Proprietary drug name(s)[$]
avilamycin	Kavault
florfenicol	Aquaflor, Nuflor
tilmicosin	Pulmotil, Tilmovet

[$]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/AnimalVeterinary/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

Established drug name	Examples of proprietary drug name(s)
chlortetracycline	Aureomycin, Aureomycyn, Chlora-Cycline, Chloronex, Chlortetracycline, Chlortetracycline Bisulfate, Chlortet-Soluble-O, CTC, Fermycin, Pennchlor
erythromycin	Gallimycin
gentamicin	Garacin, Gen-Gard, GentaMed, Gentocin, 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, Tetravet-CA, Tetroxy, Tetroxy Aquatic, Tetroxy HCA
penicillin	Han-Pen, Penaqua Sol-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, Tetra-Sal, Tetrasol, Tet-Sol, TC Vet

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, 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

Veterinary Feed Directive (VFD)
Preparedness Checklist for Producers

The implementation of Guidance for Industry 209/213 will require **increased communication among producers, veterinarians and feed mills.** Please reach out to those who are involved with your business to ensure they are prepared to help you with the implementation of these requirements.

FULL VALUE BEEF™

	YES	NO
1. Do you have a herd veterinarian?	☐	☐
2. Does your veterinarian have a valid Veterinary Client Patient Relationship (as defined by the AVMA) for the state where your cattle are located?	☐	☐
3. Have you met with your veterinarian to review all animal health management protocols, herd vaccination protocols and medications currently being used in your system?	☐	☐
4. Do you know which feed and water medications used in your system will require a VFD, prescription or remain over the counter (OTC) come January 1, 2017?	☐	☐
5. Do you have a plan in place to handle expiration dates on VFDs?	☐	☐
6. Have you identified a location to store copies of all VFDs that are written for your animals?	☐	☐
7. If you are utilizing an electronic VFD platform, have you worked with your electronic VFD provider and veterinarian to upload all of your production sites into their system?	☐	☐
8. Have you identified your potential feed milling locations and communicated this information to your veterinarian?	☐	☐
9. Do you have a plan in place to notify your feed mills of the quantity of feed needed to fulfill the VFD?	☐	☐
10. Do you have a plan in place to handle feed containing VFD medication that is left in a feed bin after a VFD expires?	☐	☐
11. Do you manufacture your own feed, manufacture feed for other clients, floor stock VFD medications or sell VFD medications (bagged Type C feed or VFD medications)?	☐	☐
12. If yes to Question 11, have you submitted an Intent to Distribute VFD feeds form to the FDA so you may sell feeds which require a VFD?	☐	☐
13. If yes to Question 11, do you have an Acknowledgment of Distribution form on file for all feed mill locations with all distributors you purchase medications from that will require a VFD?	☐	☐
14. If yes to question 11, do you have a Medicated Feed Mill License (MFML) to manufacture Category II VFD feeds?	☐	☐
15. If no to Question 14, do you have a process in place to identify which medications are appropriate for inventory in your feed mill?	☐	☐

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