

Over the past several years, the FDA has taken important steps toward fundamental change in how medically important antibiotics can be legally used in feed or water for food-producing animals. The (Veterinary Feed Directive) VFD final rule outlines the process for authorizing use of VFD drugs (animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian) and provides veterinarians in all states with a framework for authorizing the use of medically important antimicrobials in feed when needed for specific animal health purposes.

It is very important for Veterinarians working with food-producing animals to be aware of the VFD. For specific information please refer to the USDA's website which provides information at: <u>http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm</u>

Article dealing with the impact of the VFD

What is a Veterinary Client Patient Relationship?

North Carolina General Statute <u>90-181(7a)</u> defines the Veterinary Client Patient Relationship (VCPR) as follows:

a. The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instruction of the veterinarian.

b. There is sufficient knowledge of the animal by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal. This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal, or by medically appropriate and timely visits to the premises where the animal is kept.

c. The practicing veterinarian is readily available or provides for follow-up in case of adverse reactions or failure of the regimen of therapy.

For additional information on the VFD, please see the material below.

Drugs Transitioning from Over-the-Counter (OTC) to Veterinary Feed Directive (VFD) Status

Upon completion of their voluntary transition from OTC to VFD, <u>all</u> feed uses of the following drugs, alone <u>and</u> 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:

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

Drugs Transitioning From OTC to VFD Status

<u>Note:</u> 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
tylvalosin	Aivlosin

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

Upon completion of their voluntary transition from OTC to Rx, <u>all</u> 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:

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

Water SolubleDrugs TransitioningFrom OTC to RxStatus

<u>Note:</u> 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

CurrentRx Water SolubleDrugs

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