Antibiotic Use and the Veterinary Feed Directive

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We enjoy one of the safest and most affordable food supplies in the world thanks to years of hard work by many – farmers, ranchers, veterinarians, processors, packers, distributors, government agencies, and others. So that we can continue this privilege, it is our responsibility as cattle producers to understand and follow the laws and be prepared to meet the new and changing standards set in the years to come.

The US Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) specifically regulates drugs, feeds, and devices used in livestock such as cattle, sheep, goats, pigs, and poultry because they are used in animals that will enter the human food supply. It's that simple. Animal drugs are available as either over-the-counter (OTC), prescription (Rx), or through a veterinary feed directive (VFD). For prescriptions and VFD's, veterinarians are responsible for authorizing the proper medications, in a legal manner, only to those animals who truly need them. In turn, producers are responsible for the proper use and administration, according to drug label, and documentation of all prescription and VFD medications used in their animals.

Dispensing, prescribing, or authorizing a prescription or VFD product requires a valid veterinary-client-patient relationship (VCPR). *It is illegal for a veterinarian to dispense or write a prescription or VFD for an animal/herd they have not seen or are unfamiliar with.* A VCPR is important for both veterinarians and livestock producers because it communicates a type of "agreement" between parties on the responsibility and care for the animals. A VCPR exists when all of the following conditions are met (Title 21, Code of Federal Regulations, Part 530 or 21 CFR 530):

- The veterinarian has assumed responsibility for making clinical judgments regarding the health of the animal/herd and the need for medical treatment AND the client has agreed to follow his/her directions.
- There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s).
- The veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

Drugs used in food animals must be used according to their labelled directions, unless the veterinarian feels that an extra-label drug use (ELDU) is indicated. The FDA allows ELDU only under the context of an established VCPR, and only with products that are not prohibited for ELDU. Rules regarding ELDU apply to both OTC and prescription products. This is an area that is often misunderstood: *Both OTC and prescription products require veterinary oversight when used off-label.* In other words, just because you can purchase a product without a

prescription, doesn't mean you can use it any way you'd like. Withdrawal times for any product used off-label as well as per label must be provided by the veterinarian. Extra-label use of any medicated feed off-label is strictly prohibited, and has been for many years.

Changes in medicated feed laws: the Veterinary Feed Directive

Medicated feeds are currently available either OTC or by VFD. VFD's are a classification of drug defined in 1996 under the Animal Drug Availability Act that allows administration of certain "medically important" drugs in or on animal feeds. A VFD is "a written (non-verbal) statement issued by a licensed veterinarian in the course of the veterinarians' professional practice that orders the use of a VFD drug or combination VFD drug in or on animal feed."

Medicated feeds have gained a lot of attention over the past few years over concern of the potential development of antimicrobial resistance in animal and human populations. As a response to these concerns, the use of medications considered "medically important" in human medicine will be restricted in the near future to therapeutic uses only, those therapeutic and preventive uses deemed necessary for the health of the animals, under the oversight of a veterinarian. This removes the growth promotion, feed efficiency, and milk production uses from the labels of all currently approved products. Furthermore, after Jan. 1, 2017, any listed "medically important" antibiotics currently available in the feed for animals will require a VFD (Table 1). In addition, medically important antimicrobials currently available to be used in the water will require a veterinary prescription.

The changes in drug laws are undoubtedly going to cause some confusion as well as some inconvenience in the months to come. Now is the time to discuss the drug laws as well as the upcoming changes with your herd veterinarian and review medications that you currently use. Evaluate your herd health record-keeping practices since new rules will require additional recordkeeping and documentation. If you use medications in feed, understand the VFD process so that future implementation will be smooth. Most importantly, if you don't have a herd veterinarian, now is the time to establish a good veterinary-client-patient relationship. Here in the US, we want to continue to enjoy one of the safest and most affordable food supplies in the world. It's our job to ensure consumer confidence and continue to provide safe and wholesome products by the way we manage our cattle.

Next month we'll examine the VFD process further. For the most current information on drug laws or veterinary feed directives, contact your herd veterinarian or visit the FDA's website at: http://www.fda.gov/animalveterinary/developmentapprovalprocess/ucm071807.htm.

Table 1: Drugs Transitioning from OTC to VFD Status after Jan. 1, 2017*	
Drug Name	**Examples of proprietary drug names**
chlortetracycline	Aureomycin, CTC, CTC. Cloratet, ChlorMax, Chlortetracycline, Pennchlor, Deracin
chlortetracycline/sulfamethazine	Aureo S, Aureomix S, Pennchlor S
chlortetracycline/sulfamethazine/penicillin	Aureomix 500, Pennchlor 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
virginiamycin	Stafac, Virginiamycin, V-max
*Additional drugs may be approved but are not currently marketed for livestock.	
Adapted from FDA CVM. Most current list of VFD drugs can be found at: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482107.htm	