Drugs, the Law, and You

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I recently finished reading Upton Sinclair's "The Jungle," a 1906 novel that had been credited by many as starting the food safety movement in the US. One of the striking features of the story was the lack of transparency and oversight of the food industry in the early 1900's. While some may argue that certain aspects of government oversight are unwelcome in our industry, it is clear that public health has benefitted from many of the food safety laws since put in place to protect the consumer.

Here in the US, we enjoy one of the safest and most affordable food supplies in the world. Why is this so? It's actually a combination of both governmental and private factors. In addition to food safety regulations, programs such as the Beef Quality Assurance (BQA) program were developed by the beef industry in collaboration with the USDA Food Safety Inspection Service (FSIS) to provide cattlemen with important tools for avoiding additional government control. One critical component of the BQA program is compliance with regulations set forth by another agency, the US Food and Drug Administration (FDA).

The FDA is responsible for protecting public health by assuring the safety, efficacy, and security of human and animal drugs, biological products, and the food supply, among other things. The FDA Center for Veterinary Medicine (CVM) specifically regulates animal drugs, animal feeds, and animal devices. Animal drugs are available as either over-the-counter (OTC), prescription, or through a veterinary feed directive (VFD). VFD's are a classification of drug defined in 1996 under the Animal Drug Availability Act that allow administration of prescription drugs through feeds. The use of the VFD drug is permitted only under the professional supervision of a licensed veterinarian. Tilmicosin used in the feed for cattle respiratory disease is one example.

All medications (drugs) for cattle are regulated by the FDA because they are used in animals that will enter the human food supply. It's that simple. For prescriptions and VFD's, veterinarians, like physicians, are responsible for prescribing the proper medications, in a legal manner, only to those who truly need them. In turn, producers are responsible for the proper use and administration, according to drug label, and documentation of all prescription medications used in their animals.

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

- The veterinarian has assumed responsibility for making clinical judgments regarding the health of the animal/herd AND the client has agreed to follow his/her directions.

- The veterinarian has sufficient knowledge of the animal/herd to initiate a general or preliminary diagnosis of the medical condition involved. This means that the veterinarian is personally acquainted with the keeping and care of the animal/herd by virtue of timely examinations or herd visits.
- The veterinarian is readily available for follow-up evaluation, or has arranged for veterinary emergency coverage, continued care, or treatment of the animal/herd in question.
- The veterinarian provides oversight of treatment, compliance, and outcome, and maintains patient records.

The FDA allows extra-label drug use (ELDU) only under the context of an established VCPR. Extra-label use of any medicated feed off-label is strictly prohibited. No one, including your herd veterinarian, can legally prescribe the use of any feed additive other than what is on the label.

The hot topic around most co-ops and feed stores lately has been medicated feeds. Medicated feeds are currently available either OTC or by VFD. Medicated feeds have gained a lot of attention over the past few years over concern over the development of antimicrobial resistance in animal and human populations. It has been proposed that the use of medications considered "medically important" in human medicine be restricted in veterinary medicine. Under the FDA Guidance for Industry (GFI) 213, companies that supply feed medications will be voluntarily changing their labels so that any listed "medically important" antibiotics available in the feed or water for animals will require a VFD or veterinary prescription, including medicated feeds such as medicated milk replacers and chlortetracyclines. The FDA's new antibiotic policies are to be fully implemented by December 2016.

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. As cattle producers, it is our responsibility to follow the laws and be prepared to meet the new standards set in the years to come. Discuss these changes with your herd veterinarian and review medications that you currently use. Evaluate your herd health record-keeping practices now since new rules will require additional recordkeeping and documentation. Understand the VFD process so that future implementation will be smooth. If you don't have a herd veterinarian, now is the time to establish a good veterinary-client-patient relationship.

For the most current information on drug laws or veterinary feed directives, contact your herd veterinarian or visit:
http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm#listing

Many currently available medicated feed products will require a veterinary prescription, or VFD, in the future. Changes to FDA regulations involving feed medications are expected to be fully implemented by December 2016.