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New Regulations Will Impact Animal Antibiotic Use and the Role of Veterinarians

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Overview

The Food and Drug Administration has revised existing regulations involving the animal use of antibiotics that are also provided to humans (*See 21 C.F.R. Part 558*). The new rules have arisen out of a belief of bacterial resistance in humans to antibiotics even though there is no scientific proof that antibiotic resistant bacterial infections in humans are related to antibiotic use in livestock. As a result, at the beginning of 2017, veterinarians will be required to provide a “directive” to livestock owners seeking to use or obtain animal feed products containing medically important antimicrobials as additives. A “directive” is the functional equivalent of receiving a veterinarian’s prescription to use antibiotics that are injected in animals.

The Veterinary Feed Directive (VFD) Rule

In 2003, the FDA defined “medically significant” antibiotics and assigned active ingredients to classes. Several years later, the FDA established rules governing the “judicious use of antibiotics” which eliminated the use of certain antibiotics in feed to promote animal growth and gave veterinarians oversight over them. The FDA also moved to allow usage of water soluble powders containing antibiotics by prescription only. More specifically, in late 2013, the FDA called on animal drug manufacturers of “approved medically important antimicrobials” that are put into water or feed of food-producing animals to voluntarily stop claiming on product labels that these products can enhance animal growth and increase feed efficiency. The FDA also requested the manufacturers to change how they labeled their products for other uses to require veterinary oversight of such drugs when they are used for therapeutic purposes.

Antibiotics that are covered by the VFD rule include Neomycin and Terramycin, drugs that are commonly used to treat diarrhea in calves (commonly known as calf scours). Other covered drugs include Tylosin (used to treat colitis in small animals, as well as acute mastitis in cattle and mastitis in sheep and goats, and infectious arthritis in swine), Chlortetracycline (used to treat conjunctivitis in cats), Oxytetracycline (used to treat breathing disorders in livestock, and generally prevent disease and infections in livestock and poultry) and Virginiamycin (used to

prevent and treat infections in livestock, and in the fuel ethanol industry to prevent microbial contamination).

VFD Protocols

In the summer of 2015, the EPA promulgated the VFD final rule. Under the rule, which will be fully effective January 1, 2017, obtaining feed containing a covered antibiotic will require a prescription. The prescription (a VFD form) must be obtained either in-person, via email or fax, from a veterinarian licensed to practice in the particular state. In addition, mixing of antibiotics will not be allowed in any product and extra label of feed additive antibiotics will remain be prohibited.

A prescription (VFD form) is valid for up to six months, and VFD records must be maintained for at least two years by the veterinarian, feed supplier, and the user. Farmers that mix feed and supply it to another party can only do so after obtaining a distributor's license and completing all necessary forms. In addition, other requirements might apply. A VFD form can only be approved if there is a valid veterinarian-client relationship (as defined by state law) with the livestock producer.

Note: In most states, a veterinary/client/patient relationship involves the veterinarian assuming the responsibility for the clinical judgments about a livestock herd's health, and the veterinarian having sufficient knowledge about the herd by examination or on-site visits, and follow-up evaluation or animal care.

In addition, the permit must identify the feed mill or other source of the medicated feed and the animals (by group or individually) that receive the feed, and must contain specific information concerning the animals being treated and the farm(s) on which they are located. The VFD form must also list the antibiotics authorized to be used under the prescription (form), any applicable feeding rates and treatment duration.

The protocols basically mean that the companies producing feed medications will be barred from selling medications that are labeled only for growth promotion. Thus, any covered antibiotic that is contained in feed for growth promotion purposes will no longer be commercially available. In addition, as noted above, covered antibiotics will require a VFD form (a veterinarian's prescription) for usage. Thus, beginning in 2017, farmers will have to work more closely with a veterinarian to medicate their animals with covered antibiotics.

Conclusion

The VFD rule increases the regulation of raising livestock on U.S. farms and ranches. While there has been a lot of social media (and "fast-food" restaurant) attention to the use of antibiotics in livestock production, there still remains no solid scientific proof that the use of antibiotics in animals creates any human resistance to that same antibiotic. In any event, producers, feed supplies and veterinarians will have to conform to the new rules when they are fully implemented on January 1, 2017.

For a full discussion of the VFD rule in Q and A format see the HHS document at this link: <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052660.pdf>