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NEW REGULATIONS FOR ANIMAL DRUGS

Earlier this year we discussed new changes in the animal drug use regulations. One of these changes, AMDUCA (Animal Medicinal Drug Usage Clarification Act) is a federal law enforced by the FDA (Food & Drug Administration); the other is AB 611 (Assembly Bill 611) which is a new California statute. For the past year, the regulations regarding these bills were being written and will soon be implemented. Many producers have questions regarding the effect on day-to-day operations and I will attempt to answer some of the common questions in this month's column.

What is an Over the Counter (OTC) Drug?

An OTC is a drug that any producer can purchase "over the counter". It must be used according to the label. The label will specify the species of animal, the medical condition (pneumonia, foot rot, etc.), the dose, the route of administration (intramuscular, subcutaneous, oral, etc.), the withdrawal time (time from last treatment to sale or slaughter), and perhaps other information. The label on the OTC drug is a legal document and it outlines the legal use of this drug. If the species you use the drug on is different from that which is on the label, you are now using the drug in an "extralabel use" manner. Also, if the dose, route of administration, medical condition, or any other label specification is changed, this is also an "extralabel use."

What are the changes for OTC Drugs?

There will **not** be any changes for OTC drugs; however, the label dose, species, indications for use, and withdrawal times must all be followed. A prescription is **not** needed for OTC drugs used strictly according to the label.

When do I need a prescription from my veterinarian?

You are required to have a prescription from your veterinarian when you use an OTC drug in an extralabel manner, when your veterinarian dispenses a legend drug to you, and/or when a legend drug is used in an extralabel manner.

What changes does AB 611 bring about?

This California regulation will help "streamline" the distribution of drugs for use in cattle that need a veterinarian's prescription. AB 611 creates Veterinary Food Animal Drug Retailers (VFADR's). These trained and licensed retailers will be able to affix the prescription label(s) from your veterinarian onto the drug vial(s) or container(s). Now you will have three options for obtaining prescription drugs: (1) from your veterinarian, (2) from a pharmacist-via a prescription from your veterinarian, and (3) from a VFADR-via a prescription from your veterinarian.

What about drugs I order from out-of-state mail order suppliers?

For OTC drugs there will be no changes. For prescription drugs (or OTC drugs to be used in an extralabel manner) your veterinarian will need to work with you to assure appropriate labeling.

Why do I need a veterinarian's prescription?

For OTC drugs used according to label, you don't! For extralabel use, a prescription is required to ensure the quality and safety of the beef that is produced. Use of some drugs in an extralabel manner can cause violative residues in the carcass for as much as a year after the drug was given. A veterinarian's label must contain information for extended withdrawal times as well as information about dosage, route of administration, species, indicated conditions or diseases, and precautions for the use of that drug. Additionally, the veterinarian writing the prescription must be familiar with your operation and your cattle. That is to say, there must be a valid veterinarian-client-patient relationship. You can't just have your cousin, who is a veterinarian in Nebraska, write a prescription.

What other requirements will be necessary?

One of the important items for prescriptions will be record keeping by your veterinarian and by your operation. Records on the use of extralabel drugs and prescriptions will be particularly important if residue violations are traced back to your operation.

What should I do?

Sit down and visit with your veterinarian and formulate a plan regarding these new drug regulations. Discuss treatment plans that might include extralabel use of drugs. Discuss the possible need for inventory records and treatment records for extralabel drug use. This whole area is complicated and will take some getting used to by all concerned.

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