UCD VET VIEWS
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AMDUCA

In 1996 Congress passed laws which will affect livestock producers, veterinarians, and the animals they care for. The most significant of these is the Animal Medicinal Use Clarification Act (AMDUCA). The Food and Drug Administration (FDA) is publishing rules that will regulate the AMDUCA and these rules will govern the use of drugs in food producing animals such as beef cattle.

Over the Counter (OTC) drugs used according to label directions will not be affected by the new regulations. However, drugs used in an extralabel manner will be affected. The important elements regarding these regulations are (1) a valid veterinarian/client/patient relationship, (2) a prescription from your veterinarian which will be the legal document regarding the extralabel use, and (3) records of extralabel drug usage.

The label for an OTC drug used for cattle is a legal document and contains several pieces of information regarding the approved use of that drug. This label information includes the following:

Species approved (cattle, swine, lactating cattle, etc.)
Disease or condition (disease(s) for which the drug is approved)
Dosage (amount of drug to be used)
Frequency (number of times to treat, i.e., once per day, three times per day, etc.)
Route(s) of administration (oral, intramuscular, subcutaneously, etc.)
Withdrawal time (time from last treatment until the animal can be slaughtered)
Precaution or warnings (for possible adverse reactions)

The OTC use of a drug requires that these label directions be followed as written. If the OTC drug is used in a manner that differs in any way from the label, the use is termed extralabel. Additionally, if a drug not approved for cattle is appropriate for use (as determined by your veterinarian), that use is also extralabel. Any extralabel use is subject to all the AMDUCA regulations.

One of the first criteria for extralabel drug use is a valid veterinarian/client/patient relationship. In this instance, a veterinarian has assumed responsibility for making medical judgments about animal health and the need for medical treatment and the client (owner or caretaker) has agreed to follow the veterinarian's instructions. The veterinarian must have sufficient knowledge of the animal(s) to diagnose the disease or condition for which the extralabel drug use is intended. The veterinarian must be readily available for follow-up in case of adverse drug reactions or failure of the treatment regimen. This provision of the rules defines the basic veterinarian/client/patient relationship that has existed for decades. It does not include more casual relationships, however. For example, it would not be valid to phone your cousin, who is a small animal veterinarian in Iowa and visited your ranch ten years ago, to obtain extralabel drug information or a prescription for extralabel drug use.

Extralabel drug use requires a prescription from your veterinarian. This prescription must be attached to the drug container, whether it is an antibiotic bottle, or a box of pills. The prescription label should contain the following information:

Name and address of the prescribing veterinarian
Established name of the drug(s) and its active ingredient
Directions for use specified by the prescribing veterinarian
such as dosage, frequency, duration, & route of administration
Any cautionary statements
Withdrawal time specified by the prescribing veterinarian

The withdrawal time for drugs used in an extralabel manner is particularly important for food animals such as cattle. The University of California-Davis maintains one of three data banks in the U.S. on withdrawal times and other drug information for food animals. It is called FARAD (Food Animal Residue Avoidance Databank) and since information regarding these drugs is constantly changing, it requires updating on a daily basis. Your veterinarian can call FARAD and receive the latest information to assist in writing an extralabel drug prescription which includes an appropriate withdrawal time. In addition to the information contained on the prescription label, your veterinarian must keep records detailing the species of animal treated, the disease or condition that was treated with the extralabel medication, the duration of treatment, and the number of

animals treated. These records must be kept by your veterinarian for at least two years and must be available to the FDA upon request. Extralabel drug use is not permitted (1) by a lay person, (2) in animal feed, (3) where use could result in residue above a safe level, or (4) where extralabel use may present a risk to public health.

There are some drugs that are prohibited from use in food-producing animals and the FDA has specifically listed these drugs:

Chloramphenicol
Clenbuterol
Diethylstilbesterol (DES)
Dimetridazole, Ipronidazole, any other nitroimidazoles
Furazolidone (except for approved topical (skin) use)
Nitrofurazone (except for approved topical (skin) use)
Sulfonamide drugs in lactating dairy cattle (except for 3 approved drugs)
Fluoroqinolones (except as approved: Saraflox in chickens)

The FDA can add to this prohibited list if they feel it is necessary. Also, extralabel use of drugs in feeds or extralabel use of feed additives for cattle is expressly prohibited in the new AMDUCA regulations.

It is considered extralabel drug use if any conditions on an OTC label are changed, such as species of animal treated, disease or condition treated, dosage, frequency of treatment, route of administration, or duration of treatment. All of these could change the withdrawal time and will require a prescription from your veterinarian. It will require your veterinarian to keep records and it will require that you keep records regarding extralabel drug use, because the person(s) administering the treatments is also responsible for any drug residues that could occur. It is important for us to remember, we are not just raising cattle, we are producing food.

To help facilitate extralabel drug prescriptions and drug distribution, the California Veterinary Medical Association and other organizations such as the CCA pushed for state legislation which has recently taken affect. The legislation, AB611, allows for certified animal health drug distributors to affix your veterinarian's prescription label to the drug containers. This will save everyone time and money with respect to extralabel drug use. It will also aid in keeping records regarding extralabel drug use, which will be everyone's responsibility.

John Maas, DVM, MS
Diplomate, ACVN & ACVIM
Extension Veterinarian
School of Veterinary Medicine
University of California, Davis