Livestock Drug Safety:

Extralabel Drug Use (ELDU)

UC DAVIS WIFSS Western Institute for Food Safety & Security

FDA

Overview

Welcome to Extralabel Drug Use. This is one in a series of chapters on topics related to food animal drug safety. This chapter is designed to give an overview of the rules governing extralabel drug use in food producing animals in the United States.

(Photo: UC Davis School of Veterinary Medicine)

This chapter was developed by the Western Institute for Food Safety and Security, or WIFSS, and the UC Davis School of Veterinary Medicine, in partnership with the U.S. Food and Drug Administration (FDA).

Learning Objectives

After reading this chapter, you will be able to:

- Explain why extralabel drug is use is associated with tissue residues.
- Explain why veterinarians might choose to use a drug in an extralabel manner.
- Recognize the requirements for legal extralabel drug use.

Introduction

An important safeguard in the drug approval process in the United States is the development of specific label directions that specify when and how a drug will be used. When drugs are used according to these directions, tissue residues will rarely, if ever, occur.

Extralabel Drug Use

However, when drug use deviates from the label directions, the time that the drug persists in the tissues can also change. Using a drug in a way that is different from what is specified by the manufacture on the drug label is call extralabel drug use (ELDU). Several common examples of ELDU are: changing the dose or frequency of dose, adjusting the volume per injection or length of treatment, changing the route of administration, or using a drug specified for a different production class or species. Because of the risk of drug residues, on-label treatment should always be the producer's first choice. ELDU treatment should be a treatment of last resort and the only done under the supervision of a veterinarian.

(Photo: UCD-WIFSS/Mike Payne)

There are legitimate reasons for ELDU: the drug is not labeled for a specific species; the drug is not labeled for a specific disease, or the drug is not effective when the dose specified on the label is used.

AMDUCA

The FDA Food, Drug and Cosmetic Act (FD&C Act) was amended in 1994 by the Animal Medicinal Drug Use Clarification Act (AMDUCA). AMDUCA recognizes situations like the one mentioned above, and allows veterinarians, and only veterinarians, to use or prescribe drugs to be used in food animals in an extralabel manner.

AMDUCA Requirements for Legal Extralabel Drug Use

In order to protect consumers from tissue residues, however, there are important requirements that must be fulfilled for legal extralabel use of drugs in food animals. First, only licensed veterinarians are allowed to provide ELDU prescriptions for food animal medications. Producers who use medications in an ELDU manner must only do so under the direction of a licensed veterinarian. Second, only human or animal drugs that are approved by the FDA may be used in an extralabel manner. This means that pesticides, approved by the EPA—not FDA, may not be used in an extralabel manner. These requirements apply to over-the-counter (OTC) medications as well as prescription drugs. Finally, drugs may not be used in an extralabel manner in animal feed at all.

AMDUC also stipulates that food animals may only be treated with a medication in an extralabel manner for therapeutic purposes. In other words, the health of the animal would suffer without treatment. Extralabel treatment for production purposes, which includes increasing milk production, weight gain of the animal, or for reproduction, is not allowed under AMDUCA. Some drugs, and drug uses, are dangerous enough that they are completely prohibited from use in food animals. And finally, if a drug is used in a legal, extralabel manner and a residue is detected that is greater than the established drug tolerance, it is considered in violation of AMDUCA.

Safe ELDU for Veterinarians and Producers

AMDUCA provides specific requirements for veterinarians prescribing extralabel drug use. The licensed veterinarian must carefully diagnose and evaluate the condition before prescribing the ELDU. Care must be taken to ensure that the identity of the treated animal or animals is maintained. One of the most important responsibilities of the veterinarian is to establish a science-based and substantially extended withdrawal period. It is also important that appropriate measures are taken to ensure that the extended withdrawal period is observed by the client, and that thorough treatment records are maintained.

(Photo: AVMA Photo Gallery)

The producers who care for food animals are also responsible for ensuring that tissue residues will not result from extralabel drug use. Producers should work with a licensed veterinarian to develop and oversee a drug management program. Adequate treatment records and animal identification should be maintained by the producer as part of a

control system to prevent accidental contamination of the human food chain. Producers are also responsible for maintaining proper storage and accounting of all drugs and chemicals on the premises. They should provide a reliable system for employee training, as well.

Veterinarian-Client-Patient Relationship (VCPR)

One of the requirements for legal extralabel use under AMDUCA is a valid veterinarian-client-patient relationship (VCPR). A valid VCPR is established when a veterinarian has assumed the responsibility for making medical judgments regarding the health of the animals and the need for medical treatment, and the client has agreed to follow the instructions of the veterinarian. This includes recognizing and following the assigned withdrawal times. The practicing veterinarian must also be readily available for additional treatment in case of adverse reactions or treatment failure. A valid VCPR can only exist when the veterinarian is personally acquainted with the keeping and care of the animals through examination and timely visits to the premises where the animals are housed.

(Photo: UC Davis School of Veterinary Medicine)

Summary

While sometimes necessary, extralabel drug use in food animals has an increased risk of residues. Because of this, AMDUCA was published by the FDA to provide specific rules for extralabel use of medications in food animals. Extralabel drug use is only permitted when supervised by a veterinarian. The veterinarian will prescribe an extended withdrawal time and adequate animal identification and treatment records are kept to ensure that illegal residues do not occur.