Livestock Drug Safety:

Veterinary Drugs and Labels

UC DAVIS WIFSS Western Institute for Food Safety & Security

FDA

Overview

Welcome to Veterinary Drugs and Labels. 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 different classes of veterinary drugs available in the United States for food producing animals, and introduce the key components found on drug labels.

This chapter was produced 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:

- Recognize the four different types of veterinary drug labels.
- Recognize the required components that make up a drug label.
- Interpret drug label instructions.

The Importance of Drug Labels

In the U.S., there is a rigorous drug approval process in place that acts as a major safeguard protecting consumers of livestock products from drug residues. Part of that approval process includes a carefully reviewed drug label. If animal drugs are used per label instructions, they will be effective for the labeled disease or indication, safe for the treated animal, and will not result in tissue residues.

Drug Label Categories

Animal drugs may be categorized into four different classes: over-the-counter (OTC), prescription (Rx), extralabel drug use (ELDU) and Veterinary Feed Directive (VFD).

Over-the-counter Drugs (OTC)

A large portion of veterinary drugs available in the United States are approved as over-the-counter medications, meaning they don't require a veterinarian's prescription and may be purchased directly. These drugs have been determined to be safe and effective for use without the supervision of a veterinarian.

(Photo: UC Davis-School of Veterinary Medicine)

Prescription Drugs (Rx)

Veterinary drugs which have special safety concerns related to the animal, the administrator or food safety are approved as prescription drugs. They might also be referred to as "legend drugs" because these medications are required to have the warning or legend statement that says: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian". These medications must be prescribed by a veterinarian and may not be purchased without this prescription.

Extralabel Drug Use (ELDU)

(Photo: UC Davis-WIFSS/Michael Payne)

When either an over-the-counter or prescription drug is used differently than described on the manufacturer's label, it's called extralabel, or off-label drug use. Briefly, extralabel drug use can only be performed under the supervision of a veterinarian who will apply his or her own label to the medication and provide alternative directions, including an extended meat withdrawal period and milk discard period.

Veterinary Feed Directive (VFD)

(Photo: UC Davis-WIFSS/Jeff Hall)

A variety of medications for both production and therapeutic purposes are mixed into animal feeds, called a medicated feed. Many of these medicated feeds are available over the counter. However, some require a prescription from the veterinarian. These prescription-only medicated feeds are called Veterinary Feed Directive or VFD. VFDs must always be used according to the label directions, never extralabel.

Components of a Drug Label

Whether OTC, prescription, extra label or VFD, the label includes the necessary details that allows the drug to be safely used and, in the case of food animals, protect the human food chain from drug residues. This drug label information may be applied by the manufacturer or on a label attached by the veterinarian.

Information that may be found on a label include: active ingredient, also known as generic or established name of the drug, animal species/class or individual animal identifier, dose, duration of therapy, route of administration, withdrawal times, and any cautionary statements. In addition, for prescription drugs or veterinarian's extralabel prescription, the label must include the veterinarian's name and contact information.

Sometimes the same drug will have different manufacturers resulting in a different appearing label. But all labels will have the same components.

All of the drugs above have the same active ingredient, but they are different formulations with different directions for use. FDA's way of identifying medications is through the issuance of a new animal drug application number (NADA), an abbreviated new animal drug application number (ANADA), or a conditional new animal drug application number (CNADA). All of these are unique identifiers which can be found on the manufacturer's label. The presence of these identifying numbers ensures that the drug has gone through the FDA drug approval process.

Summary

In this lesson you've learned that drugs can be classified as: over-the-counter, prescription, extralabel drug use and Veterinary Feed Directive. All drug labels have similar information describing how to safely use the drug. By now, you should be familiar with the components found on a drug label and understand what they mean. Drug labels are an important part of the drug approval process that helps ensure the safety of food animals and consumers.