



Guidelines for Veterinary Prescription Drugs

Key Points

- Veterinary prescription drugs are labeled for use only by or on the order of a licensed veterinarian. Incidents involving the sale and use of prescription drugs without a prescription should be reported to the proper state authority and the U.S. Food and Drug Administration.
- Veterinary prescription drugs are to be used or prescribed only within the context of a veterinarian-client-patient relationship (VCPR).
- Veterinary prescription drugs must be properly labeled before being dispensed.
- Appropriate dispensing and treatment records must be maintained.
- Veterinary prescription drugs should be dispensed only in quantities required for the treatment of the animal(s) for which the drugs are dispensed. Avoid unlimited refills of prescriptions or any other activity that might result in misuse of drugs.
- Any drug used in a manner not in accordance with its labeling should be subjected to the same supervisory precautions that apply to veterinary prescription drugs.

Comment on
this policy
(AVMA Members Only)

The AVMA has prepared the following guidelines as a resource regarding the use and distribution of veterinary prescription drugs. Veterinarians making treatment decisions must use sound clinical judgment and current medical information and must be in compliance with federal, state, and local laws and regulations.

Veterinary Prescription Drugs

Veterinary prescription drugs are those drugs restricted by federal law to use by or on the order of a licensed veterinarian [Section 503(f) Food, Drug, and Cosmetic Act]. The law requires that the drug sponsor label such drugs with the statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

Veterinarian/Client/Patient Relationship

A VCPR exists when all of the following conditions have been met:

- The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
- The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premises where the animal(s) are kept.
- The veterinarian is readily available for follow-up evaluation, or has arranged for emergency coverage, in the

event of adverse reactions or failure of the treatment regimen.

Veterinary Prescription Orders

Orders issued by licensed veterinarians authorize drug distributors to deliver veterinary prescription drugs to a specific client, or authorize pharmacists to dispense such drugs to a specific client.

Veterinarians should assure compliance with relevant regulations (e.g. VCPR) of their State Board of Pharmacy and State Board of Veterinary Medicine, and applicable federal regulations.

Labeling and Record Keeping

Adequate treatment records must be maintained by the veterinarian for at least two years (or as otherwise mandated by law), for all animals treated, to show that the drugs were supplied to clients with whom a VCPR has existed. Such records must include the information set forth under Basic Information for Records, Prescriptions, and Labels.

Food animal owners must also keep treatment records. Owner treatment records have been developed by several producer organizations and are available in conjunction with quality assurance programs.

All veterinary prescription drugs must be properly labeled when dispensed. A complete label should include all the information set forth under the section on Basic Information for Records, Prescriptions, and Labels.

Basic Information for Records (R) Prescriptions (P), and Labels (L)

- Name, address, and telephone number of veterinarians (RPL)
- Name (L), address, and telephone number of clients (RP)
- Identification of animal(s) treated, species and numbers of animals treated, when possible (RPL)
- Date of treatment, prescribing, or dispensing of drug (RPL)
- Name, active ingredient, and quantity of the drug (or drug preparation) to be prescribed or dispensed (RPL)
- Drug strength (if more than one strength available) (RPL)
- Dosage and duration
- Route of administration (RPL)
- Number of refills (RPL)
- Cautionary statements, as needed (RPL)
- Expiration date if applicable
- Slaughter withdrawal and/or milk withholding times, if applicable (RPL)
- Signature or equivalent (P)

The actual container must bear the veterinarian's name, address, name of the drug (active ingredient), identification of the animal(s) to be treated, adequate directions for proper use, and cautions/precautions including milk and meat withdrawal times. This information may be on the label applied by the manufacturer, or on a label attached to the product by the veterinarian.

If there is inadequate space on the label for any of the other required information, the veterinarian must provide the additional information on a separate sheet that accompanies the drug dispensed or prescribed.

State law and other regulations such as the Pasteurized Milk Ordinance may require more information than is stated in these guidelines. Specific label and record keeping information is required when drugs are prescribed for extralabel use (see the next section on AMDUCA).

When veterinary prescription drugs are dispensed to companion animal owners, the AVMA recommends that such drugs be placed in child-resistant containers. Such containers are mandated by law in certain states.

Handling, Storage and Disposal

The veterinarian should inform clients to whom prescription drugs are delivered or dispensed about appropriate drug handling, storage, and disposal.

In the clinic, veterinary prescription drugs should be stored separately from over-the-counter drugs, and be easily distinguishable by the professional and paraprofessional staff. Drugs should be stored under conditions recommended by the manufacturer. All drugs should be examined periodically to ensure cleanliness and current dating.

Food animal clients should be advised that veterinary prescription drugs should be securely stored, with access limited to key personnel.

Animal Medicinal Drug Use Clarification Act (AMDUCA) Compliance in Veterinary Medical Practice

With passage of the AMDUCA by Congress in 1994, the extralabel use of approved animal or human drugs in animals became a codified, FDA-regulated activity. Veterinarians may utilize drugs in an extralabel manner in their regular course of practice when the health of an animal is threatened or death may result from failure to treat. Under AMDUCA regulations, extralabel use means the actual or intended use of a drug, by or on the order of a veterinarian, in a manner that is not in accordance with approved labeling. Any deviation from the label, by veterinarians or lay persons is an illegal use, unless the use meets the requirements of AMDUCA. Deviations from the label include, but are not limited to:

- Use in a species not listed in the labeling.
- Use for indications not listed in the labeling.
- Use at dosage levels, frequencies or routes of administration other than those stated in the labeling.
- Deviation from the labeled withdrawal time based on these different uses.

Extralabel use is legal only when ordered by a veterinarian and within the context of a VCPR.

Guidelines for all Animals:

This document is intended to provide a summary of the AMDUCA requirements and does not list all the regulations that may apply. Veterinarians are strongly encouraged to familiarize themselves with the complete regulations. Information is available at www.fda.gov/cvm.

AMDUCA regulations include but are not limited to the following:

1) Extralabel use is only allowed when the health of an animal is threatened, or suffering or death may result from failure to treat.

2) Record requirements-

- Identify the animals, either as individuals or a group.
- Animal species treated
- Number of animals treated

- Condition being treated
- The established name of the drug and active ingredient(s)
- Dosage prescribed or used
- Duration of treatment

If applicable, specified withdrawal, withholding, or discard time(s) for meat, milk, eggs or animal-derived food.

- Keep records for a minimum of 2 years
- When requested, these records must be made available to FDA

3) Label requirements-

- Name and address of the prescribing veterinarian
- Established name of the drug(s)
- The class/species or identification of the animal or herd, flock, pen, lot or other group of animals being treated
- The dosage, frequency, route of administration and duration of therapy
- Any cautionary statements
- If applicable, veterinarian specified withdrawal, withholding or discard time for meat, milk, eggs or any other food

Guidelines for extralabel use in food producing animals:

In addition to the requirements for extralabel use in all animals there are regulations specific for food-producing animals.

Extralabel drug use is only allowed if there is no approved animal drug that is labeled for such use, or that contains the same active ingredient in the required dosage form and concentration. Alternatively, an approved animal drug exists, but a veterinarian finds, within the context of a veterinarian/client/ patient relationship, that the approved drug is clinically ineffective for its intended use.

It is important to note that AMDUCA does not permit extralabel use of drugs in animal feed. AMDUCA also does not permit extralabel drug use for production purposes.

Prior to prescribing or dispensing a food-animal drug for extralabel use the veterinarian must:

- Make a careful diagnosis and evaluation of the conditions for which the drug is to be used.
- Assure that the identity of the treated animal(s) is carefully maintained.
- Use appropriate scientific information to establish a substantially extended withdrawal period prior to marketing milk, meat, eggs or other edible products from the treated animals.
- Take appropriate measures to ensure that the recommended withdrawal times are met and no illegal drug residues occur.
- If there is insufficient scientific information available to determine a withdrawal interval, the veterinarian must not use the drug or the treated animal must not enter the food supply.

Use of a human drug, or an animal drug that is only approved for use in nonfood-producing animals, has further restrictions. These drugs are not permitted if a drug that is labeled for use in a food-producing animal can be used in a labeled or extralabel manner.

The extralabel use of certain drugs is prohibited in food animals. This list may be amended by the Food and Drug Administration. Thus, the following list is accurate as of the publication date of this document.

- Prohibited therapy in food animals: chloramphenicol, clenbuterol, diethylstilbestrol, dimetridazole, ipronidazole, other nitromidazoles, furazolidone, nitrofurazone, glycopeptides, fluoroquinolones.

- Prohibited therapy in lactating dairy cows: any sulfonamide except for approved uses of sulfadimethoxine, sulfabromethazine and sulfaethoxyridazine.
- Prohibited therapy in female dairy cattle 20 months of age or older: phenylbutazone.
- Prohibited therapy in chickens, turkeys, and ducks: adamantane and neuraminidase inhibitor classes of drugs that are approved for treating or preventing influenza A.

Guidelines for extralabel use in nonfood-producing animals:

AMDUCA also applies to medical decisions in nonfood producing animals. There is greater latitude for extralabel use in nonfood producing animals. However, the requirements stated above for "all animals" must still be followed. In addition, veterinarians should consider the following when treating nonfood-producing animals:

- Veterinarians may use approved animal and human drugs for therapeutic purposes in an extralabel manner so long as there is no threat to public health.
- An approved human drug may be used for treatment in an extralabel manner even when an identical, approved animal drug exists.
- Extralabel use of a drug labeled for another animal species can be used only if there is no approved, appropriate drug that is labeled for use in the patient's species or if an approved drug exists for the patient's species but is found by the veterinarian to be clinically ineffective.
- Extralabel use without a VCPR is illegal in all animals.

Guidelines for compounding of approved new animal and approved human drugs in all animals:

Compounding from FDA-approved drugs is considered extralabel drug use under FDA rules.

Compounding is the customized manipulation of an approved drug(s) by either a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a particular patient. For example, mixing two injectable drugs is compounding. Preparing a paste or suspension from crushed tablets is another example of compounding. Likewise, adding flavoring to a drug is compounding.

Compounding is not allowed unless there is no approved new animal or approved new human drug that, when used per label or in an extra label fashion, can appropriately treat the condition diagnosed.

- Compounding must be done by or under the order of a veterinarian.
- Compounded drugs must not be used for production or performance purposes.
- A compounded human drug cannot be used in a food-producing animal if a legally compounded animal drug can instead be used.
- Compounded drugs must be prepared from FDA-approved drugs
- The volume of compounded drug must be commensurate with the anticipated need for use in individual patients.
- State laws on compounding must also be followed.
- A veterinarian must be cognizant of the need to maintain a safe food supply. Specifically, veterinarians must not allow entry of a treated animal into the food chain, if there is insufficient scientific evidence indicating a proper withdrawal interval after treatment.

Background:

- [AVMA Brochure: Extralabel Drug Use](#)
- [Use the Interactive Extralabel Drug Use Algorithm](#)