



# Vet Call

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## Proper drug use

*Cattle producers and their veterinarians have the right to judiciously use a number of valuable drugs, vaccines, insecticides and other pharmaceuticals in beef production. Judicial use implies that there is a legal and ethical responsibility to use those products in such a way as to assure consumers their food is wholesome and without chemical residues or other controllable risks. The use of drugs in food animals is regulated by the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM), while vaccines are regulated by the United States Department of Agriculture (USDA). The Environmental Protection Agency (EPA) regulates pesticides.*

### Follow label directions

Drugs that are approved for use in cattle provide specific instructions on their labels to indicate proper usage, dosage, route of administration [intramuscular (IM), subcutaneous (sub-Q), etc.], duration of treatment and withdrawal time. If a product's label does not provide information about its use for cattle, or if you are considering using the product in ways not listed on the label, you should not use this product for cattle except when your veterinarian gives you specific instructions for extra-label use and provides a written or verbal prescription for its use.

Extra-label drug use is not encouraged. If found necessary, it should only be carried out within the requirements of the Animal Medicinal Drug Use Clarification Act (AMDUCA) regulations. These regulations include requirements for:

- ▶ a veterinary/client/patient relationship to exist;
- ▶ documentation of the inadequacy and inappropriateness of approved treatments;
- ▶ maintenance of adequate treatment records and animal identification (ID); and
- ▶ significantly extended withdrawal times or other methodologies to assure the safety of the food supply.

A proper veterinary/client/patient relationship is defined as one in which the veterinarian has assumed the responsibility for making medical judgments regarding the health of the animals and the need for medical treatment. The owner or caretaker has agreed to follow the instructions of the veterinarian.

In addition, the veterinarian has sufficient

knowledge of the animals to initiate a general or preliminary diagnosis of the medical condition of the animals. This means the veterinarian has recently seen, and is personally acquainted with the keeping and care of, the animals through examination of the animals and/or by medically appropriate and timely visits to the premise where the animals are kept. And finally, the veterinarian is readily available to follow up in cases of adverse reactions or therapy failure.

### Illegal drug usage

Under no circumstances can you justify the use of illegal products such as chloramphenicol, clenbuterol, diethylstilbestrol or dipyrone. Even though some of these products are approved for use in horses, pets or humans, and therefore can be purchased through normal animal health product outlets, they are illegal to use in cattle or other food animal species not listed on the label.

Similarly, gentamicin and neomycin use in cattle, while not illegal, has been discouraged by the American Veterinary Medical Association (AVMA), the Academy of Veterinary Consultants (AVC), the American Association of Bovine Practitioners (AABP) and the National Cattlemen's Beef Association (NCBA).

Compounded products generally do not meet the requirements of the AMDUCA. Compounding generally implies the unregulated manipulation of any drug.

Compounded products are not produced under federal inspection and are therefore not assured of adequate quality control, sterility guarantees, adequate labeling or pharmaceutical information.

With few exceptions, compounded products are considered unsafe and inappropriate for use in food animals. Reputable veterinarians and pharmaceutical suppliers will avoid these practices. In some

cases, illegal compounding involves the mixing of approved products, changing the form of an approved product or mixing an oral product for use as an injectable.

In other cases, bulk chemical is illegally obtained and a counterfeit of an approved or unapproved

drug is produced. Drugs compounded from illegal bulk products are especially dangerous, as there is no inspection to guarantee purity or potency.

Regardless of the type of illegal compounding, the cattle treated with such a product are considered adulterated and cannot legally enter the food system.

Don't let someone give your cattle a compounded product that is presented as a "generic" version of an approved drug. True generic products are legal copies of drugs for which the patent period has expired. True generic drugs are produced under federal inspection; whereas, compounded drugs are not produced under the same standards.

### Exceptions

Fortunately, veterinarians and beef producers have a variety of effective, approved, name-brand and generic products for most medical conditions affecting cattle. Occasionally, rare occurrences such as poisonings require the use of medications that are not specifically approved for that purpose in food animals, and veterinarians must utilize their right to use a drug in an extra-label fashion.

In addition, some medical conditions may require the use of an approved drug for the purpose on the label, but at higher than label doses. This is also extra-label drug use and

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requires that the veterinarian shoulder additional responsibility for the treatment protocol and withdrawal period. Drugs cannot be used in an extra-label fashion in feed or for production purposes (growth, reproduction, lactation), and they cannot be used simply because they are cheaper than approved products. In addition, there is no legal provision for the extra-label use of pesticides.

Restrictions on the treatment of food

animals are more extensive than for nonfood animals for obviously good reasons. We (veterinarians and producers) must not jeopardize food safety, the food supply and consumer confidence by taking our responsibility as a food supplier lightly.

For more information about AMDUCA, compounding and proper drug use, see:

- ▶ [www.fda.gov/ora/compliance\\_ref/cpg/cpgvet/cpg608-400.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg608-400.html);
- ▶ [www.fda.gov/cvm/default.html](http://www.fda.gov/cvm/default.html);

- ▶ <http://www.avma.org/scienact/amduca/amduca2.asp>; and/or
- ▶ Compounding: What's legal, what's not. V.R. Fajt, *Bovine Veterinarian*, March 2003.



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