

# Regulations Concerning Food Animal Drug Use

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## Abstract

As a Veterinary Technician, you are involved daily in the practice of administering medications to animals. These administrations may be done according to the label directions, or the treatment regimen may be altered from the label. This altered use is referred to as extralabel, or off-label use. The Animal Medicinal Drug Use Clarification Act (AMDUCA) has moved extralabel drug use in veterinary medicine from an approach of “illegal but tolerated if you do it this way” to “legal if you follow specific guidelines”. This paper presents portions of the AMDUCA regulations as published in the Federal Register. **These sections have been selected to highlight key areas of the regulations and should not be treated as the full text of the regulations.** Directions for obtaining the full text of appropriate documents are included below. In addition, anyone working with dairy animals should be aware of the Pasteurized Milk Ordinance (PMO) regulations and their state regulations regarding drugs on dairies.

## Purpose of the AMDUCA Regulations

The AMDUCA actually carries few specifics which help us guide extralabel drug use. The specific regulations were promulgated by the Center for Veterinary Medicine of the Food and Drug Administration (FDA-CVM).<sup>1</sup> These regulations were required for the AMDUCA to become law, and were published in the Federal Register on December 7<sup>th</sup>, 1996. Section 530.2 of these regulations states:

*“The purpose of this part is to establish conditions for extralabel use or intended extralabel use in animals by or on the lawful order of licensed veterinarians of Food and Drug Administration approved new animal drugs and approved new human drugs. Such use is limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat. This section implements the Animal Medicinal Drug Use Clarification Act of 1994...”*

This section embodies several key concepts of the regulations: 1) Legal extralabel use is only possible “by or on the lawful order of licensed veterinarians”. 2) Only drugs approved for use in animals or humans may be legally used under these regulations. (The term “new” refers to drugs approved since the Federal Food, Drug and Cosmetic Act of 1938.) 3) Extralabel use is only provided for in these regulations when it relates to the health of the animal. Extralabel use for production purposes is not provided for in the regulations, making such use illegal.

It is very important to realize that the AMDUCA was not intended to give veterinarians “free rein” for drug use in food animals. The official AMDUCA Federal Register notice contains both a discussion of comments received by the FDA Center for Veterinary Medicine and the actual regulations.

In addition to the AMDUCA regulations, it is also important to be familiar with relevant Compliance Policy Guidelines (CPGs). These documents are developed as guidance for FDA personnel in the field. They are not binding on either the FDA or on citizens, but are used to help FDA personnel determine when regulatory action is indicated. A CPG relevant to this topic is *Compounding of Drugs for Use in Animals (CPG 7125.40)*.<sup>2</sup>

When making therapeutic and compounding decisions, the actual text of the act, regulations, and compliance policy guides should be relied upon. The complete regulations are much more extensive and should be consulted for guidance concerning all areas of extralabel drug use. It is important not to rely on the opinions or interpretations of “pseudo-experts” when you have the capability to obtain the original documents and address questions directly to the Center for Veterinary Medicine. The CVM office of surveillance and compliance (301-594-1761) is where the buck ultimately stops. Original copies of these documents may be obtained from:

1. The FDA-CVM homepage (<http://www.cvm.fda.gov/>). There is a search engine on this site to help you locate documents.
2. Communications staff, FDA-CVM, 7500 Standish Place, HFV-12, Rockville, MD 20855, (301-594-1755).

## A Veterinary-Client-Patient Relationship (VCPR)

Extralabel drug use is valid only within a valid VCPR. Section 530.0 of the regulations defines a VCPR as:

- (i) *A valid veterinarian-client-patient relationship is one in which:*
  - (1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
  - (2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
  - (3) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) is kept.

### Extralabel Use Requirements

The following section of the AMDUCA regulations is presented for discussion. **You should read the regulations in their entirety as this is not the full text.**

*“Subpart C—Specific Provisions Relating to Extralabel Use of Animal and Human Drugs in Food-Producing Animals*

*Sec. 530.20 Conditions for permitted extralabel animal and human drug use in food-producing animals.*

- (a) *The following conditions must be met for a permitted extralabel use in food-producing animals of approved new animal and human drugs:*
  - (1) *There is no approved new animal drug that is labeled for such use and that contains the same active ingredient which is in the required dosage form and concentration, except where a veterinarian finds, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug is clinically ineffective for its intended use.*
  - (2) *Prior to prescribing or dispensing an approved new animal or human drug for an extralabel use in food animals, the veterinarian must:*
    - (i) *Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;*
    - (ii) *Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;*
    - (iii) *Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and*
    - (iv) *Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment.*

- (b) *The following additional conditions must be met for a permitted extralabel use of in food-producing animals an approved human drug, or of an animal drug approved only for use in animals not intended for human consumption:*
  - (1) *Such use must be accomplished in accordance with an appropriate medical rationale; and*
  - (2) *If scientific information on the human food safety aspect of the use of the drug in food-producing animals is not available, the veterinarian must take appropriate measures to assure that the animal and its food products will not enter the human food supply.*

- (c) *Extralabel use of an approved human drug in a food-producing animal is not permitted under this part if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the particular use.”*

### Compounding Regulations

What about drugs that are mixed, repackaged, or reformulated in a veterinary practice or by a compounding pharmacist? Section 530.13 in the AMDUCA regulations addresses this issue. In addition, the CPG for compounding is essential reading.

*Sec. 530.13 Extralabel use from compounding of approved new animal and approved human drugs.*

- (a) *This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs.*
- (b) *Extralabel use from compounding of approved new animal or human drugs is permitted if:*
  - (1) *All relevant portions of this part have been complied with;*

- (2) *There is no approved new animal or approved new human drug that, when used as labeled or in conformity with criteria established in this part, will, in the available dosage form and concentration, appropriately treat the condition diagnosed. Compounding from a human drug for use in food-producing animals will not be permitted if an approved animal drug can be used for the compounding;*
  - (3) *The compounding is performed by a licensed pharmacist or veterinarian within the scope of a professional practice;*
  - (4) *Adequate procedures and processes are followed that ensure the safety and effectiveness of the compounded product;*
  - (5) *The scale of the compounding operation is commensurate with the established need for compounded products (e.g., similar to that of comparable practices); and*
  - (6) *All relevant State laws relating to the compounding of drugs for use in animals are followed.*
- (c) *Guidance on the subject of compounding may be found in guidance documents issued by FDA.*

### **Prohibited drugs**

There is a group of drugs prohibited from extralabel use in food animals. This list may be found in Section 530.41 of the AMDUCA regulations. A February 7, 2002 CVM Update indicated that all uses of nitrofurans in food producing animals was prohibited as of May 7, 2002.<sup>3</sup> This update contained the following comments and list of drugs prohibited for extralabel use in food producing animals.

*The current list of prohibited drugs includes furazolidone and nitrofurazone, but it contains the parenthetical statement (except for approved topical use). FDA plans to remove this parenthetical statement. Once this prohibition is in place, the revised list will state that the following drugs (both animal and human), families of drugs, and substances are prohibited for extra-label uses in all food-producing animals.*

- (1) *Chloramphenicol;*
- (2) *Clenbuterol;*
- (3) *Diethylstilbestrol (DES);*
- (4) *Dimetridazole;*
- (5) *Ipronidazole;*
- (6) *Other nitroimidazoles;*
- (7) *Furazolidone, Nitrofurazone, other nitrofurans;*
- (8) *Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxyipyridazine);*
- (9) *Fluoroquinolones; and*
- (10) *Glycopeptides.*

### **Other areas**

In addition to the sections discussed, the AMDUCA regulations contain guidance on necessary records, the use of human-labeled drugs in food animals, advertising and promotion, and labeling. Also, it would be wise to discuss colloidal silver, DMSO, ionophores, dipyrone, and phenylbutazone with your dairy inspector(s) before going down one of these roads. Many of these have also been the subjects of CVM updates.

### **Conclusion**

The AMUDUCA regulations provide guidance on all aspects of appropriate and legal drug use in food animals. If you are in doubt about a practice, you should make the necessary efforts to find out whether or not the practice is permitted.

### **References**

1. AMDUCA - Federal Register: November 7, 1996 (Volume 61, Number 217), Page 57731-57746, 21 CFR Part 530, Extralabel Drug Use in Animals; Final Rule, Department Of Health And Human Services, Food and Drug Administration, Docket No. 96N-0081, RIN 0910-AA47, ACTION: Final rule. From the Federal Register Online via GPO Access [wais.access.gpo.gov].
2. Compliance Policy Guideline 7125.40 (608.400), Compounding of Drugs for Use in Animals, available on the web at [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgvet/](http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/).
3. CVMUpdates are available, grouped by year, on the CVM website at <http://www.fda.gov/cvm/index/updates/nitroup.htm>.