

DRUG STORAGE REQUIREMENTS AND VETERINARIAN-CLIENT-PATIENT RELATIONSHIP (VCPR)



BASICS

OVERVIEW

- As the public's concern for food safety continues to be directed toward the producer, a well-defined and well-documented veterinarian-client-patient relationship (VCPR) is a significant factor in ensuring that animal products are safe, wholesome, and acceptable.
- Veterinarians are the initial control point to assist in establishing, defining, refining, and practicing "best-practice" pharmaceutical use programs.
- The Veterinary Feed Directive (VFD) is a new regulatory requirement for the veterinarian that will require increased oversight.

GEOGRAPHIC DISTRIBUTION

This chapter focuses on requirements within the United States. Regional regulations will vary but many concepts remain the same.

REQUIREMENTS

- The regulations below are specific for a dairy; however, the concepts could be applied to other operations.
- Most of these requirements pertain to sanitizers and veterinary drugs.
- The following may be exempt if their use and storage will not serve as a potential source of contamination of milk: topical antiseptics, vaccines and other biologics, and injectable or oral formulations of vitamins and/or minerals.
- The fundamental concept is reducing the potential for contamination of milk.
- Segregation of drugs for use in lactating and non-lactating animals is essential.
- Administrative procedures:
 - From Pasteurized Milk Ordinance 2015; Item 15r—Drug and Chemical Control
 - This item is deemed to be satisfied when
- 1. Cleaners and sanitizers, used on dairy farms, shall be purchased in containers from the manufacturer or distributor which properly identify the contents or, if bulk cleaners and sanitizers are transferred from the manufacturer's or distributor's container, that the transfer only occur into a dedicated end-use container which is specifically designed and maintained according to the manufacturer's specifications for that specific product. The label on the dedicated end-use container shall include the product name, chemical description, use directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor.

2. Equipment used to administer drugs is not cleaned in the wash vats and is stored so as not to contaminate the milk or milk contact surfaces of equipment.
3. Drugs intended for treatment of non-lactating dairy animals are segregated from those drugs used for lactating dairy animals. Separate shelves in cabinets, refrigerators or other storage facility satisfy this item.
4. Drugs shall be properly labeled to include the name and address of the manufacturer or distributor for OTC drugs), or veterinary practitioner dispensing the product for Rx and extra label use drugs. If the drug is dispensed by a pharmacy on the order of a veterinarian, the labeling shall include the name of the prescribing veterinarian and the name and address of the dispensing pharmacy, and may include the address of the prescribing veterinarian.
5. Drug labels shall also include:
 - a. Directions for use, and prescribed withholding times
 - b. Cautionary statements, if needed
 - c. Active ingredient(s) in the drug product
6. Unapproved and/or improperly labeled drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor.
7. Drugs are stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the containers, utensils or equipment.

VETERINARIAN-CLIENT-PATIENT RELATIONSHIP (VCPR)

- This relationship is essential and the foundation for the routine treatment recommendations as well as extralabel drug recommendations in veterinary medicine.
- All aspects must be met for the establishment of a valid VCPR.
- From 21 CFR Part 530
- A valid VCPR is one in which:
 - 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
 - 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)
 - The practicing veterinarian is readily available for follow-up 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) are kept.

RECORD KEEPING REQUIREMENTS FOR EXTRALABEL DRUG USE

- To use any approved drug (veterinary or human) in food-producing animals, the veterinarian must work through the AMDUCA regulations.
- An algorithm at the AVMA web page may be useful:
<https://www.avma.org/KB/Resources/Reference/Pages/AMDUCA2.aspx>
- Once the decision is made to use a drug in an extralabel manner, the following record keeping must be observed by the recommending veterinarian (from 21 CFR Part 530.5).
 - a. As a condition of extralabel use permitted under this part, to permit FDA to ascertain any extralabel use or intended extralabel use of drugs that the agency has determined may present a risk to the public health, veterinarians shall maintain the following records of extralabel uses. Such records shall be legible, documented in an accurate and timely manner, and be readily accessible to permit prompt retrieval of information. Such records shall be adequate to substantiate the identification of the animals and shall be maintained either as individual records or, in food animal practices, on a group,

herd, flock, or per-client basis. Records shall be adequate to provide the following information:

1. The established name of the drug and its active ingredient, or if formulated from more than one ingredient, the established name of each ingredient
2. The condition treated
3. The species of the treated animal(s)
4. The dosage administered
5. The duration of treatment
6. The numbers of animals treated
7. The specified withdrawal, withholding, or discard time(s), if applicable, for meat, milk, eggs, or any food which might be derived from any food animals treated.

LABEL REQUIREMENTS FOR EXTRALABEL DRUG USE

- There are specific requirements for label information for extralabel drug use.
- The prescribing veterinarian must determine and specify a withdrawal time for the drug in question.
- Information below from 21 CFR Part 530.12

Any human or animal drug prescribed and dispensed for extralabel use by a veterinarian or dispensed by a pharmacist on the order of a veterinarian shall bear or be accompanied by labeling information adequate to assure the safe and proper use of the product. Such information shall include the following:

- (a) The name and address of the prescribing veterinarian. If the drug is dispensed by a pharmacy on the order of a veterinarian, the labeling shall include the name of the prescribing veterinarian and the name and address of the dispensing pharmacy, and may include the address of the prescribing veterinarian
- (b) The established name of the drug or, if formulated from more than one active ingredient, the established name of each ingredient
- (c) Any directions for use specified by the veterinarian, including the class/species or identification of the animal or herd, flock, pen, lot, or other group of animals being treated, in which the drug is intended to be used; the dosage, frequency, and route of administration; and the duration of therapy
- (d) Any cautionary statements
- (e) The veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal or animals.

VETERINARY FEED DIRECTIVE (VFD)

- A veterinary feed directive (VFD) is a written statement from a licensed veterinarian that authorizes a client to obtain and use a VFD drug in or on animal feed.
- Extralabel use of drug with VFD is illegal.
- Full implementation of VFD is scheduled for January 1, 2017.
- Draft Guidance for Industry #120; VFD states that the veterinarian must:
 - be licensed to practice veterinary medicine
 - operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements
 - write VFD orders in the context of a valid VCPR
 - issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug
 - prepare and sign a written VFD providing all required information

- include required information when a VFD drug is authorized for use in a drug combination that includes more than one VFD drug
- restrict or allow the use of the VFD drug in combination with one or more OTC drug(s)
- provide the feed distributor with a copy of the VFD
- provide the client with a copy of the VFD order
- retain the original VFD for 2 years
- provide VFD orders for inspection and copying by FDA upon request



MISCELLANEOUS

SEE ALSO

- Extra-label Drug Use and Compounding (www.fiveminutevet.com/ruminant)
- Food Animal Residue Avoidance Databank (FARAD) (www.fiveminutevet.com/rumiant)

ABBREVIATIONS

- AMDUCA= animal medicinal drug use clarification act
- AVMA= American veterinary medical association
- FDA= food and drug administration
- OTC= over the counter
- Rx= prescription
- USDA= United States department of agriculture
- VCPR= veterinarian client patient relationship
- VFD= veterinary feed directive

Suggested Reading

Title 21 CFR Part 530—Extralabel Drug Use In Animals; www.ecfr.gov.

Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA); <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/ucm085377.htm>

AVMA Extralabel Drug Use Algorithm: <https://www.avma.org/KB/Resources/Reference/Pages/AMDUCA2.aspx>

England, J.J. 2002. Biosecurity: safeguarding your veterinarian-client-patient relationship. *Vet Clin North Am Food Anim Pract.* Nov; 18(3): 373–8, v.

Grade “A” Pasteurized Milk Ordinance 2015 Revision; U.S. Department of Health and Human Services PHS/FDA Milk Ordinance, <http://www.idfa.org/docs/default-source/d-news/2015-pmo-final.pdf>

Veterinary Feed Directive (VFD) -

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm> viewed 05/29/16

Draft Guidance for Industry #120; Veterinary Feed Directive

Regulation <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf> viewed 05/29/16

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