



# Veterinary Compounding

Veterinarians must occasionally use compounded drugs to meet a specific patient's medical need. The purpose of this brochure is to explain the requirements for compounding products for veterinary use and the distinction between FDA approved drugs and compounded drugs.

## What is compounding?

It is the manipulation of a drug to make a different drug to meet the needs of a particular patient. For example, mixing two injectable drugs is compounding. Creating an oral suspension from crushed tablets is compounding. Adding flavoring to a commercially available drug is compounding.

Compounding can be performed by a veterinarian, or by a pharmacist upon receipt of a veterinarian's prescription for a particular patient. A veterinarian must have a veterinarian-client-patient relationship in order to legally prescribe or prepare a compounded product.



## Federal regulations require that in order to compound a drug legally:

- A valid Veterinarian-Client-Patient relationship (VCPR) must exist.
- The health of an animal must be threatened or suffering or death may result from failure to treat.
- There must be no FDA-approved, commercially available animal or human drug that, when used as labeled or in an extralabel fashion in its available dosage form and concentration, will appropriately treat the patient.
- The product must be made from an FDA-approved commercially available animal or human drug.
- The product must be compounded by a licensed veterinarian or a licensed pharmacist on the order of a veterinarian within the practice of veterinary medicine.
- The compounded product must be safe and effective.
- The amount of product compounded must be commensurate with the need of the animal identified in the VCPR-based prescription.
- For animals produced for human consumption, the veterinarian must establish an extended withdrawal interval for the compounded product and ensure food safety. Compounding is not permitted if it results in violative food residue, or any residue that may present a risk to public health.
- No drug may be compounded for food animals from drugs listed on the prohibited list.
- Veterinarians must comply with all aspects of the federal extralabel drug use regulations including record-keeping and labeling requirements.
- All relevant state laws relating to compounding must be followed.

## FDA Regulations:

FDA regulations describe specific circumstances under which veterinarians, or pharmacists upon veterinarians' prescriptions, are legally permitted to compound drug products for extralabel use in animals. Under these regulations, compounding may only be performed using FDA-approved animal or human drugs and only when no approved use of an approved animal or human drug is available, in the relevant dosage form and concentration, to appropriately treat the diagnosed condition. In food animals, approved animal drugs must be preferentially used over approved human drugs.

Veterinarians may occasionally face situations, however, where they diagnose conditions in non-food animals for which no FDA-approved animal or human drug is available for use to relieve the animal's suffering or prevent the animal's death. In these situations, veterinarians may find it necessary to compound, or prescribe for a pharmacist to compound, from non-FDA-approved substances to satisfy the requirements of good veterinary medical practice. The veterinarian is then responsible for the safety and efficacy of the compounded drug. In cases where no approved drug or combination of approved drugs can adequately address a specific patient's need, veterinarians & pharmacists must carefully assess whether the use of an unapproved substance in a compounded veterinary drug is consistent with state law & FDA policy.

### Generic vs. Compounded Drugs

Compounded drugs are not the same as generic drugs. Generic drugs are FDA-approved. To receive FDA approval, generic drugs must demonstrate bioequivalence to the "pioneer brand name" drug. Generic drugs can be identified by the ANADA number on their label and by cross-checking with a drug reference, e.g. the FDA Green Book of Approved Animal Drug Products. In contrast, compounded drugs are extemporaneously prepared products that lack FDA approval. The concept is that compounded drugs with their possible flaws are better than no drug at all and suitable for a small patient population.

*We hope this information has helped explain veterinary compounding requirements and the distinctions between FDA approved drugs and compounded drugs.*



# Questions To Ask Your Compounding Pharmacist

- *What FDA approved drug will be used to compound the prescribed product?*  
FDA approved animal or human drugs should preferentially be used to compound preparations.
- *How long will it take to compound the prescribed drug?*  
Pharmacists should compound pursuant to receipt of a prescription. State regulations may permit compounding in anticipation of historical need.
- *How are expiration dates for compounded drugs determined?*  
Expiration dates are obtained from compounded drug stability data when available, or, are calculated using criteria established by the US Pharmacopoeia.
- *How are adverse events associated with compounded products reported?*  
Pharmacists and veterinarians should report adverse experiences associated with any drug to the FDA CVM.



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REQUIREMENT	BENEFIT	FDA APPROVED DRUG: NEW ANIMAL DRUG (NADA)/ GENERIC ANIMAL DRUG (ANADA)	COMPOUNDED DRUG
FDA Approval	Independent FDA substantiation of manufacturers drug claims	YES	NO
Tested in target animal species in laboratory and field trials	Scientific demonstration of drug's safety and efficacy	YES	NO
Manufactured according to current Good Manufacturing Practices (cGMP's)	Ensures each drug unit is manufactured within specification for therapeutic consistency	YES	NO
Manufacturing facilities inspected and approved by FDA	Ensures manufacturer compliance with FDA regulations governing product quality	YES	NO
On-going stability testing of drugs	Ensures drug shelf life matches labeled expiration date	YES	NO
Labels approved by FDA	Means everything on the label is scientifically substantiated	YES	NO
Advertising/Promotional material reviewed by FDA	Means nothing is false or misleading about the materials	YES	NO
Adverse Events/Lack of Efficacy reported to FDA	Permits unanticipated yet significant post-marketing experiences to be communicated back to the veterinarian	YES	NO
Analytical Testing of Product Prior to Release for:  Strength Identity Purity	Ensures that product contains what is represented on the label	YES YES YES	NO NO NO
Patient-specific dosing:  Modified dosage form, concentration, or route of administration	Provides enhanced medication compliance	NO  NO	YES  YES
Flavor added		NO	YES

## Additional Resources

- FDA-Center for Veterinary Medicine – [www.fda.gov/cvm](http://www.fda.gov/cvm) and [www.fda.gov/cvm/index/amduca/amducatoc.htm](http://www.fda.gov/cvm/index/amduca/amducatoc.htm)  
[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/greenbook/greenbook.html](http://www.fda.gov/cvm/greenbook/greenbook.html)
- National Association of Boards of Pharmacy – [www.nabp.net](http://www.nabp.net)
- American Veterinary Medical Association – [www.avma.org](http://www.avma.org)
- American Association of Bovine Practitioners – [www.aabp.org](http://www.aabp.org)
- American Association of Equine Practitioners – [www.aaep.org](http://www.aaep.org)