

Drug Compounding 101

by James P. Morehead, DVM

The AAEP Executive Committee and the AAEP Professional Conduct and Ethics Committee, along with the PLIT and the AVMA have all recognized the importance of educating veterinarians in the area of drug compounding. All concerned with this educational process realize this is not a colorful topic, and thus is difficult to hold one's attention long enough to adequately educate them. All also realize that if we continue to relay the message with updates as things change, then we will reach our audience with at least some of the information. This issue we will first give you some compounding basics and short bytes of timely, pertinent, and, hopefully interesting examples of how we would recommend veterinarians deal with compounded drugs and compounding pharmacies will be included in each issue of EVE. The AAEP seeks to be the best source of continuing education for equine practitioners and our goal is to "leave no veterinarian behind."

Compounding Basics

Compounding: is any manipulation to produce a dosage from a drug, (other than that manipulation that is provided for in the directions for use on the labeling of the approved drug product).

The intent of compounding: to provide a customized formulation for a specific need of a specific animal, within the context of a valid Veterinary-Client-Patient-Relationship (VCPR).

Compounding is a very necessary service for the equine veterinarian. It is important for us to understand when it is appropriate to use compounded products and when it is not.

The "laws" which govern drug products (including compounded products), their manufacture and use includes; the Food Drug and Cosmetic Act (FDCA), the Animal Medicinal Drug Use Clarification Act (AMDUCA) and individual State Pharmacy Board Regulations.

Technically speaking, the Food Drug and Cosmetic Act does not distinguish between compounding and drug manufacturing. Drug manufacturing of course comes under the authority of the FDA, and includes strict requirements related to Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), data demonstrating safety, efficacy and a number of other parameters. Obviously, compounded products cannot meet the requirements of an FDA approved product. However, the government recognizes the need for compounded products in both human and veterinary medicine. To this end, the government has "guidelines" for compounding products. These are referred to as Compliance Policy Guidelines or CPG.

So here is what we have: under strict interpretation of the law, compounding is illegal, however the government recognizes the need for compounded products in specific situations. As such, they have provided these "guidelines" and as long as everyone plays by the rules, the government will exercise what it calls discretionary enforcement. (They will leave us alone.)



For the practitioner, we need to remember the "criteria" for using compounded products.

There are a number of these criteria, and we won't discuss all of them at this time. But foundational to using any compounded product is; there must be no approved

animal or approved human drugs, which are available in the appropriate dosage or concentration to treat the disease or condition. If an approved product is available and appropriate to use for that specific condition, then we are required to use it.

We will continue to provide additional information on compounding in future newsletters. A few things for equine practitioners to consider with respect to compounding:

- Compounding can be done only by veterinarians or licensed pharmacists. If you are using compounded products from a pharmacist, the compounding should only be done on order of a valid prescription from you.
- The prescribing veterinarian assumes responsibility/liability when using these products.

There are no requirements for stability or potency testing of compounded products.

Compounded products and generic drugs are not the same—at all. A compounded product is not a generic anything.

Develop a good relationship with an ethical, professional compounding pharmacist. Contact your state pharmacy board for advice on reputable compounding pharmacies, and to verify licensure in your state for those out of state compounding pharmacies you wish to use.

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