

# Controversies Over Compounding



by HEATHER SMITH THOMAS

Compounding is the manipulation of a drug product to produce a dosage or formulation tailored to more adequately meet the needs of a specific patient. This can be done by mixing two drugs together or creating a more palatable oral product by adding flavoring or crushing tablets and mixing them with fluid, etc. Compounding can be done by a licensed veterinarian or by a licensed pharmacist on the prescription of the veterinarian.

FDA (Food and Drug Administration) regulations must be met in order for compounding to be legal. Technically, only FDA-approved drugs should be used for treating animals—drugs that have gone through the required testing processes to prove efficacy and safety. There are a limited number of approved drugs for use in horses however, so there are certain instances in which compounding is necessary.

The FDA has established guidelines for veterinarians to follow in determining the situations in which compounding is allowed. Problems arise when raw materials from questionable sources are used or when illegal compounding duplicates an approved drug just to produce a cheaper product. In these instances, the resulting product may not be effective nor safe, putting the health of the horse at risk. The compounded product may not contain enough active ingredient to treat the medical condition (therefore ineffective, and the horse may die from the medical condition). Or it may itself be harmful (if questionable sources or the wrong dosage is used in putting the product together), creating further problems or the death of the horse.

Examples of illegal compounding causing harm include the deaths of at least six horses in Louisiana in 2006, after they were given a compounded clenbuterol product that was many times more potent than the FDA-approved Ventipulmin. The latter is the only licensed clenbuterol product in the U. S. and worldwide that is used as a prescription drug to treat horses with airway obstruction. Deaths occurred after only one dose of the illegal product, reportedly smuggled in from Belize in Central America, and a number of other treated horses became severely ill.

Earlier that year, at least one horse in Canada died and others suffered serious reactions after receiving a compounded version of an injectable iron-sucrose product

purchased from a feed store. The counterfeit product mimicked Hippiron 1000, a licensed legal Canadian product.

The most recent event that came to public attention was the deaths of 21 polo horses in Florida on April 19, 2009, after they received injections of a compounded vitamin-mineral supplement containing lethal levels of selenium. These tragedies highlight the need for caution and are a reminder to veterinarians and horse owners of the reasons that compounding is basically illegal and unethical except in certain allowable situations.

Charlotte Lacroix, DVM, JD (Veterinary Business Advisors Inc., Flemington, New Jersey), a veterinarian who is also a lawyer, says we need to have compounded drugs in the animal industry because there are not enough approved animal drugs available. In some instances, there no

approved drugs to address certain health issues. “Your drug choices are these: you should first use an approved drug that hasn’t been manipulated. Whether it’s approved for horses or for humans or another species, this is where you start,” she says. A veterinarian can prescribe a drug designed for another species (off label, for a horse), in a situation where it is the only medication that will treat a certain condition.

“Your next choice: if the drug is not in the formulation you need for that horse—as when you need less of it or more of it, or in a liquid form, or delivered in a certain way—your veterinarian can have a compounding pharmacy manipulate the FDA-approved product in the way it needs to be changed. For instance, bute tablets can be crushed and have flavoring added,” she explains.

If the approved drug is being manipulated to ease delivery or being used on a different species, that’s allowable, because it has been proven to contain what the label says it contain, and it has proven to be safe and effective. “Safety and efficacy are the two most important criteria for any drug,” she says.

“What often happens, however, is that drug compounders will make these drugs from bulk instead of using the FDA products. That’s not legal,” says LaCroix. Even



**A compounded medication (crushed pills, mixed with water and molasses and put into a dose syringe) being given to a horse.**

**Continued on next page**



## Down on the Farm Cont'd.

though bulk compounding (starting from the raw material) is reproducing a drug that is already available, it hasn't gone through any tests for safety and efficacy and may not be the same in these aspects.

"It becomes very problematic if a compounder is copy-cattening an approved drug. That's when it becomes fraudulent and illegal. The problem is that most horse owners want the cheapest drug out there. When their veterinarian gets it compounded illegally from a pharmacist, the veterinarian (who may not know enough about the drug laws) may not know that it's illegal," she says.

Gastrogard and Ulcergard, and antibiotics such as enrofloxacin, are examples. "The drugs that are copycatted are much cheaper, but some of them have less (or none) of the active ingredient they're supposed to have or too much—like what happened with the polo horses in Florida," explains Lacroix. So horse owners need to let their veterinarians know that they want to use only FDA-approved drugs.

"They should be asking their veterinarians about these drugs. The authorized drugs are going to be more expensive. Even the generic drugs are more expensive than a compounded copycat drug. The generics have to be approved, and made under good manufacturing processes," she says.

The cheapest products are very likely copycat products that are illegal, with no standards for safety or efficacy. You don't

know where the raw materials originated. "In the U. S., there are FDA-registered facilities for producing these materials but that doesn't mean that the FDA inspects them," she says.

The client who buys a drug from a veterinarian is relying on it being safe, and effective—able to treat the condition for which it is prescribed. In some instances, compounded drugs do not contain enough of the active ingredient to be helpful or the ingredient loses its potency due to the way it was produced by the compounder. Cheaper is not always better.

"But we don't want horse owners to get the idea that we don't want their veterinarians to use any compounded products. We just want to make sure there is compliance with the guidelines for safe compounding, since there is definitely a need for compounding," says Lacroix.

Pergolide is an example of a necessary drug, important to the health of horses with Cushings syndrome. It was a human drug for treating Parkinson's disease and also used in horses. When it was taken off the market, it had to be compounded. There was controversy at first, over whether the FDA would allow it to be compounded for horses, but it is now allowed. "There is a very short list of drug compounding products allowable by FDA, to do from bulk. Many of these are products that are allowed to treat poisoning," she says.

"Typically, horse owners shouldn't have to ask their veterinarian where a drug comes from, because the veteri-

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## Situations In Which Compounding Is Allowed

Compounding can be done legally only when there is no commercially available FDA-approved product with appropriate dosage form and concentration that can treat the patient. In these instances, the prescribing veterinarian and the compounding pharmacist are responsible for the safety and efficacy of the compounded product, and it can be created only after the veterinarian has established a valid client-patient relationship, has made the diagnosis for that particular animal and written a prescription.

The veterinarian and the pharmacy must comply with FDA regulations and requirements, since failure to meet these requirements may result in enforcement action. The compounded product must be made from an FDA-approved commercially available animal or human drug, and the health of the animal must be threatened in order to justify use of the compounded product for treatment. The compounding pharmacy must have the ability to compound the drug appropriately and it must be safe and effective.

### Situations considered illegal include:

*(with possible enforcement actions taken)*

- compounding by a pharmacy prior to receiving the prescription.
- producing a drug in bulk, using commercial scale manufacturing equipment, or selling it for general resale.
- producing a drug from unapproved human or animal drugs or drugs that have been removed from the market due to safety issues.
- the drug is a copy of a commercially available approved product
- a bulk drug is used to compound the product.
- the compounded product is not labeled adequately for use as specified by the prescribing veterinarian.

narian is supposed to be doing what's in the best interest of the horse. But the use of compounded products is consumer driven. Most equine owners are always comparing and shopping prices, and might find that one veterinarian's prices are cheaper than another. It may be because that vet is using an illegally compounded product. There is market pressure for compounding," she says.

And there are some veterinarians who are unaware of the illegality, since there are compounding phar-

macies that will sell them a product created from bulk and call it a generic, when it's not. "The compounding pharmacies make millions of dollars this way," explains Lacroix. You may even see some items advertised, in spite of the fact they are not FDA-approved products.

Lacroix is hoping the equine industry and the veterinarians become more educated and sensitive to these issues, "So we can better ensure the welfare of the horses—to prevent instances like the polo ponies who died last April." 🐾

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