

Compounded Phenylbutazone (Bute)

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U.S. veterinarians recently received a letter from the Food and Drug Administration reminding us that use of compounded bute is prohibited by law. If you are not already familiar with the term “compounding”, it essentially means manufacture and sale of a drug from a raw, bulk product in a non-FDA approved form. As veterinarians, we do sometimes legally use compounded drugs when the form, concentration, etc. are not available commercially. The FDA allows this in some limited circumstances if it is to the clear benefit of the patient. However, if it is done simply because it is cheaper, minimally more convenient, etc. these are not considered valid reasons and it is illegal to prescribe such drugs.

Until recently, bute was not commercially available in a powdered form that was FDA approved. Thus many veterinarians turned to compounding pharmacies such as Wedgewood and others to provide a compounded powdered bute. However, for the last several months a powdered FDA approved form has been widely available, and veterinarians must switch to this form or risk censure by the FDA.

The compounding question extends to many products commonly used by veterinarians and horse owners. Why are products required to be FDA approved? The approval process ensures the following:

- 1) Products are produced in an approved facility with high standards of quality control, which is regulated by the FDA. This ensures that the concentration is what is listed on the label and that all ingredients are effective and safe. Compounding pharmacies may have internal testing, but are not required to adhere to strict federal standards. This is one reason compounded drugs are often less expensive than their registered, approved counterparts.
- 2) Pharmaceutical companies have extensive liability insurance such that in the rare event of an error in manufacturing, they are able to pay insurance settlements, etc. Compounding pharmacies generally do not have this protection, so there is little recourse if a problem occurs. Lawsuits may fall back upon the veterinarian, and since the veterinarian was essentially breaking the law by using a non-approved product, their own liability insurance does not cover the event.

Some guidelines recently provided to equine veterinarians by our national group, the American Association of Equine Practitioners, are as follows:

A valid Veterinarian-Client-Patient relationship must exist.

The health of the 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. (It is currently illegal to compound from bulk drug sources for veterinary use, with very rare exceptions).

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. (These vary from state to state so it is important the veterinarian be informed regarding these requirements in his or her state).

Thus, as equine veterinarians, it is clear that we should use compounded drugs in relatively rare circumstances, and unfortunately cannot legally respond to requests from clients for “generic” Adequan and other compounded drugs that do not meet the above guidelines. The relatively recent death of 21 polo horses in Florida that received an improperly compounded vitamin mixture injection reminds us all that these guidelines are not arbitrary and about limiting consumer choices, but rather about ensuring the safety and well-being of our equine patients.