

Recognizing the 'Red Flags'

Products that cost less than their FDA-approved constituents.

This suggests that a bulk drug was used rather than the FDA-approved product. Bulk drugs are purported to be versions of FDA-approved substances that are sourced internationally and have not been certified for purity. Importing bulk drugs is generally prohibited.

Products with names that imply effect.

These are not legitimately compounded products. The efficacy, safety, purity, stability and concentration of these substances have not been tested, and there is substantial risk in administering them to a horse. Often, these have names like "Bleeder Stop" or "Monster Energy."



FAQs

What is FDA approval and why does it matter?

FDA approval is a guarantee that the efficacy, potency, sterility and safety of a medication have been proved. Absent this approval, there are risks to horse health and of medication violations for horsemen.

How can I tell if a medication has FDA approval?

All FDA-approved medications have an NDA/ANDA number on the label. These can be researched for specific drugs on the FDA's website. Additionally, a small number of drugs that are generally recognized as safe are permitted under FDA rules.

Is generic the same as compounded?

No. Generic drugs have FDA approval. While generics can be used in compounding medications, generic drugs cannot be compounded.

Additional Resources

FDA's extra-label drug use rules:

www.fda.gov/animalveterinary/resourcesforyou/ucm380135.htm

Link to search for FDA-approved medications by trade name or NADA/ANDA number:

animaldrugsatfda.fda.gov/adafda/views/#/search

AAEP's compounding guidelines:

aaep.org/guidelines/drug-compounding

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Guide to Compounded Medications: What Horsemen Should Know

What is compounding?

Compounding is the manipulation of an FDA-approved drug by a pharmacist or veterinarian to meet the specific needs of an individual patient. Examples include mixing two or more FDA-approved medications in a single syringe or vial, changing the concentration of a drug, adding flavoring, and changing the delivery method (e.g., making an oral liquid suspension or paste from medication originally provided in tablet form).

Why is compounding important?

Compounding is not inherently bad or illegal. Compounded medications can be critical to restoring the health of a horse. It is important that veterinarians be able to prescribe appropriately compounded medications.



What are the Risks?

Some compounded products have contained substances other than those on the label and resulted in medication violations associated with severe penalties.

Some products have contained the correct substances but in concentrations that deviated wildly from the labeled concentration, resulting in medication violations and, in some instances, horse deaths.

Some compounded products have been contaminated with bacteria and resulted in illness or death in treated patients.

In most cases, the effects of combining medications are unknown. Some medications may have increased or decreased effect when combined with others—as occurs when omeprazole and ranitidine are administered together.

What is Legitimate Compounding and How do I Recognize it?

Drugs approved by the FDA are the safest option for the horse and the horseman. Compounded medications are not FDA-approved drugs. However, the FDA recognizes the need for compounded medications and consents to their use if the following requirements are met:

1. The prescription is made under a valid veterinarian-patient-client relationship. The prescribing veterinarian must have sufficient knowledge of the horse to initiate a diagnosis and take responsibility for making medical judgments. The client agrees to comply with the veterinarian's instructions.
2. The health of the horse is threatened, the horse is suffering, or death may occur if the horse is not treated. Compounding is not permissible when based solely on convenience or cost.

3. There is no commercially available FDA-approved drug that when used as labeled will appropriately treat the animal.

4. Compounding is performed by a licensed veterinarian or pharmacist for a prescription issued by a licensed veterinarian.

5. Preparations are compounded from FDA-approved animal or human drugs. Compounding from bulk material is generally prohibited. These bulk materials are not controlled to ensure purity or that they even contain the drug (or amount of drug) on the label.

6. The scale of compounding is limited. Compounding is not intended to permit evasion of the FDA approval process for mass production and distribution of prescription medications.



Compounded products are not subject to required testing for purity, stability, concentration or efficacy.