What’s a “compounded” drug vs. an FDA approved drug?

Recently, the use of “compounded” medications has been in the news, and there has been much discussion in the veterinary world about using compounding and FDA-approved drugs. The FDA (Food and Drug Administration) regulates drug or medication use in the U.S., both for human use and veterinary use. Its role is to protect the public/consumer and help ensure that drugs available in the U.S. are safe and effective. Here are some definitions to help clarify the differences.

**FDA-approved drug** must meet rigorous testing to demonstrate safety and effectiveness before the drug is approved and available for use in the U.S. The quality of FDA-approved drugs available on the market is monitored by the FDA, including monitoring manufacturers- their facilities and their production processes. The FDA can stop production, impose fines and recall medications. Veterinarians and physicians can also report any “adverse affects” or problems with drugs that they use to the FDA. Some drugs have been taken off of the market after initial approval because significant new adverse affects have shown up after more wide-spread use of the drug.

FDA-approved drugs are labeled for a specific use and dosage and a specific species: some drugs are labeled for human use; other drugs are labeled for veterinary use in a specific animal and indication.

There are different types of drugs available in the U.S.:
1. **prescription veterinary drugs**- only to be sold/used under the direction of a veterinarian; require a prescription to be purchased by a consumer
2. **prescription human drugs**- can be used “extra-label” for animals by veterinarians
3. **OTC = “over-the-counter” drugs**- are available to consumers without a prescription; have clear labeling on their intended use: dosage, benefit of drug, side-effects, etc.

- Some drugs are available “OTC” at a lower dose for a specific use (e.g. ranitidine/Zantac® for gastric reflux in people; ibuprofen/Advil®), but as “prescription only” at a higher dose &/or different use (e.g. ranitidine for ulcer treatment; higher doses of ibuprofen for migraines/etc.); the reason for this is the OTC indication for a drug is deemed safe for people to decide to take themselves, with the labeling giving information for the consumer; whereas the “prescription only” indication requires evaluation by a physician/veterinarian first to review the need for the drug, determine a specific diagnosis, and monitor the patient
- Brand name drug vs. generic drug- both are FDA-approved drugs; when a drug is first developed, the company who did the research and obtained initial FDA approval for its use, can obtain a patent on the drug; they can then sell the drug exclusively, with their trademarked Brand name (e.g. Banamine®). The active ingredient and the amount present (e.g. flunixin meglumine for Banamine®) must be listed on the label. The active ingredient is also the **generic name** of the drug. After so many years, the patent will expire on the Brand name drug- only then can other companies manufacture that drug as a generic. A generic drug has the same active ingredient and should be bioequivalent to the Brand name drug. Manufacturers of generic drugs may also have their own Brand name for the drug. Both Brand name drugs and generic drugs have the active ingredient and the quantity present listed on the label. Sometimes there can be some difference in a generic vs. a Brand name drug (e.g. if the carrier or coating affects absorption), but they should have the same quantity of the active ingredient.

**Extra-label drug use:**
Many medications are used “off-label” or “extra-label” by veterinarians. This means that the FDA-approved drug is used on a different species, via a different route (e.g. given IV instead of intra-uterine), or in a manner that is different than what is specifically on the label. It is expensive and time-consuming
for drug companies to get FDA approval and a label for every potential use of a drug. There are often many potential beneficial uses of a drug beyond what’s on the label. Species such as llamas, and even sheep & goats, often have very few drugs with specific labels for use in them. Our patients often need and can benefit greatly from a treatment that is “off-label”. Veterinarians learn about other uses of a drug from veterinary school, research studies, publications in veterinary journals, & information presented at continuing education seminars. The veterinarian assumes the responsibility that s/he is using an “extra-label” drug in an appropriate manner. We often need to use drugs “extra-label” for our equine patients to provide optimum medical treatment.

Drug use in “food animals” (animals whose meat or milk would be consumed by people) is also regulated by the FDA. The goal is to prevent drug residues in meat or milk that could be harmful to people or contribute to antibiotic resistance. Some drugs are prohibited for use in “food animals” (can’t be used at all/no “extra-label” use is allowed). Some antibiotics and other drugs are necessary for the treatment of illness and can be legally used in food animals, but they have specific recommendations on the label for a “withdrawal time”. This is the minimum time that must lapse after a drug is administered before slaughter or the use of the milk for human consumption. This allows for the drug to be out of the animal’s system, so there will be no significant drug residue present in the food supply.

Compounding or a compounded medication:

If a medication/drug is not available as an FDA-approved drug, a medication legally can be “compounded” by a compounding pharmacy. Using a compounded medication is only allowed for a specific individual patient and must be special ordered when needed. Sometimes a special formulation, dosage or flavoring is needed to be able to administer a medication to our patients. A compounded medication may be needed in these cases. As your veterinarians, we select compounding pharmacies that we think are reliable and provide a good quality product. Compounded medications however do not go through the rigorous testing and monitoring as FDA-approved products. Testing of some compounded products has found that they don’t always contain the amount of medication as on the label. FDA-approved drugs should be used and are preferred if available. However, in some cases compounded medication is all that’s available for a particular use.

Pergolide (generic name), a drug used for the treatment of equine Cushing’s disease/pituitary dysfunction (PPID), is a good example of a drug that was until very recently only available as a compounded medication. Several years ago, this drug was available as Permax™, an FDA-approved medication for use in people with Parkinson’s disease, but was taken off the market. Thanks to a push by the AAEP, veterinarians, and horse owners, the FDA allowed the drug to be kept available to veterinarians through compounding pharmacies. Therefore veterinarians were still able to prescribe/order this medication from a “compounding pharmacy” for their patients. It’s available as flavored granules, powder, capsules, flavored treats (Gourmed’s®), or liquid (although the liquid form has a short shelf life <=30 days). This medication can often really improve the quality of life and prolong the life of horses diagnosed with PPID.

In November 2011, an FDA-approved form of pergolide that was specifically labeled for use in horses to treat PPID became available for the first time with the brand name “Prascend®. It is available as a 1 mg tablet in bottles of 60 or 160 tablets. These tablets can be dissolved in water and given orally or given whole with grain. It’s recommended to not crush the tablets & to avoid human exposure to the drug. Pregnant or lactating women should wear gloves when administering this product. The availability of Prascend® provides a high quality formulation of pergolide to help improve the quality of life of horses diagnosed with PPID. See our web site for more information on PPID & Prascend® under “equine”.

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