Conversations with a Vet

Aug 31, 2010
Your Horse's Medications, 'Extralabel' Use and the FDA
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When you think of "extralabel" use of a drug, what do you think of (and no this doesn't mean putting "extra" labels on your horse's bottle of bute to explain to your barn manager instructions for your horse's care)? Do you fully realize what goes into a bottle of your horse's medications prescribed for your horse to you by your veterinarian? Welcome to the world of the Food and Drug Administration (FDA).

The FDA originally founded in the early 1900's was the public agency charged with protecting consumers from unsanitary food products and later in the mid 1930's with protecting consumers (humans) against unsafe drugs and medical devices (via the Federal Food, Drug and Cosmetic Act-FFDCA). In 1968, the Act was expanded to cover animal drugs with the original intent to ensure drugs used in animals (mostly livestock) were safe and effective for their use and did not cause harm or toxicity to the humans who consumed the products of these treated animals (i.e milk, meat, eggs etc, note also this is why you see many of your horses drugs with the label "not for use in horses intended for food" or similar warnings). Drugs used for animals are subject to the same testing that is required for human drugs, and all drugs used in veterinary medicine must be approved the FDA. When a new product is introduced, it must go through a New Animal Drug Application (NADA) in which the researchers/drug company must show not only that it works, but that it is safe (has a wide margin of safety), that manufacturing, processing, and packaging all conform to strict guidelines of GMP and GLP (Good Manufacturing or Laboratory Practices respectively) and many other criteria. All these requirements are administered by the Center for Veterinary Medicine (CVM) of the FDA.

When a drug company develops a drug (e.g. an equine sedative) they will typically test the compound over several years. They will use in vitro (cell cultures, chemical analysis) testing then in vivo (animal testing usually laboratory rats/mice) testing, and finally they must test it for the intended use (as a sedative) on the species desired (horses). There are a battery of tests that include target animal efficacy testing, pharmacology (how long the drug lasts, how long it stays in the body, which organs it remains in etc) and toxicology testing (how much of the drug is too much and what organs are affected). Drug companies must show the FDA this information and data prior to licensing. For the drug company, this is a tremendous 'up front' investment in time and money, without any guarantee that the drug will pass all of the tests. Unlike human medicine (one species), veterinary medicine must encompass a wide variety of species in which a drug may work very well in one species but be toxic in another (e.g. cats lack certain key liver enzymes necessary for the metabolism of many drugs, e.g. acetaminophen making some of these drugs toxic in these species). In the true meaning of the FFDCA prior to 1996, the FDA required users (veterinarians) to follow strict guidelines and label directions or they could be subject to fines. Therefore, if a drug company had (e.g.) an antibiotic licensed for use in dogs only (e.g. enrofloxicin-baytril) for a skin condition it could not be used for horses for a similar condition. Also, approved human drugs (not licensed in animals) would similarly not be permitted for use in animals (note: ironically many drugs need to be tested in animals first

before used in humans) and finally compounding two approved licensed drugs was also not permitted (unless tested and applied for licensing).

These limited treatment options soon became too cumbersome, restrictive and potentially resulted in untreated or inadequately treated animals and so in 1994 Congress and the FDA approved S.340 the Animal Medicinal Drug Use Clarification Act (AMDUCA). In 1996 the FDA published regulations for AMDUCA. In October of 1996, the President signed the Animal Drug Availability Act to allow 'extralabeling' use of drugs for animals under certain conditions. These restrictions were that prescribed extralabel use could only be used for certain approved animal or human drugs for animals under certain conditions and they must be given by or on the order of a licensed veterinarian within the context of a valid veterinary-client-patient relationship. This now allowed veterinarians (and to the benefit of clients and their patients) the flexibility on treatment options under many conditions, however when potentially using these drugs for your horse's condition under which your vet may be prescribing these drugs be aware that your vet is making the best decision option based on his/her expertise on the drug and the condition of your horse. The drug if used in an 'extralabel' fashion may not have gone through (or only limitedly) the extensive safety testing in your horse for that particular condition. If you are curious if a drug is approved for use for your horse for his/her condition you can go to the FDA website (Animal Drugs @ FDA) at www.accessdata.fda.gov/scripts/animaldrugsatfda

Remember your veterinarian has your horse's health in his/her best interest and together with his/her knowledge and experience with the drug in other species or different conditions you and your veterinarian can work as a team in resolving your horse's condition knowing that you both now have the best options for treatments available. Happy trails and healthy horses.