

# AAEP NEWS

## Compounding 102

by James P. Morehead, DVM

*The AAEP Board of Directors is committed to informing the members on the legal use of compounded medications. This article follows part 1 (Compounding 101) from last month with examples to further clarify the principles.*

Federal regulations require that in order to compound a drug legally:

- **A valid Veterinarian-Client-Patient relationship (VCPR) must exist.** You cannot order compounded drugs for owners living elsewhere unless their horses are under your care in your practice.
- **The health of the animal must be threatened or suffering or death may result from failure to treat.** This is why the FDA does not allow the compounding of injectable deslorelin. You cannot make a case that the mare will die if she doesn't ovulate on time. Additionally, the FDA has mechanisms in place to allow for importation of Ovuplant. This also applies for any other drug that you may desire to have compounded. If the health of the animal is not threatened, then you cannot get it compounded legally.
- **There must be no FDA-approved, commercially available, animal or human drug that, when used as labeled or in an extra-label fashion in its available dosage form and concentration, will appropriately treat the patient.** Oral altrenogest is commercially available and is an FDA-approved product to be given daily. One may consider daily dosing inconvenient but inconvenience does not count as a reason to compound a long-acting injectable product.
- **The compounded product must be made from an FDA-approved, commercially available animal or human drug.** You should not compound phenylbutazone paste whether it's apple-flavored or at twice the concentration because it's already available as an FDA-approved product. If you do decide to compound your own phenylbutazone paste, then you are required to make it from the FDA-approved powder or tabs on the market. The FDA allows compounding when the approved product is not in the required concentration, but it is difficult to convince the FDA that your apple-flavored, compounded phenylbutazone paste at two times the normal concentration is needed for the health of the animal.
- **The product must be compounded by a licensed veterinarian or a licensed pharmacist on the order of a veterinarian within the practice of veterinary medicine.** We must remember that the pharmacist is only following



our direction and the liability falls solely on the prescribing veterinarian. Should an adverse reaction occur and you are found negligent, then 'standard of practice' claims for your defense may not be admissible. The fact that the use of compounded drug substitutes and the off-label

use of medical devices is common practice will not constitute a viable defense in a malpractice suit. The AVMA-PLIT has stated their feelings on the use of compounded medications which can be reviewed at [www.avmaplit.com](http://www.avmaplit.com).

- **The amount of product compounded must be commensurate with the need of the animal identified in the VCPR-based prescription.** You should only order the specific amount of product you need, for that particular animal, at the time you need it. You should not order excess.
- **All relevant state laws relating to compounding must be followed.** If you do not know your applicable state laws then call your State Pharmacy Board and get informed.
- **The expiration date of a compounded drug should be for the duration of therapy.** In other words, if you have a compounded product that is to be used on a horse for 30 days, at the conclusion of those 30 days, the product has expired.
- **Veterinarians cannot use compounded drugs to merely save money over other FDA-approved available products that a compounding pharmacy may claim are similar.** There are medical devices for the veterinary field that are being sold and promoted illegally for off-label use as drugs for intra-articular or intravenous use for the treatment of DJD. Claims of this nature should put you on guard and should steer you away from such compounding pharmacies for ethical and liability reasons (The AAEP is currently addressing this issue amongst the compounding pharmacies relative to their exhibition status in the annual trade show held during the convention each year).
- **The use of compounded medications is a necessary part of equine practice.** The use of compounded medications should be on an as-needed basis only, keeping on hand

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### Equine Identification, cont.

- A 134.2 Mhz microchip has been recommended by the ESWG as the preferred microchip for a couple of reasons:
  - > It is the international standard
  - > It supports a 15-digit identification number, which is what the USDA required in their NAIS plan
- Currently, the recommended microchip is unavailable in the United States; therefore, the AAEP has not made a strong push to our membership about implanting chips until this particular chip, and readers to support this chip, become readily available.
- The current microchip widely used in the United States is the 125 Mhz chip. It is believed that horses with this microchip already implanted will be “grandfathered” into the system.
- While the AAEP is part of the ESWG, our focus has always been directed towards the best interest of the horse, rather than specific chips or data storage issues.

It is important to note that the horse industry has not initiated equine identification. This has come as a result of a mandate from the USDA. If clients have concerns over animal identification, they should contact the USDA or their Congressional representative. The role of the Equine Species Working Group is merely to try to make this system workable for the horse industry with as few problems as possible.

More information can be found at [www.equinespeciesworkinggroup.com/home.html](http://www.equinespeciesworkinggroup.com/home.html).

### Board Member Profile: District IV Director James P. Morehead



The AAEP would like to welcome James P. Morehead, DVM, the new board representative for District IV, which includes Alabama, Arkansas, Kentucky, Louisiana, Mississippi and Tennessee.

Dr. Morehead received his DVM in 1983 from the University of Missouri-Columbia College of Veterinary Medicine. Between 1983 and 1986, Dr. Morehead was employed at Equine Medical Associates, Inc., in Edmond, Okla. From 1986 until 1990, Dr. Morehead worked at Rood and Riddle Equine Hospital in Lexington, Ky. Since 1991, he has been the owner of Equine Medical Associates, PSC, in Lexington, Ky. Dr. Morehead has also served as the resident veterinarian of Three Chimneys Farm in Midway, Ky., since 1999. He served as the 2004 president of the Kentucky Association of Equine Practitioners. Dr. Morehead joined the AAEP in 1984 and has been an active member, serving two terms on the Reproduction/Perinatology Committee and one term on the Infractions Committee. Dr. Morehead also served on the Purchase Exam Guidelines Task Force and chaired the Drug Compounding Task Force. In 1998, he was a member of the Ad Hoc Bony Lesions in Sale Yearlings Committee. Dr. Morehead attended the AAEP's 2002 Leadership Development Workshop, and is currently a member of the Professional Conduct and Ethics Committee and the Equine Species Working Group with the American Horse Council that is addressing the National Animal Identification System.

Dr. Morehead will serve on the board through 2009.

### Compounding 102, cont.

- what is needed now or what you would normally expect to be needed in the short-term to care for your patients.
- **Supplying an illegally compounded medication, because your client requested it, is no excuse. YOU are the responsible and liable party.**
- **Just because the FDA does not take action against a compounding pharmacy does not mean that the FDA agrees with their practices.**

The AAEP is very concerned about the continued use of illegally compounded drugs. As such, further efforts will be made to educate members on this issue in the coming months as well as control mechanisms put in place regarding the participation of certain companies involved in the AAEP Trade Show as well as advertisements in *Equine Veterinary Education*.