**Veterinary Compounding**

Compounding, consistent with the Food and Drug Administration (FDA) Extra-Label Drug Use regulations, is the customized manipulation of an approved drug(s) by a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a particular patient. Common examples of appropriate compounding in veterinary practice are mixing two injectable drugs, preparing an oral paste or suspension from crushed tablets or adding flavoring to a drug. Compounded preparations are required to be prepared from FDA-approved animal or human drugs. The FDA and federal courts have held that federal drug laws prohibit compounding from bulk chemicals or raw pharmaceutical ingredients as such compounds are unapproved new animal drugs. For more information on compounding from bulk drugs, see AVMA policies on "Compounding from Unapproved (Bulk) Substances in Food Animals" and "Compounding from Unapproved (Bulk) Substances in Non-Food Animals.

Compounded preparations are not equivalent to generic drug products. Generic drug products are FDA-approved, which requires a demonstration of bioequivalence of safety and efficacy with the pioneer FDA-approved drug product. Generic animal drug products are identified by an Abbreviated New Animal Drug Application (ANADA) number on their label or in FDA drug references. In contrast to generic drugs, compounded preparations lack FDA approval.

Veterinarians need to be aware that compounding, including formulation in a novel drug delivery system (e.g. transdermal), may impact the pharmacokinetics of a drug. This may result in drug concentrations that are above or below the therapeutic range and lead to the development of an adverse drug event, including therapeutic failure. In order to minimize the risk of adverse events associated with compounded preparations, the following actions are recommended:

1. The decision to use a compounded preparation should be veterinarian (not pharmacist) driven, and occur within a veterinarian-client-patient relationship. The veterinarian should make that decision utilizing evidence-based medicine.

2. Compounding should be implemented in compliance with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Compliance Policy Guide 608.400 titled "Compounding of Drugs for Use in Animals." Use of compounded preparations in food animals may have food safety concerns that preclude their use unless information exists to assure avoidance of violative drug residues.

3. Use of a compounded preparation should be limited to:

   a. Those individual patients for which no other method or route of drug delivery is practical; or

   b. Those drugs for which safety, efficacy, and stability have been demonstrated in the specific compounded form in the target species; or

   c. Disease conditions for which a quantifiable response to therapy or drug concentration can be monitored.

4. Use of a compounded preparation should be accompanied by the same precautions followed when using an approved drug, which include counseling of the client regarding potential adverse reactions, including therapeutic failure, and attention to the potential for unintended human or animal exposure to the drug. Further, clients should be informed that the compounded preparation
has not been evaluated by the FDA for potency, purity, stability, efficacy or safety, and client consent should be obtained.

a. Veterinarians should report suspected adverse events including therapeutic failure and quality defects involving compounded preparations to the compounding pharmacist, the State Board of Pharmacy and the FDA Center for Veterinary Medicine. Instructions for reporting adverse events to FDA can be found at the FDA website. Pharmacists should instruct pet owners to contact both the prescribing veterinarian and pharmacist immediately if a compounded preparation is associated with an adverse event, including therapeutic failure, and quality defects.

5. Veterinarians should comply with all aspects of the federal extralabel drug use regulations including record-keeping and labeling requirements and urge compounding pharmacies to do the same. The compounded preparation should be labeled that it is not FDA approved.

It is not legal for compounded preparations to be developed in large quantities and sold to third parties (including veterinarians and companies) or wholesalers for resale to individual patients. However, the AVMA asserts veterinarians should be able to legally maintain sufficient quantities of compounded preparations in their office for urgent administration needs or emergency situations.

Advertising and promotional material from the compounding pharmacy should not be interpreted as FDA assurance of proven efficacy, safety or quality.

One element in evaluating the quality of a compounded preparation is whether the compounding procedure follows the guidelines of the United States Pharmacopeia (USP). These guidelines can be found in Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations, USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations, and specific USP drug monographs if available. The USP general chapters and drug monographs define good compounding practices and provide information about compounded preparations that have acceptable strength, quality, purity, and stability to minimize patient harm due to lack of sterility, excessive bacterial endotoxins, and content errors.

Another element in evaluating the quality of a compounding pharmacy is whether the pharmacy is accredited by an independent accreditation body. For example, the Pharmacy Compounding Accreditation Board (PCAB) offers accreditation to compounding pharmacies that meet high quality and practice standards. Further information and a listing of PCAB-accredited pharmacies are available at www.pcab.org. Be aware that independent accreditation is different from association or professional training center memberships that may lack quality assurance programs and inspections.

AVMA advocates for quality assurance oversight of all compounded preparations to ensure that these preparations are prepared and evaluated in a manner consistent with current potency, purity and stability standards.