COMPOUNDING DRUGS FOR EXOTIC SPECIES

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The American Veterinary Medical Association defines a compounded drug as “...any drug that is manipulated based on a licensed practitioner’s prescription, but in accord with an FDA-approved label, to meet the medical needs of a specific patient.” Manipulation includes mixing, diluting, concentrating, flavoring, or changing a drug’s dosage. Compounded drugs lack FDA approval and have not undergone safety and efficacy testing. Examples of compounding include mixing two injectable drugs, creating an oral suspension from crushed tablets or from an injectable solution, or adding flavoring to a commercially available drug.

The concern over compounding is that manipulating a drug may alter its stability, absorption, and depletion. The compounded drug’s safety, efficacy, and concentration can not be assured because the drug has not been FDA approved or inspected. Administration of compounded drugs can potentially result in drug concentrations leading to adverse events or treatment failure. In addition, compounding from bulk (raw) ingredients may involve the use of poor quality, unregulated chemicals.

While compounded drugs are commonly administered to all species, they are often essential when treating exotic species such as birds, rodents, ferrets, and rabbits. Many exotic pets cannot take pills, and often, commercially available drugs are formulated in concentrations inappropriate for small exotic patients. Also, for exotic patients who require multiple drugs simultaneously—a situation that can be very stressful for high strung or fragile exotic pets—compounding enables the mixing of several drugs together so that they can be administered at one time. Drugs commonly compounded for exotic species include antibiotics, antifungal agents, analgesic/anti-inflammatory drugs, vitamins, gastrointestinal motility modifying agents, cardiac medications, and heavy metal chelators.

The FDA is currently reviewing the laws governing the compounding of drugs for veterinary use. The whole issue of drug compounding is currently a hotly debated legal topic. According to the Animal Medicinal Drug Use Clarification Act of 1994, compounding is a form of extralabel drug use. The Federal Food, Drug, & Cosmetic Act does not distinguish compounding from manufacturing or other processing of drugs for use in animals. The FDA’s position on veterinary compounding is most clearly stated in the 2003 Compliance Policy Guide on Compounding of Drugs for Use in Animals. At the time of this writing, the FDA is reviewing this document and promises to publish a revised guide in the future.

The current FDA guidelines state that in order for a drug to be compounded legally, the following conditions must be met:

- There must be a valid veterinarian–client–patient relationship.
- The animal’s health must be threatened, or suffering/death will result from a failure to treat.
- The compounded product must be made from FDA-approved, commercially available animal or human drugs. An FDA-approved drug is a drug whose manufacturer has demonstrated safety, efficacy, and product quality to the US FDA for the labeled indication.
- Compounding must be performed by a licensed veterinarian or pharmacist following the orders of a veterinarian.
- The compounded drug must be safe and effective.
- Veterinarians must comply with federal extra-label drug use regulations including record keeping and labeling.
- All state laws regarding compounding must be followed.

In addition to federal laws governing drug compounding, individual states also have specific regulations that vary from state to state. Some states have provisions for in-office use of compounded drugs. Such laws enable pharmacists to fill a veterinarian’s prescription for a non-commercially available compounded product only if it is to be given in the veterinarian’s office. Such laws prohibit the veterinarian from dispensing the compounded drug or selling it to other veterinarians. Other states ban in-office use of compounded products. Veterinarians should contact their state boards of pharmacy and veterinary medicine to determine specific state regulations.

FDA extra-label drug use regulations specifically permit compounding from FDA-approved drugs only. However, as the AVMA states, “Compounding for non-food animals may be necessary when no approved drug exists to treat a pet’s condition. Because of an absence of approved drugs for certain conditions, vets require compounded drugs to treat conditions in a number of different species.”

FDA compounding regulations also cover compounding from bulk drug sources. A bulk drug is an active ingredient or chemical in unfinished form intended for manufacture into a finished dosage form. Compounding from bulk pharmaceutical ingredients (other than from the nine approved ingredients listed in Appendix A of the FDA Compliance Policy Guide on Compounding Drugs) for animals is illegal. However, the FDA has traditionally allowed “regulatory discretion” for years as it relates to veterinarians and pharmacists compounding drugs from bulk ingredients for non-food animals. As the AVMA states, “…drugs compounded from bulk for non-food animals are occasionally edically necessary within a vet–client relationship when no FDA-approved drug exists... Such compounding is necessary
to preserve the well-being of many companion, exotic, and performance animals."

In sum, as the laws regarding compounding stand now, it is the veterinarian’s responsibility to determine if a prescribed compounded drug is likely to be safe and efficacious. It is the pharmacist’s responsibility to prepare compounded drugs according to the veterinarian’s prescription using compounding practices described by the National Association of the Boards of Pharmacy. Both veterinarians and pharmacists should report adverse reactions to compounded drugs to the FDA.

It is likely that the laws regarding veterinary compounding will change in the future. At the time of this writing, the AVMA has petitioned the FDA for a policy change regarding drug compounding for animals, so that veterinarians will have the discretion to compound bulk drugs to produce medically necessary products otherwise unavailable for non-food animals. The International Academy of Compounding Pharmacists has campaigned the FDA to allow compounding from bulk ingredients for non-food animals. As a result of these actions, the FDA is revising the Compliance Policy Guide on Compounding Drugs and will likely come out with new guidelines in the near future.