Compounding and Extralabel Use of Drugs in Exotic Animal Medicine

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KEYWORDS

• Avian • Compounding pharmacy • Exotic animals • Extralabel drug use (ELDU) • Extemporaneous compounding • United States Pharmacopeia (USP)

KEY POINTS

- Extralabel drug use (ELDU) is the use of a Food and Drug Administration–approved drug in a manner different from what is indicated on the approved label.
- Drug compounding is the process by which a veterinarian or pharmacist prepares a medication in a manner not stipulated on the label to create a compound specifically tailored to the needs of an individual patient. Drug compounding is one type of ELDU.
- A common reason for drug compounding in exotic animal practice is to create a formulation in a vehicle, strength, and flavor suitable for oral drug delivery to exotic animals.
- The compounding pharmacist and pharmacy are invaluable partners in maintaining a high standard of care for safe and effective drug preparation for exotic patients.
- All pertinent federal and state pharmacy and veterinary medicine laws and regulations must be strictly followed when compounding medications in the veterinary hospital and when working with compounding pharmacies.

INTRODUCTION

Extralabel drug use (ELDU) and drug compounding are vital aspects of safe and effective drug delivery to patients in exotic animal practice.[1] Drug compounding is the process by which a veterinarian or pharmacist prepares a medication in a manner not stipulated in the product labeling to create a compound specifically tailored to the needs of an individual patient. Compared with the number of drugs approved by the US Food and Drug Administration (FDA) for use in humans, the number of drugs

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approved for use in veterinary species is low.[1] Within this subset of approved veterinary medications, there is only a tiny handful of FDA-approved drugs for use in birds and other exotic animals. Even though current federal law permits veterinarians to use and prescribe drugs that are FDA-approved for human use in an extralabel fashion, most medications are only available in formulations impractical or unsafe for use in exotic pets. Compounding also allows access to medications that are not currently commercially available, such as drugs discontinued by pharmaceutical companies for economic reasons or as a result of voluntarily or federally mandated withdrawals and drugs unavailable for use due to temporary shortages.[1]

WHAT IS EXTRALABEL DRUG USE?

ELDU is the use of an FDA-approved drug in any manner different from what is indicated on the approved label. The US Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), an amendment to the US Federal Food, Drug, and Cosmetic Act of 1938, allows veterinarians to legally use and prescribe FDA-approved human and veterinary drugs in an extralabel fashion with certain important exceptions, some of which are discussed later. EDLU includes the use of the drug in a different species from that stipulated on the approved label or any changes in the dose or dosage, frequency, duration of therapy, or route of delivery as well as any manipulation of the drug itself not described in the product labeling (compounding). As an example, some avian practitioners dispense injectable formulations of enrofloxacin to be given orally to birds. This is ELDU not only because there are no FDA-approved injectable solutions of enrofloxacin for use in avian species but also because oral use is not a labeled route of delivery for injectable formulations. FDA regulations limit ELDU in veterinary medicine to situations where an animal's health is threatened or where the animal may suffer or die without treatment. A decision tree is assigned by AMDUCA for prioritizing ELDU in animal patients as follows: (1) use an FDA animal drug approved for use in the target species, (2) use an FDA animal drug approved for use in another species, (3) use an FDA-approved human drug, and (4) use a compounded preparation. A decision tree diagram for compounded preparations can be found in **Fig. 1**.

WHAT IS DRUG COMPOUNDING?

Any manipulation of a drug not described on the FDA-approved product labeling is considered compounding. Types of drug manipulation include (but are not limited to) changes to the concentration of a liquid medication (eg, diluting and concentrating), flavoring, mixing of 2 or more drugs together, and the creation of a liquid formulation for oral administration from tablets, capsules, injectable solutions, or bulk substances (active pharmaceutical ingredients [APIs]). In veterinary drug law, compounding is considered 1 type of ELDU.

INDICATIONS FOR DRUG COMPOUNDING IN VETERINARY MEDICINE

In companion animal practice, the most common reason why veterinarians use and prescribe compounded medications is the lack of availability of an approved drug that is practical and safe for administration to a patient. Another common reason for prescribing compounds for companion animals is due to drug shortages or market withdrawals of an approved product.[1] Novel, voluntarily accepted dosage forms, such as medicated treats, as well as long-acting implants and compounded topical transdermal gels, are also popular in companion animal veterinary practice.[1]