Compounding: Current Practices

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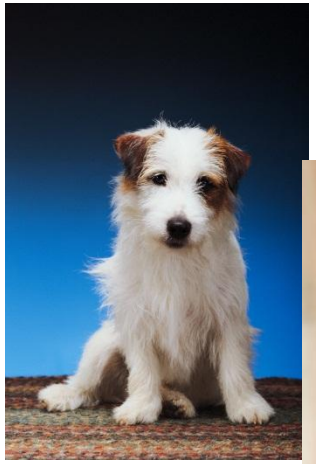
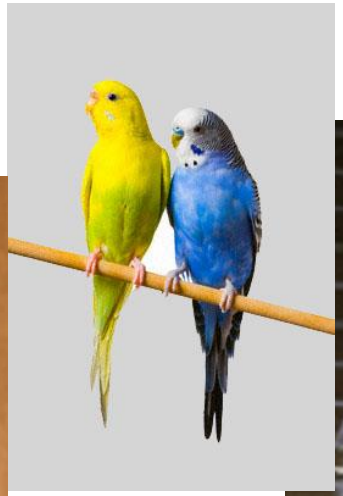
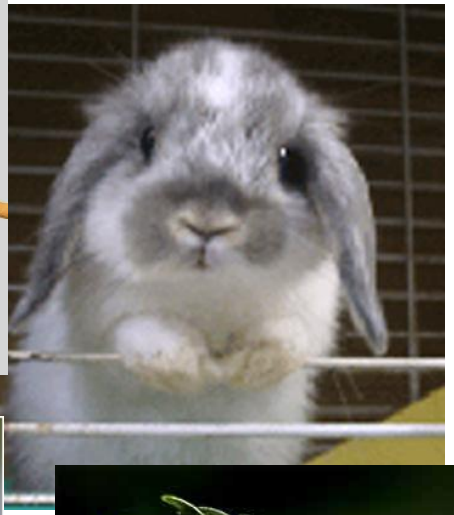
Many Species, Many Sizes, Many Conditions




Compounding: The Wider Scope

- FDA drug approval needs
  - Many species, many sizes, many conditions
- Legal homes for certain unapproved drugs
- Commercial availability
- Enforcement needs
- Education
  - Knowledge of rules
  - Understanding labels
- Drug alternatives

Needs for compounding

- When drug is commercially unavailable
  - No drug was ever approved
  - Withdrawn human drugs
  - Sponsor ceases sale
  - Temporary unavailability

Needs for compounding

- When the approved drug is inadequate for compounding
  - Concentration too low
  - Negative effects on quality
  - Patient cannot tolerate it
  - Flavoring cannot mask objectionable taste

Needs for Compounding – ex.

- Lack of appropriate dosage size
  - Available drugs too large for some cats, dogs, exotics
  - Available drugs too small for some wildlife, exotics, zoo animals
- Lack of formulation
  - liquid, transdermal, ophthalmic, etc.
- Lack of availability
  - Recalls, production problems (temporary)
  - No FDA approved drug (cisapride, metronidazole benzoate)

Inappropriate compounding

- Mimics
- Economics

Inappropriate compounding

- Compounding from bulk ingredients when the formulation can be reasonably made from an FDA approved drug
  - Compounding: any manipulation of an (approved) drug beyond that stipulated on the label
  - Manufacturing: using bulk ingredients (Active Pharmaceutical Ingredients or API) for a drug formulation. These are unapproved new animal drugs, which are subject to FDA approval (per FDA and according to federal courts).

Compounding Limitations

- Lack of studies / data demonstrating:
  - Efficacy – does the product work?
  - Stability – how long is the "shelf" life?
  - Purity – are there other ingredients in the formulation which may be harmful?
  - Potency - actual amount of drug in the formulation, is the correct amount there?
  - Sterility (ophthalmic, injectable products) – are sterile products actual sterile?

Compounding Limitations

- Lack of studies / data demonstrating:
  - Bioequivalence – similar rate and extent of drug absorption as an approved drug
    - Higher or lower peak concentrations or extent of absorption leading to toxicity or treatment failure
    - Dissolution – does the oral formulation dissolve similarly to the FDA approved drug.
    - PLO fluoxetine is only 10% absorbed compared to PO fluoxetine. Higher doses do not overcome poor absorption.

AVMA Policies

- Veterinary Compounding Policy
- Bulk Compounding policies
  - For non-food animals
  - For food animals

AVMA Resources

- AVMA Compounding webpage
- Compounding 101 video

AVMA Resources

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