# VETERINARY PHARMACY

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# VETERINARY PHARMACY


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# COMMUNITY VETERINARY PHARMACY

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# WHY

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# WHY

U.S. vs Franck's Lab

2012 and 2013 surveys conducted by 5 state Veterinary Medical Associations[5]:

- 1/3 DVMs knew of a dispensing error that occurred at a community pharmacy
- 1/10 reported the error caused harm to an animal

2015: only 4% of graduating pharmacists received any veterinary pharmacotherapy training[4]

There is a significant need for large scale programs, led by trained veterinary pharmacists, to serve as ambassadors between veterinary medicine and the community pharmacy.

Image: http://content.time.com/time/nation/article/0,8599,1893280,00.html

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# THE OPPORTUNITY

Federal Trade Commission: $24 billion currently spent worldwide on veterinary prescriptions[1]

## ANTICIPATED GROWTH: $33 BILLION BY 2020

Nearly 80 million U.S. households have pets.[2]

Trends in prescription filling indicate that animal medications are increasingly sought in community pharmacies.[3]

Recent surveys:
50% of NC DVMs send up to 75% of their prescriptions to a pharmacy
75% of compounded medications are sent to community pharmacies

AVMA: medications are no longer a significant source of income for DVMs

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# ANATOMICAL AND PHYSIOLOGICAL CONSIDERATIONS

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# ORIENTATION

## HORIZONTAL

Solid dosage forms should be given with small amount of food or 6 mL of liquid.

**Doxycyline can cause esophageal erosion**

# CEPHALIC INDEX

## BRACHYCEPHALIC

Susceptible to airway obstruction and adverse effects of drugs that cause respiratory depression

# CEPHALIC INDEX

## DOLICHOCEPHALIC

Keen olfactory ability

More “real estate” for drug administration

# SUBQ SPACE

## VASCULAR PERFUSION

Large, vascular subcutaneous space can accommodate large fluid volumes.

# GI TRACT

## LOW PH

Carnivorous diet

Increased bioavailability of weak acids

SR and XR formulations may release prematurely

# GI TRACT

## SHORTER THAN HUMANS

Significantly shorter in canines

Different dosing frequency

SR and XR formulations may not release at all

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# GI TRACT

## HORSES & RABBITS

Herbivores – developed hindgut (cecum)

Avoid certain antibiotics (e.g. macrolides)

# SALIVA

## CATS, HORSES, RABBITS

Alkaline saliva – buccal route more bioavailable with some medications

# GESTATION

**Dog = 63 days**

**Cat = 63 days**

Horse = 11 months

Cow = 10 months

Rabbit = 31 days

# VITAL SIGNS

## FEVER THRESHOLD

Humans 100 degrees

Horses 102 degrees

Dogs & Cats 103 degrees

Rabbits 104 degrees

# VITAL SIGNS

## SPECIES VARIABILITY

Heart rate

Respiratory Rate

# DRUG DISPOSITION

## DISTRIBUTION

Body composition

Protein binding

Blood volumes

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# HORSES & RABBITS

## ANTIBIOTIC CHEAT SHEET

**GOOD:**

Sulfas

Quinolones

Chloramphenicol

Metronidazole

**BAD:**

Beta-lactams

Macrolides

Lincosamides

Note: horses and rabbits are also exquisitely sensitive to glucocorticoids.

Corticosteroids = BAD

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# METABOLISM

## GLUCURONIDATION - CATS

Acetaminophen
Opioids
BZDs
Steroids
Salicyclates
NSAIDs

# METABOLISM

## DIAZEPAM - CATS

Oral diazepam can cause fulminant hepatic failure. Avoid chronic therapy and check serum transaminase levels 5 days after starting.

# METABOLISM

## ACETYLATION - DOGS

Dapsone
Hydralazine
Isoniazid
Procainamide
Sulfonamides

# ELIMINATION

## SPECIES VARIABILITY

More acidic urine pH

Significantly higher GFR

# ELIMINATION

## BIRDS & REPTILES

Renal portal system

Nephrotoxic agents (aminoglycosides)

Renally eliminated meds (cephalosporins)

# PHARMACOGENETICS

## WHITE FEET, DON'T TREAT

**Herding dogs**: ABCB1 genetic polymorphism
Caution: loperamide

Cats: ABCG2 P-gp pump
Caution: enrofloxacin

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# DOGS

## PHARMACOKINETICS / DYNAMICS

Dogs have nearly 30% more blood/kg than humans do, which can affect drug concentrations in the blood.

Dogs have a faster glomerular filtration rate, so renal elimination of drugs may be more rapid.

## OF NOTE

Levothyroxine may be x10 (or more) than human doses. Also frequency may be BID

Seizure medications may be dosed much higher than what is seen in human medicine.

Some antibiotics (e.g. ciprofloxacin) may be dosed much higher than human doses.

Different breeds of dogs may have varying pharmacokinetics for a given drug.

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# CATS

## PHARMACOKINETICS / DYNAMICS

Cats are deficient or limited in several metabolic pathways:

- Glucuronidation
- Hydroxylation
- Demethylation

Cats may use different hepatic CYP isoenzymes to metabolize drugs.

## OF NOTE

**Cats may not adequately convert prednisone to prednisolone.**

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# TOXICOLOGY PRINCIPLES

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pet poison control

HOME SEARCH EMERGENCY CHECKLIST ABOUT CONTACT

If you have any reason to suspect your pet has ingested something toxic, please contact your veterinarian or the Animal Poison Control Center's 24-hour hotline at **(888) 426-4435**.

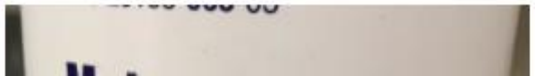
**For more information, please click any category or specific toxin shown below.**

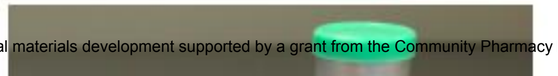
ALL | FOOD | HERBALS | HOUSEHOLD PRODUCTS | HUMAN PRESCRIPTIONS | ILLICIT & RECREATIONAL DRUGS | OTC MEDICATIONS | PLANTS

# PET POISON CONTROL









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# TOXICOLOGY PRINCIPLES

Contact veterinarian or Animal Poison Control Center!

**1-888-426-4435**

Hydrogen peroxide 3%

Dogs: 2.2 mL/kg PO; max 45 mL/dog; may repeat once in 10-15 minutes if needed

Not reliable emetic in cats

Animals that cannot vomit:

- Horses
- Rabbits

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# TOXICOLOGY: DOGS

Do not flavor compounds with artificial flavors of known toxins!

## XYLITOL = HUMAN ORAL GABAPENTIN FORMULATION

- Sulfonamides: keratoconjunctivitis sicca
- Estrogens: myelosuppression – counsel about transdermal medications
- NSAIDS (e.g. ibuprofen, naproxen, aspirin): GI bleeding, renal toxicity
- Ethanol (solvent, preservative): ataxia, coma
- Xylitol (common sweetener, sugar alcohol): life-threatening hypoglycemia, acute hepatic failure
    - Note: Xylitol may also be found in orally dissolving tablets
- Onions/garlic/leeks/chives: lethargy, hemolytic anemia
- Phenobarbital: hepatotoxicity

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# TOXICOLOGY: CATS

**Acetaminophen** (as little as ½ 80-mg chewable tablet): methemoglobinemia, death

## TOPICAL = SYSTEMIC

- NSAIDS: renal toxicity
- Dry-pilling (e.g. doxycycline): esophageal erosion and strictures
- Propylthiouracil: immune-mediated hemolytic anemia
- Alpha lipoic acid: death
- Azo dyes: methemoglobinemia
- Benzoic acid derivatives
- Permethrin: dog formulations can not be used on cats!
- Oral diazepam: fatal fulminant hepatic necrosis
- Propylene glycol (>10% volume)

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# TOXICOLOGY: LARGE ANIMAL AND EXOTICS

- Ferrets – rubber (plungers on syringes!), estrogens, fiber

## NSAIDS + PREDNISONE = STOMACH BE GONE

- Horses
  - Some oral antibiotics, corticosteroids, NSAIDs
  - Drugs that slow or delay gastric rate: opioids, anticholinergic agents
  - Plants: red maple, fescue
- Birds
  - Avoid topical dosage forms
  - No oil vehicles (aspiration risks!)
  - Avoid: corticosteroids, alcohols, sodium chloride

Rabbits – some oral antibiotics, corticosteroids

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# COMMUNITY PHARMACY TOXINS

- 5-HTP
- Acetaminophen
- Alpha lipoic acid
- Aspirin
- Caffeine
- Dextromethorphan
- Ibuprofen
- Imidazolines (Afrin, Visine)
- Iron
- Naproxen
- Phenazopyridine
- Phenylephrine
- Pseudoephedrine
- Vitamin D
- Tea tree oil

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# VETERINARY PRESCRIPTIONS

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# VETERINARY PRESCRIPTIONS

- Pet owners are “clients.” The pet is the “patient.”
- **SID (*semel in die*) means “once daily”**
- Veterinarians rarely prescribe PO liquids as per 5 mL
  - Ex: Amoxicillin 250 mg/5 mL suspension may be prescribed as 50 mg/mL
- Veterinary Intake Forms
  - Weight-based dosing
  - Patient and Client should be on prescription
- Dispensing
  - Algorithms and checklists for dispensing
  - Auxillary label cheat sheets
- Veterinarians must be entered correctly as “D.V.M.” in software

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# KEY INFORMATION

- What applies to humans may not be relevant or valid for veterinary patients.
  - Refer to veterinary drug references (Plumbs, Saunders)
  - Veterinary Medical Guides
  - Disease State Guides

- NABP 2015: Pharmacies that provide care for non-human patients must have access to veterinary information.
  - C.E. Opportunities (e.g. PowerPak by G. Davidson)

- All insulin products require a prescription when used in animals.

- Veterinary-only drugs could potentially interact with human-labeled drugs being concurrently administered.
  - Interaction checkers can be unreliable in veterinary medicine.
  - Some drug-drug interactions are **intentional** (e.g. **ketoconazole + cyclosporine**)

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# KEY INFORMATION

- Do not substitute drug products (especially insulins) or change dosage forms without first contacting the veterinarian.
    - 10% of DVMs have reported that harm has been caused to an animal when an outside pharmacy made an unauthorized substitution.

- **It is ILLEGAL to recommend an OTC product or supplement for use in an animal patient.**
    - **Must have prescription from veterinarian.**

- **Do not ask a veterinarian for their NPI number.**
    - It is illegal for veterinarians to have one.
    - DEA number is not an appropriate substitution.
    - State license number is acceptable for verification.

- Performance animals: counsel appropriately for adverse drug reactions

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# KEY INFORMATION

- ADR = Ain't Doin' Right
  - Valuable information from client

- Even if animal does not go outside, heartworm medication is absolutely necessary. Owners bring the environment in with them!

- Administered volumes should be limited in some animals (e.g. birds, ferrets, rabbits).

- Levothyroxine
  - 0.8 mg is an appropriate dose. Human dosage forms are typically not suitable (need for multiple tablets).
  - Thyro-Tabs Canine – FDA approved
  - May be taken with or without food. Importantly medicine must be given same way each day to minimize variations in serum levels.

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# KEY INFORMATION

- Diltiazem – choice of dosage form depends on frequency
  - Can manipulate dosage forms to provide smaller doses for cats
  - Open extended-release capsules to expose inner tablets; repackage beads into smaller doses
  - Ex: contents of a 120 mg CD capsule can be used to fill the small end of a #4 capsule to achieve ~ 45 mg CD diltiazem per dose

- Human insulin syringes may over or under-dose patient.
  - Refer to insulin “cheat sheet.”
  - Vetsulin should be dispensed with U-40 syringes.
  - Counsel the owner to SHAKE the insulin prior to dosing.
  - Note: Blood samples should be taken from the marginal ear vein or paw pads.

- Clavamox (veterinary-labeled product) contains differing ratio of amoxicillin : clavulanate than human-labeled products.
  - Clavamox ratio = 4:1
  - Human-labeled products are expressed in terms of amoxicillin (only) while veterinary products are expressed in terms of both compounds.

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# VETERINARY-ONLY PRESCRIPTION DRUGS

**Antimicrobial Agents**

Cefovecin (Convenia)

Enrofloxacin (Baytril)

Marbofloxacin (Zeniquin)

Pradofloxacin (Veraflox)

Florfenicol (Nuflor, Osurnia Otic)

Tilmicosin (Micotil, Pulmotil)

Tylosin Tartrate (Tylan)

**NSAIDs**

Carprofen (Rimadyl)

Deracoxib (Deramaxx)

Firocoxib (Previcox, Equioxx)

Robenacoxib (Onsior)

Flunixin meglumine (Banamine)

Phenylbutazone (Butazolidin)

**Hormonal Drugs**

Diethylstilbestrol (DES)

Estriol (Incurin)

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# VETERINARY-ONLY PRESCRIPTION DRUGS

**Phenylpropanolamine (Proin)**
– urinary incontinence in dogs

**Trilostane (Vetoryl)**
– hyperadrenocorticism in dogs

**Peroglide mesylate (Prascend)**
– PPID in horses

**Oclacitinib maleate (Apoquel)**
- Allergic dermatitis and atopic dermatitis in dogs

**Maropitant (Cerenia)**
- Prevention of acute vomiting and vomiting due to motion sickness

**Cisapride**
- Prokinetic

**Potassium bromide**
- Epilepsy in dogs
- Caution: salt intake

**Pimobendan (Vetmedin)**
- Congestive heart failure in dogs and cats

**Clenbuterol (Ventipulmin)**
- COPD or heaves in horses

**Domperidone (Equidone)**
- fescue toxicosis in horses
- diagnostic tool for PPID in horses
- prokinetic agent in dogs and cats

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# REGULATORY AND ETHICAL ISSUES

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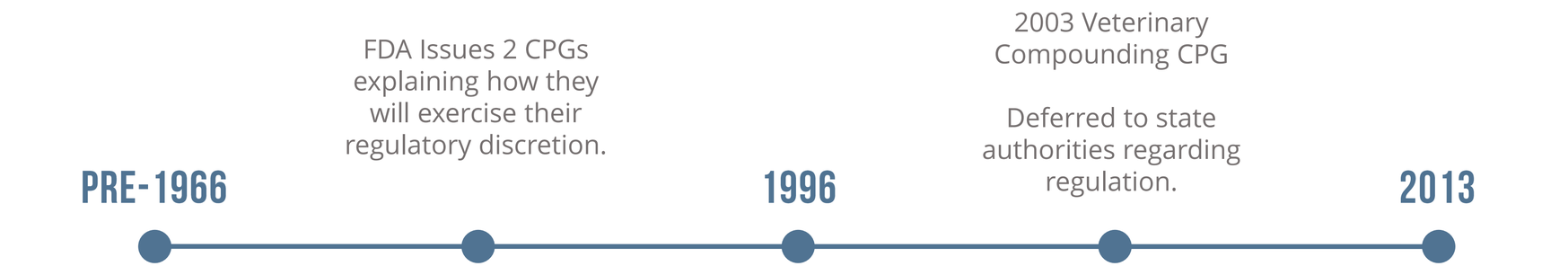
# TIMELINE REGULATORY CONSIDERATIONS

## VETERINARY PHARMACY



### PRE-1966

All extra-label drug use considered illegal.

DVMs could only use meds approved for indication, species, dose, route and duration on label.

### 1996

FDA Issues 2 CPGs explaining how they will exercise their regulatory discretion.

AMDUCA legalized extra-label use.

Legalized compounding since compounds are always extra-label use.

Did not address compounding from bulk chemicals.

Prohibited use of certain drugs in food animals.

### 2003

2003 Veterinary Compounding CPG

Deferred to state authorities regarding regulation.

### 2013

DQSA

Followed NECC Tragedy.

Oversight of human compounding. No veterinary compounding guidance.

FDCA; 503a updates, 503b Outsourcing Facility, cGMP requirements

CPG = Compliance Policy Guide; internal guidance documents for FDA inspectors
AMDUCA = Animal Medicinal Drug Use Clarification Act
DQSA = Drug Quality and Securities Act

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# BULK COMPOUNDING

## KEEP ADEQUATE RECORDS TO DEMONSTRATE COMPLIANCE!

1. Compounding performed by or under supervision of licensed pharmacist.

2. Drug dispensed after receipt of valid prescription for individually identified animal patient.

3. Species of animal identified on prescription and statement that compounded drug cannot be made from FDA approved drug.

   FDA Drug Shortages:
   https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

4. Label identifies species of animal patient, name of animal patient and name of owner/caretaker.

5. Compounding ONLY for non-food animals.

6. Bulk drug must be acquired from FDA registered supplier with valid certificate of analysis.

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# BULK COMPOUNDING

## KEEP ADEQUATE RECORDS TO DEMONSTRATE COMPLIANCE!

**7** Drug must be compounded in compliance with USP chapters 795 and 797.

**8** Drug cannot be sold or transferred – can only be dispensed to identified animal patient.

**9** Adverse effects reported to FDA within 15 days.

FDA Form 1932a

**NC** Veterinary office may administer compounded product but is prohibited from dispensing or reselling products.

Label Products “Not For Resale.”

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# 2015 – FDA DRAFT GUIDANCE FOR INDUSTRY #230

- Anticipatory compounding – based on historical activity over a 14 day period in previous 6 months
- Species, patient name, caretaker information on Rx and label
- **Bulk drugs NOT to be used in food producing animals**
  - **High priority for FDA!**
- Prescriber statements:
  - Why bulk vs. FDA-approved product?

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# NON-FOOD ANIMALS

## FLOW CHART FOR EXTRA-LABEL DRUG USE


Identical human product can be used for the sole reason of cost.

Use before compounding unless:

- Drug isn't available (drug shortage)
- Incorrect strength
- Unacceptable dosage form
- Valid reason why product isn't clinically appropriate

Use approved product as source of active ingredient when possible unless:

- Allergic reaction
- Excipients would adversely affect compound

Bulk ingredients should be obtained from reputable source.

Should be accompanied by certificate of analysis.

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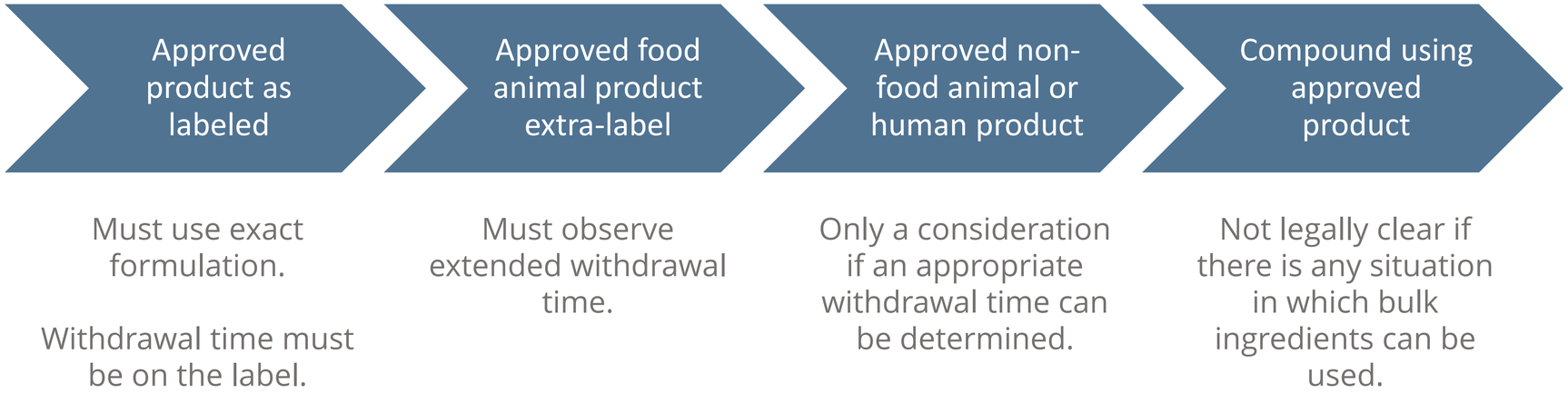
# FOOD ANIMALS

## FLOW CHART FOR EXTRA-LABEL DRUG USE




FARAD (Food Animal Residue Avoidance Database) – withdrawal times resource
Food animal classification is based on the intended use of the animal, not only the species.
No law is in place designating species that are always considered food animals.

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# FOOD ANIMALS

- Generally considered food animals by FDA:
  - Cattle, swine, chickens, turkeys, sheep, goats, ornamental fish
- Also consider non-meat food sources:
  - Milk, eggs, honey
- Withdrawal times must be calculated
  - Expressed in terms of days for meat and eggs
  - Expressed in hours (multiples of 12) for milk

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# OTHER LEGAL CONSIDERATIONS

- Valid veterinarian-client-patient relationship must exist.
- Compounds must be clinically different from the commercially available product.
- Labeling appropriately: not for use in food-producing animals.
- AVMA Position on compounding:
  - Counsel regarding potential adverse reactions
  - Accreditation (PCAB, ACHC, etc)
- USP <800>
- Association of Racing Commissioners International (ARCI)
- Immunizing pharmacists: humans only

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# OTHER LEGAL CONSIDERATIONS

## FAIRNESS TO PET OWNERS ACT

Veterinarians required to provide pet owners with a copy of pet's prescriptions, whether or not requested and prior to offering to fill or dispense the medication.

Veterinarian may not require payment for the prescription or require the pet owner to sign a waiver or disclaim liability.

Currently in committee: www.congress.gov/bill/115th-congress/house-bill/623

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# NON-STERILE COMPOUNDING

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# COMPOUNDING OVERVIEW

- Oral suspensions
    - Oil – longer BUD, aspiration risks, stability concerns
- Oral pastes
- Oral capsules
- Chewable treats
    - No propylene glycol in cats
- Transdermal gels
    - Counsel
- Suppositories
- Poloxamer 407 Gel
    - Otic application – caution: nonsterile
- Polyox 301 Bandage
    - Dispense with water applicator
- Medicated feed

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# FORMULA AND COMPONENT SELECTION

- Verified and peer-reviewed formulas
- United States Pharmacopeia (USP)
  - *USP Compounding Compendium*
  - Formulas developed for veterinary use
- Professional Compounding Centers of America (PCCA)
- Primary peer-reviewed literature
- *International Journal of Pharmaceutical Compounding*
- Trissel's Stability of Compounded Formulations
- USP compounding defaults when no information is available

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# USP <795> BEYOND-USE-DATE DEFAULTS

| Compounded Preparation | Beyond-Use-Date | Examples |
|---|---|---|
| Water-Containing Oral Formulations | 14 days, stored at controlled cold temperature | Solutions, suspensions, pastes |
| Nonaqueous Formulations | Earliest expiration date of any API or 6 months, whichever is earlier | Capsules, fixed oil suspensions |
| Water-containing Topical/ Dermal and Mucosal Liquid Semisolid Formulations | 30 days | Ointments, gels |

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# TOXICITY CONCERNS

## EXCIPIENTS, FLAVORS, PRESERVATIVES AND DYES TO AVOID

- Alcohols – dogs, cats, birds
- Azo dyes – cats
    - Use cyanocobalamin for color tracer
- Benzocaine, benzoic acid derivatives – cats
- Cremophor – dogs
- Polysorbate 80 – dogs
- Xylitol – dogs, birds

- Flavors:
    - Avocado – birds
    - Chocolate – dogs, birds
    - Garlic, onions – dogs, cats
    - Grapes, raisins – dogs

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# FLAVOR – KEY POINTS

- Flavor preferences correlate strongly with natural diets.

- Cats – not interested in sweet flavoring
  - Lack sweet taste receptors on tongues
  - Can leave out stevia and other sweeteners when compounding

- Dogs – marshmallow can help with bitter tasting meds (eg. clindamycin)

- Birds – prefer color and movement over flavor (gummy worms are great!)
  - Chickens LOVE blueberries.

- Horses – surprising flavor preferences from a recent study
  - Apple NOT preferred. Fenugreek top ranked.
  - Peppermint – use caution with flavoring. Very concentrated.
  - Caution with molasses. Can inactivate some fluoroquinolones.

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# FLAVOR – KEY POINTS

- Rule of thumb: add no more than 3% final volume.
- Check flavor guides.
- Oil vs. water
- Do not use flavoring powders.
- Flehman's reaction (cats, horses) could make future medication administration impossible.
- **Always ask the animal's caregiver!**
- MUST consider impact on drug stability and bioavailability when flavoring compounds.
    - Test pH! (Grape flavoring is notorious.)

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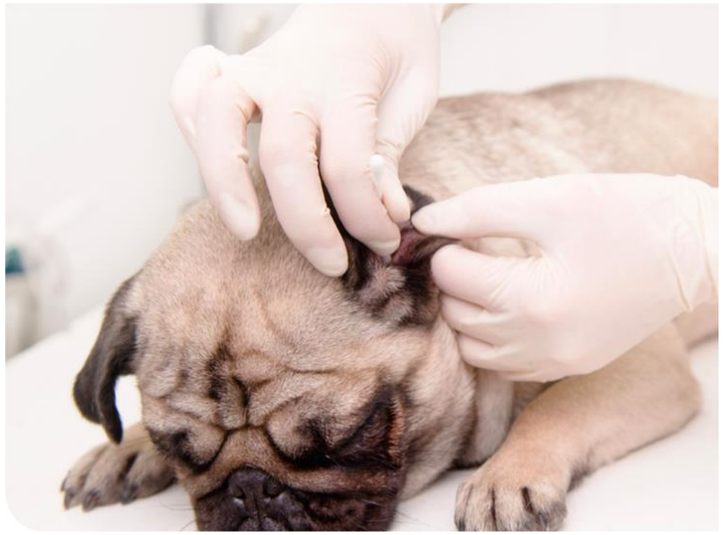
# POLOXAMER 407 GEL

- Thermo-reversible
  - Cold = liquid
  - Warm = solid/gel
- Water soluble – avoid water 10-14 days
- Holds drug at site of action
- Quickly gels, will normally absorb over 3-5 days.
- Routes: otic, rectal, ophthalmic, topical, nasal, injectable
- Otic application – do not use if tympanic membrane is ruptured!
- Commonly 20-30% gel
  - 20% for large powder volumes
  - 30% for otic application
- Routinely administered by vet
- Dispense 2 doses
- Do not refrigerate



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# POLYOX 301 BANDAGE

- Only available from PCCA at this time.
- Originally developed as oral mucosal bandage.
- Adheres to wet wound surface very well.
- Great for hard to bandage areas.
- Sloughs off after several hours – similar to changing bandages
- Does NOT interfere with healthy tissue growth.
- Generally 1% antibiotic, 1% antifungal, 0.1% steroid

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# TRANSDERMAL GELS

- PLO = Pluronic Lecithin Organogel
- Make in store OR order pre-made (caution)
- If making in store – must sit overnight; plan ahead!
- Primarily used in cats.
- Caution drugs with low therapeutic index.
- Not for systemic antibiotic absorption.

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# ADDITIONAL CONSIDERATIONS

- Refills – counsel!
  - Sync patients when possible.
- Do not compound flea and tick heartworm preventatives.
- Itraconazole – let DVM know if you are using powder, not considered efficacious
- Metronidazole
  - Available as HCl or benzoate. Benzoate preferred for PO medications (less bitter and metallic tasting)
  - Don’t use benzoate in cats unless DVM specifically says to. Due to metabolic limitations the drug can accumulate, causing toxic effects.
  - Multiply dose by 1.6 to get equivalent benzoate dose.
- Methimazole – make in 2.5 mg increments if possible, makes dose adjustments easier

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# ADDITIONAL CONSIDERATIONS

- Potassium Bromide
  - Can use sodium bromide instead but alert DVM
  - Do not use broth or bouillon bases (sodium content)
  - Caution owners about dogs drinking salt water at the beach!
  - Polyuria, polyphagia and weight gain are common.
  - Regular follow-up at the DVM for therapeutic drug monitoring is absolutely necessary!

- Do not just pull drugs off the shelf for compounding. Think! (eg. methylcellulose)

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Educational materials development supported by a grant from the Community Pharmacy Foundation.

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Educational materials development supported by a grant from the Community Pharmacy Foundation.