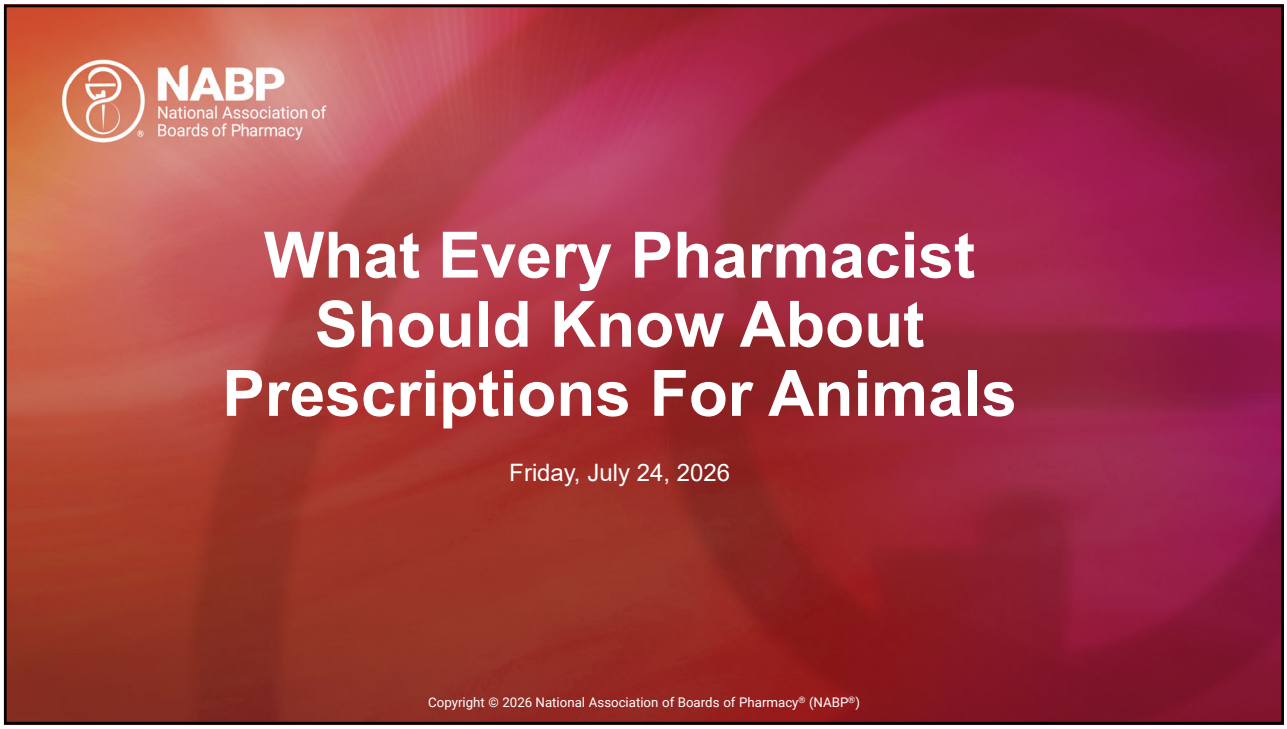

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Financial Disclosures

Gigi Davidson declares that she does not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this continuing pharmacy education (CPE) activity within the past 24 months.

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What Every Pharmacist Should Know About Prescriptions For Animals

Gigi Davidson, BSPharm, DICVP, FACVP, FSVHP
CEO, VetPharm Consulting

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July 24, 2026

4

Financial Disclosures

Our speaker Gigi Davidson and the NABP staff involved in the planning of this activity do not have any current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this CPE activity within the last 24 months.

Gigi Davidson is a member of the USP Compounding Expert Committee, but all opinions expressed in this activity are solely her own.

"I, Gigi Davidson, declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria."

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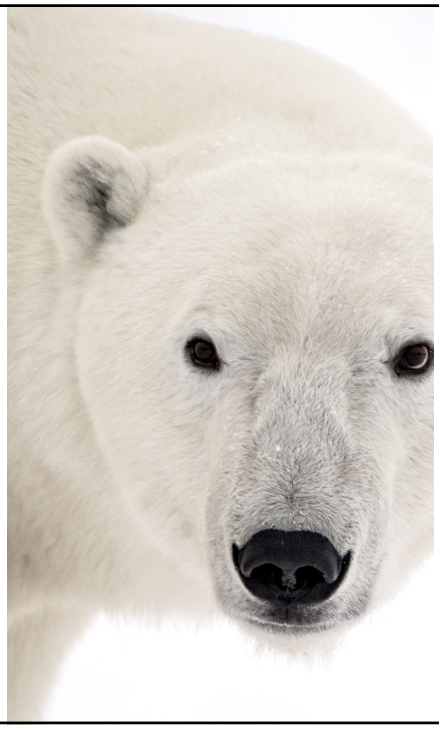


Learning Objectives

At the conclusion of this program, the participating pharmacist or technician will be able to:

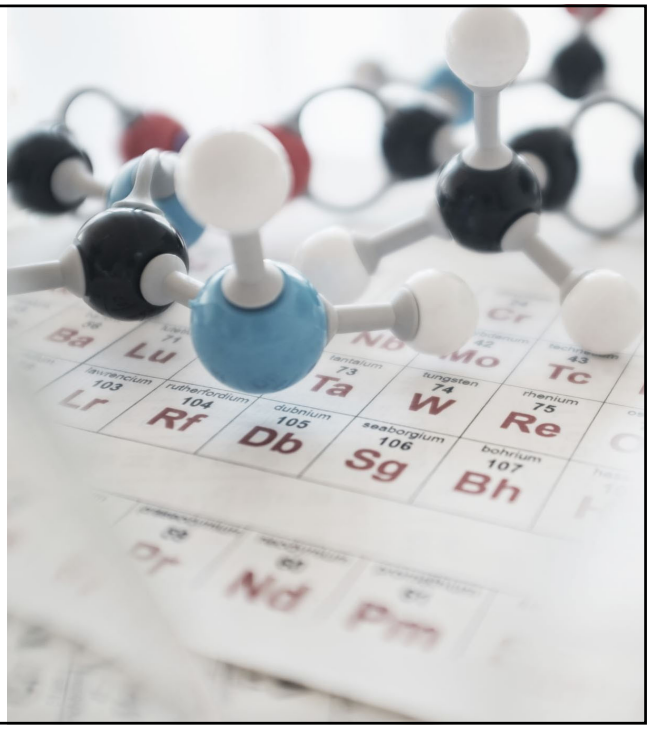
1. Discuss the **processes used to verify** veterinary prescriptions.
2. Review **legal boundaries** for dispensing and compounding drugs for animal patients.
3. Explain the various **categories for compounding with bulk drug substances for animal patients** as described in Guidance for Industry #256.
4. Describe **excipients and drugs that may be toxic** to animal patients.
5. List **veterinary-only drugs** that are not used in human medicine.
6. Outline **key criteria for evaluating veterinary drug information formularies**.

6

What Is the Likelihood You Will Be Asked to Dispense a Prescription for Animals?

- 77% of Pharmacists Routinely Serve Animal Patients*
  - Chains
  - Online Pharmacies
  - Independent Community Pharmacies
  - Hospital Pharmacies (employee scripts for their pets)
  - Nuclear Pharmacies
  - Home Infusion Pharmacies
  - Clinical Niche Specialty Pharmacies (eg, oncology, transplant, etc)

*Sorah, E. and Davidson, G., 2015, June. Royal K. Dispensing errors for non-human patients in the community pharmacy setting: A survey of pharmacists and veterinarians. In Poster presented at: Society of Veterinary Hospital Pharmacists, 34th Annual Meeting.
*Mingura, M., 2017, June. Community pharmacists and veterinary prescriptions: An analysis of prevalence, type, training, and knowledge retention. In Poster presented at: Society of Veterinary Hospital Pharmacists 36th Annual Meeting.]



7

Navigating Veterinary Prescriptions

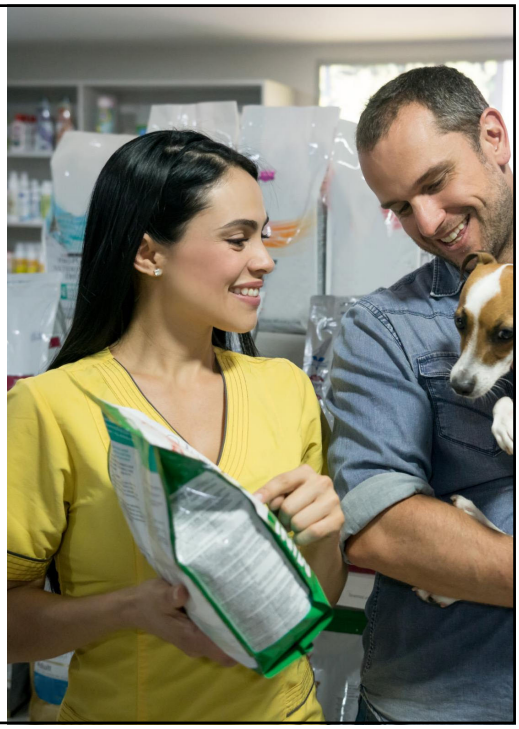
How will you verify the prescription details?

How will you identify the regulatory boundaries?

How will you understand veterinary-only drugs and dosages?

How will you know which excipients/ ingredients are safe for a given pet patient?

How will you counsel the pet owner?



8

How Will You Verify The Prescription?

Verify the legal foundation of the prescription:

All of the requirements for a human prescription, plus:

- **Legitimate prescriber** (state veterinary license verification – **not** National Provider Identifier (NPI)
  - NPI is for Medicare/Medicaid; veterinarians may not prescribe for humans
  - Written by a Doctor of Veterinary Medicine (DVM) or Veterinariae Medicinae Doctoris (VMD- from Univ Pennsylvania); MDs/DOs may not prescribe for animals
  - State license verification through state veterinary medical board
  - Do not ask for DEA numbers for non-controlled substance prescriptions
- **Valid Veterinarian-Client-Patient Relationship (VCPR)**

9

How Will You Verify the Prescription?

VCPR:

- Requires that the veterinarian has **sufficient knowledge of the animal** to make clinical judgments, **typically** through a recent examination or timely visit to the location where the animal is kept.
- The veterinarian assumes **responsibility for medical decisions,** while the **client (owner or caretaker) agrees to follow the veterinarian's instructions.**
- Most federal and state laws **require a valid VCPR before prescriptions** for animal drugs and compounded preparations can be prescribed, dispensed, or authorized for extra-label use under the Animal Medicinal Drug Use Clarification Act (AMDUCA).
- Pharmacists should recognize that VCPR requirements **vary by state, particularly regarding telemedicine,** and may affect the legality of prescribing and dispensing veterinary medications.

10

How Will You Verify The Prescription Details?

Learn to Speak "Veterinarian"

- Be familiar with **veterinary terminology and context**
- **Examples of unique abbreviations:**
  - SID = once daily
  - OD = once daily or right eye
  - EOD = every other day
  - OTM = oral/transmucosal
  - IM = intramuscular or intramammary
  - IU = international units or intrauterine
  - WDT = withdrawal time (this means for a food-producing animal!)
- **Unusual dosing constraints:**
  - Mg/kg dosing "divided BID, TID, QID, etc" = total daily dose by weight divided into equal doses by frequency

11

How Will You Verify the Prescription Details?

Verify the clinical information:

- Don't extrapolate from human pharmacology to verify drug and dosing—use a veterinary drug information resource
- **Examples:**
  - **Levothyroxine** dosing is considerably higher and more frequent in dogs (22 mcg/kg/dose q12h) than in humans (1.6 mcg/kg/dose q24h) = **14X higher!**
  - **Cisapride** was removed from the human market for safety reasons and fatalities from drug interactions, but is commonly used safely in cats
  - **Insulins and dosing are species-specific,** and human insulins must not be substituted without a veterinarian's order
- How do I determine this for drugs I am not familiar with?

12

Evaluating a Veterinary Drug Formulary

	Weight	What "excellent" looks like
Editorial governance & transparency	10	Named editorial board with veterinary pharmacology expertise; documented peer review; update cadence & "last reviewed" dates on every monograph; clear errata process; conflict-of-interest statement.
Evidence quality & citations	15	Primary citations (current drug labels, CVM/Green Book items, consensus guidelines, peer-reviewed PK/PD), dated and specific; strength of evidence noted; ELDU statements supported by data rather than hearsay.
Species breadth & depth	10	Meaningful coverage across dogs, cats, horses, common exotics, food animals and (if relevant) bees/aquaculture; life-stage and breed notes where dosing differs; physiologic states (pregnancy, lactation, renal/hepatic disease).
Dosing rigor & clarity	10	Weight-based dosing (mg/kg) with justified ranges; max dose caps where safety matters; intervals stated as q24h/q48h (not ambiguous abbreviations); route-specific guidance (PO vs OTM vs SQ, etc.); sentinel warnings (e.g., "cats: do not exceed…").
Food-animal compliance (residues & withdrawals)	8	Meat/milk/egg withdrawal times or explicit "no ELDU" where applicable; clear links to residue resources; VFD/VCPR context where relevant; species/product specificity.
Regulatory accuracy (ELDU, prohibitions, labeling)	8	AMDUCA rules correct; prohibited drugs lists accurate; compounding vs approved-product hierarchy stated; office-stock limitations described correctly.
Safety content	10	Contraindications, clinically meaningful interactions, organ-impairment adjustments, high-alert drug flags, overdose management, and monitoring parameters (what to check, when, and target ranges).
Formulation & compounding guidance	7	Approved products listed first; when compounding is appropriate, provide specific concentrations, beyond-use dates with justification, excipient cautions by species (e.g., xylitol, propylene glycol, benzyl alcohol).
Practical use tools	5	"How to give" tips by species/route (OTM in cats, intramammary technique, in-water dosing), client-friendly phrasing, syringe volumes, dilution/prep instructions, and handling of hazardous drugs.
Update cadence & version control	7	Routine content refresh (e.g., quarterly), visible version history, deprecation notes when guidance changes.
Usability & accessibility	5	Fast search; synonyms/brand-generic mapping; consistent units; printable monographs; mobile-friendly; accessibility for color/contrast; abbreviations minimized or explained.
Integration & interoperability	3	Export to PDF/CSV; stable links/DOIs; optional EHR order sentences; cross-links to calculators (renal dosing, infusion rates).
Independence & bias controls	2	Funding sources disclosed; no promotion skewing content or placement.

Score: 85–100 exemplary (publishable standard), 70–84 strong (safe for routine clinical use; minor gaps), 50–69 baseline (usable with caution; verify gaps), <50 weak

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How Will You Understand Veterinary-Only Drugs and Dosages?

- Some drugs are labeled **only** for use in non-humans
  - Enrofloxacin, Marbofloxacin, Orbifloxacin
  - Carprofen, Grapiprant, Firocoxib, Robenicoxib
  - Cefovecin, Ceftiofur
  - Trilostane
  - Pergolide
  - Pimobendan
- These drugs are not labeled for humans because they:
  - Failed the human R&D process
  - Are toxic to humans at therapeutic doses
    - Enrofloxacin causes visual and auditory hallucinations in humans
    - Carprofen causes photolytic dermal necrolysis
    - Cefovecin does not bind significantly to human plasma proteins, thereby eliminating the long-acting effect

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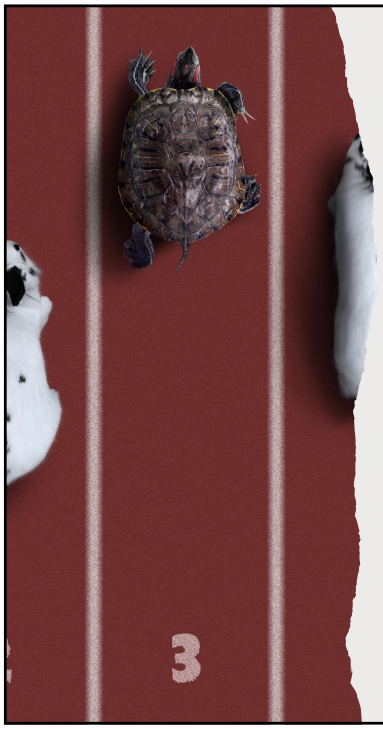

How Will You Identify the Animal Drug Regulatory Boundaries?

15

Veterinary Regulatory Lines

- AMDUCA
- FDA Guidance for Industry #256 (GFI #256)
- USP Compounding Standards
- State Pharmacy Practice Act(s)

16

Animal Medicinal Drug Use Clarification Act (AMDUCA)

- Enacted 1996
- Legalized extralabel use (ELDU) of animal drugs under certain conditions:
  - Companion animals (dogs, cats, horses, exotics, etc)
  - Food animals with restrictions and a prohibited list for ELDU (cattle, swine, chickens, turkeys, honeybees, food fish, etc)
  - Compounding (with FDA-approved products only as starting ingredients)
- Allowed veterinarians to legally use human drugs in animals
- Did not address compounding with bulk drug substances (BDS) directly (because BDS have no FDA-approved "label")
  - Only implied: "nothing in this part shall be construed as permitting compounding from bulk drugs"

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AMDUCA

- Boundaries:
  - Do not dispense drugs in an extralabel fashion to food-producing animals
    - ELDU Prohibited List for Food Producing Animals
  - Do not dispense medicated feeds or water mixes that contain antimicrobials for food-producing animals
    - Requires a Veterinary Feed Directive (not a prescription) from the veterinarian
    - VFD distributors must be registered with FDA
  - Do not compound with bulk drug substances (APIs) without complying with FDA Guidance for Industry #256

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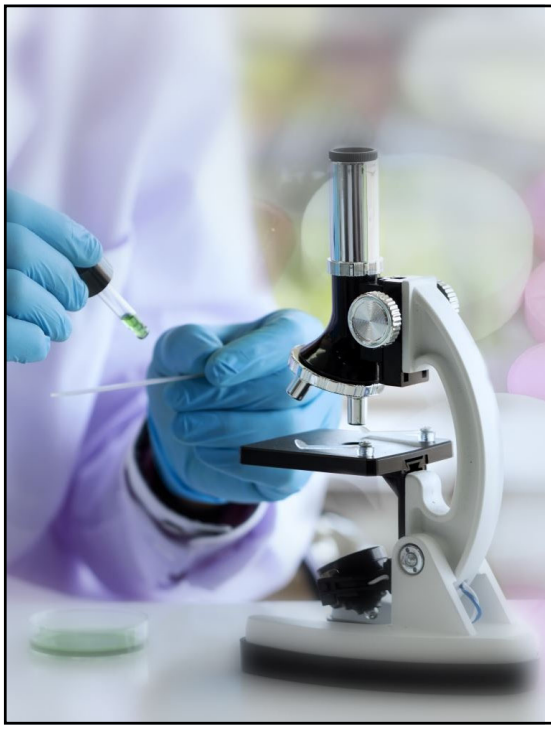

Guidance for Industry #256 (GFI #256)

- FDA's compliance tool for regulating grey areas of law (although not binding)
- Various guidances since 1994 addressing BDS to compound for animals
  - Tried to mirror human compounding guidance
  - Drug Quality and Security Act 2013 changed the ability to mirror
- 2022: GFI #256 finalized, enforcement started April 2023
- Categorized compounding with BDS into 3 buckets (categories) with governing lists

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GFI #256 Buckets and Lists

A

Compounding for one specific non-food-producing animal:

Patient-specific prescriptions

No list

B

Compounding for future non-food-producing animals:

Office "stock" (office use)

List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals

C

Compounding for food-producing animals and Free-Ranging Wildlife

Drugs for use as antidotes for food-producing animals

List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species

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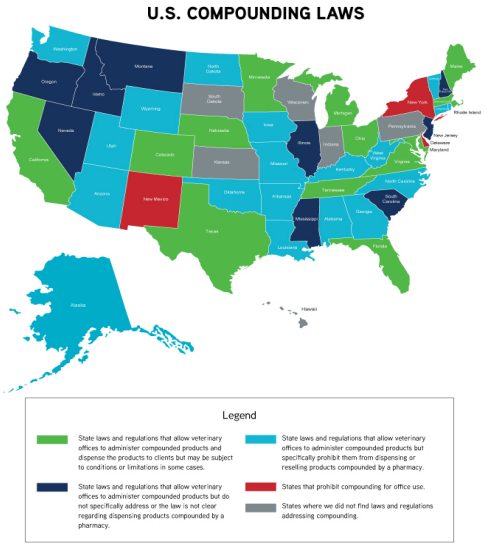
GFI #256 Office Use Compounding for animals—Tension with States

- Drug Quality and Security Act (DQSA) "office use" restrictions apply to human compounding only
- State-to-state variance on "office use" compounds for animals
- Check state rules for regulatory priority



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Bucket A: Patient-specific non-food-producing animals

Prepared under direct supervision of licensed RPh or DVM

Dispensed by:

- Pharmacy to animal caregiver or to animal's DVM
- Veterinarian to animal caregiver or to DVM in same practice
- NOTE: dispensing to 3rd party (eg, by pharmacy to another pharmacy or to a DVM who did not write the Rx; wholesaling through compounding broker) is NOT permitted.

22

Bucket A: Patient-specific non-food-producing animals

Drug is not a copy of a *marketed FDA-approved or indexed drug**

- Essential Copy: Same **active ingredient** or **active moiety (eg, doxycycline hyclate and monohydrate)**
- Essential Copy: Same route of administration **(eg, oral tablet = oral liquid)**

Or, if it is a copy, there is a difference that will produce a *clinical difference* in the identified patient as determined by the prescribing veterinarian

- Retain a copy of Rx with medical rationale as supplied by veterinarian
  - The Center of Veterinary Medicine (CVM) discourages drop-down menus on electronic prescribing platforms
- Examples of unacceptable rationale are supplied in guidance (eg, economic reasons, preferred compounder)

*FDA makes it very clear that GFI #256 is still to be followed even in drug shortages. CVM FDA has alternative strategies to obtain drugs during shortage at https://www.fda.gov/animal-veterinary/product-safety-information/animal-drug-shortage-information.

23

Bucket A: Patient-specific non-food-producing animals

Adverse events must be reported within 15 days on FDA Form 1932a

- Footnote 31: Adverse events include those occurring in animals, reports of lack of effectiveness, or adverse events occurring in humans from product exposure.

Product defects must be reported within 15 days on FDA Form 1932a

- Footnote 32: A product defect includes product quality issues in the drug product, product components, or product labeling. Examples of product defects include sterility failures, endotoxin failures, media fill failures, suspected cross contaminations, and incorrect potency.

Labeling:

- The statement : Report suspected adverse reactions to the [pharmacist or veterinarian who compounded the drug] and to FDA using online Form FDA 1932a must appear on the label of the dispensed compound.
- The compounding facility must have an adverse event reporting system in place. Ask to see their 1932a's.
- The compounding facility must report their compounded preparation failures to FDA as an adverse product defect.

24

Bucket A: Patient-specific non-food-producing animals

The labeling of the compounded drug includes all of the following:

- name of drug;
- strength of drug;
- species of the patient;
- patient identification;
- the name, address, and contact information for the compounding pharmacy or veterinarian and name of prescribing veterinarian;
- a beyond-use date;*
- the statement, "Report suspected adverse reactions to the [pharmacist or veterinarian who compounded the drug] and to FDA using online Form FDA 1932a";
- the statement, "This is a compounded drug. Not an FDA-approved or indexed drug."; and
- the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

* * Note: The lot number is not required by GFI# 256 but may be required by state law and is strongly recommended for recall.

25

Bucket B: Office stock for non-food-producing animals

Prepared under the direct supervision of a licensed RPh or DVM

Prepared in a state- or federally-licensed pharmacy or veterinary practice

The veterinarian who stocks the drug dispenses or transfers it only to the owner or caretaker of the animal patient or to another veterinarian in the same practice.

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Bucket B: Office stock for non-food-producing animals

- The Office Stock "Positive" List
- *https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals*
- Species, dosage form, strength
- This changes frequently
  - Eg, Amlodipine feline approval

DOGS, CATS, HORSES

Bulk Drug Substance (BDS)	Species	Dosage form(s)	Strength/concentration	Reasons
Amlodipine besylate (1/19/2023)	dog, cat	oral solution	1.25 mg/ml	Amlodipine besylate in these dosage forms and strengths are needed for urgent use in dogs and cats. No FDA-approved amlodipine drug products in suitable dosage forms and strengths are available for use in these patients.
		oral suspension	1.25 mg/ml	
		capsule	0.625 mg	
		tablet	0.625 mg	
		mini-tab	0.625 mg	
Apomorphine hydrochloride (8/11/2016)	dog	solution for injection	2.5 mg/ml	Apomorphine in a 2.5 mg/ml solution for injection is needed for urgent use in dogs. No FDA-approved injectable apomorphine drug product in this concentration is available for use in dogs.

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Bucket B: Office stock for non-food-producing animals

The label contains all of the following:

- name of drug;
- strength of drug;
- the species of the patient(s) and the **indication for which the drug will be used;**
- the name, address, and contact information for the compounding pharmacy or compounding veterinarian;
- the name, address, and contact information for the veterinarian ordering the office stock;
- a beyond-use date;
- the statement, "Report adverse events to FDA using online Form FDA 1932a";
- the statement, "This is a compounded drug";
- the statement, "Not for use in food-producing animals"; and
- the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

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Bucket C: Antidotes for food-producing animals, sedatives and analgesics for free-ranging wildlife

Prepared under direct supervision of a licensed veterinarian or pharmacist in a state or federally licensed facility

The drug is compounded from a bulk drug substance on the "List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species;

- Must meet list requirements for:
  - Species (eg, beef cattle, beef calves, sandhill cranes, "free-ranging wildlife," Canadian geese)
  - Dosage form
  - Strength

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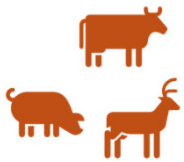
Bucket C: Antidotes for food-producing animals, sedatives and analgesics for free-ranging wildlife



The prescribing veterinarian has a valid veterinarian-client-patient relationship

The veterinarian establishes and documents a scientifically-based withdrawal time that ensures residues of the:

- (1) antidote,* or
- (2) sedative or anesthetic are not present in the animal at the time of slaughter or harvest, or the veterinarian ensures that the animal does not enter the food supply

* Note: The DVM has no responsibility to determine when the poison has depleted.

The prescribing veterinarian ensures that the animal does not enter the food supply too soon or at all

- Tagging free-ranging wildlife with withdrawal time and DVM contact information

30

Bucket C: Antidotes for food-producing animals, sedatives and analgesics for free-ranging wildlife

The label contains all of the following:

- name of drug;
- strength of drug;
- the species of the patient(s) and the indication for which the drug will be used;
- the name, address, and contact information for the compounding pharmacy or compounding veterinarian;
- the name, address, and contact information for the veterinarian ordering the antidote or the wildlife professional ordering the sedative or anesthetic;
- a beyond-use date;
- the statement, "Report adverse events to FDA using online Form FDA 1932a";
- the statement, "This is a compounded drug";
- the statement, "Not for use in food-producing animals"; and
- the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

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The Other Lists…

Nominated Bulk Drug Substances Currently Under Review

https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-currently-under-review

As long as a substance is on this list, FDA will "ordinarily refrain from taking enforcement action." GFI #256 FAQ #15 recently clarified to confirm this.

Bulk Drug Substances Reviewed and Not Listed

https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-reviewed-and-not-listed

These substances may not be used to compound once on this list.

The "But, no one has nominated it, and I have an Rx" List

If a substance is not nominated and does not appear on any lists, it may only be used to compound for patient-specific, non-food-producing animals under the conditions in Bucket A.

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What about 503B facilities compounding for animals?

- The facility must compound at least one sterile product to qualify for 503B status and must comply with 503B requirements as described in the DQSA.
- AMDUCA and GFI #256 apply to any compounding with bulk drug substances for animals
  - **GFI #256 Footnote 21:** "Sections 503A and 503B of the FD&C Act (21 U.S.C. §§ 353a, 353b), which provide certain statutory exemptions for compounded human drugs, **do not apply to drugs compounded for use in animals."**
  - **Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry Footnote 3:** Drugs compounded from bulk drug substances for use in animals are not within the scope of this guidance. For policies pertaining to compounding drug products from bulk drug substances for use in animals, see the Center for Veterinary Medicine guidance for industry #256 Compounding Animal Drugs from Bulk Drug Substances (August 2022).
- FDA CVM developing GFI #256B to address regulatory boundaries and expectations for 503B facilities providing compounds for animals.

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USP Compounding Standards

- **USP compounding standards (<795>, <797>, <800>, <825>) are not "self-enforcing."**
  - They become enforceable when a regulator, accreditor, or contract **adopts them and ties them to consequences** (eg, licensure, accreditation, certification, reimbursement, or regulatory action)
- Always check with your state board of pharmacy to see if they enforce USP compounding standards:
  - In entirety
    - By reference to the current USP standards chapter numbers
    - By insertion of the entire USP chapter(s) in the rule (necessitates update every time USP revises)
  - Selectively
    - By inclusion of certain standards in state board rules
- **Note:** USP substance monographs for BDS will always be enforced by FDA if not by state boards

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State Pharmacy Practice Rules

State	USP_795_Adoption_Status	USP_797_Adoption_Status	USP_800_Adoption_Status	Office_Use_to_Veterinarians	Veterinary_Compounding_Notes
North Carolina	Adopted by reference in 21 NCAC 46 .2801(d).	Adopted by reference in 21 NCAC 46 .2801(e).	Not expressly named in rule; HD safety generally addressed through USP adoptions/other guidance.	Allowed to supply compounded products to practitioners for administration in office; must comply with applicable federal law.	No resale; annual NABP Business e-Profile update required if compounding.
Florida	Adopted in state rules; see 64B16-27.700 and 64B16-27.797 for sterile.	Adopted in 64B16-27.797 for CSPs.	HD handling addressed in state rules; practice must be consistent with USP.	Expressly allowed with written agreement; specific label elements required for 'veterinary office use'.	Limits on quantities reasonable for intended use; records retrievable in 72 hours.
California	Adopted via CA BOP regs; aligns with USP (effective Jun 17, 2025 text).	Adopted; CA sterile compounding regs align with USP 797; new rule text effective Jun 17, 2025.	Adopted/enforced in state regs for HD handling.	Allowed in limited quantities: 14-day NON-sterile; 7-day sterile (non-ophth); 28-day sterile ophthalmic (per patient).	Must follow FDA GFI #256 when compounding from bulk for animals; furnishing for administration in office; limited furnishing per patient.
Ohio	Adopted via state rules in Chapter 4729:7-2.	Adopted; sterile compounding exemptions and rules in Chapter 4729:7-2-02+.	HD handling addressed in state rules and guidance.	Permitted to sell non-patient specific compounded drugs to veterinarians for direct administration, with limits; vets may personally furnish up to 7â€'day supply.	Nonresident pharmacies must meet Ohio requirements; specific limits and definitions apply.
Maine	Adopted via state rules; Board Chapter 42 references USP standards.	Adopted via state rules; sterile compounding in Chapter 42 crossâ€'references USP.	HD handling aligned to USP via Board rules.	Permitted for nonfood-producing animals under Chapter 42; labeling and quantity limitations; verification and recordkeeping required.	Authority in 32 M.R.S. Â§13722; rule effective May 15, 2023 (per state site).
Texas	Incorporated by reference; 22 TAC Â§291.131 updated Apr 2024 to align with revised USP 795.	22 TAC Â§291.133 proposed/updated 2024â€"2025 to align with revised USP 797.	State enforcement via TSBP rules; HD handling required in sterile/NS compounding SOPs.	Permitted 'in reasonable quantities' with written agreement; labeling and recordkeeping required.	Texas Vet Board 22 TAC Â§573.44 governs veterinarians; food-producing animals must follow federal guidelines.
Arizona	State CGCP rule requires compendial standards; aligns with USP.	Sterile compounding requirements in state rule; aligns with USP 797 via references.	HD handling requirements incorporated via state CGCP and sterile rules.	May provide to medical practitioners for administration only; must label 'Not For Dispensing' and 'For Office or Hospital Administration Only'.	Prepackaging/anticipatory compounding allowed with limitations; labeling and BUD per compendial guidance.

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How Will You Identify the Regulatory Boundaries?

- **Follow the Drug Legal Use Hierarchy:**
  - An **FDA-approved drug (for animals or humans)** should be dispensed, if possible:
    - Mandated by the AMDUCA
    - If not available or appropriate, then may compound under Extralabel Use provisions of AMDUCA
  - If **compounding:**
    - Start with an FDA-approved drug, if possible
    - If not available or appropriate, then may consider using bulk-drug substance
  - If using **bulk drug substance:**
    - Use only USP monographed substances obtained from an FDA-registered supplier, document justification for use, and follow the lists/conditions for use in each GFI #256 “bucket”
  - Follow any state-specific compounding rules

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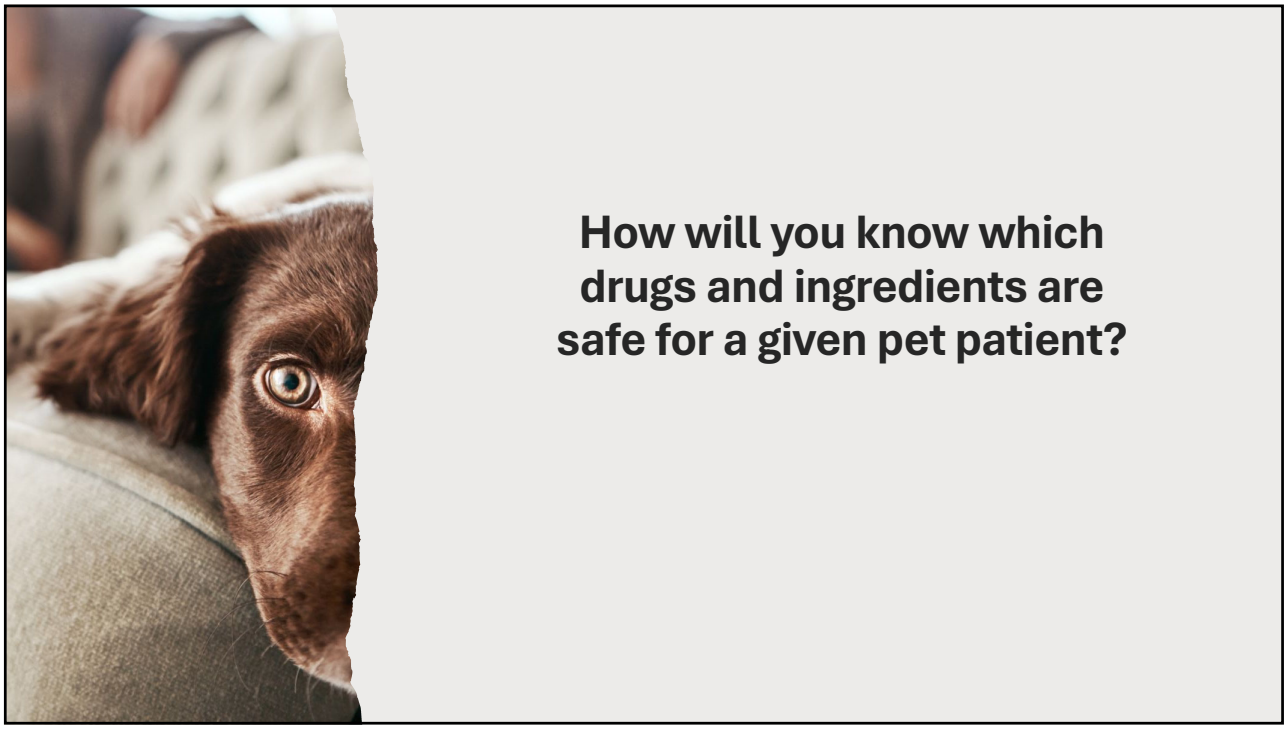

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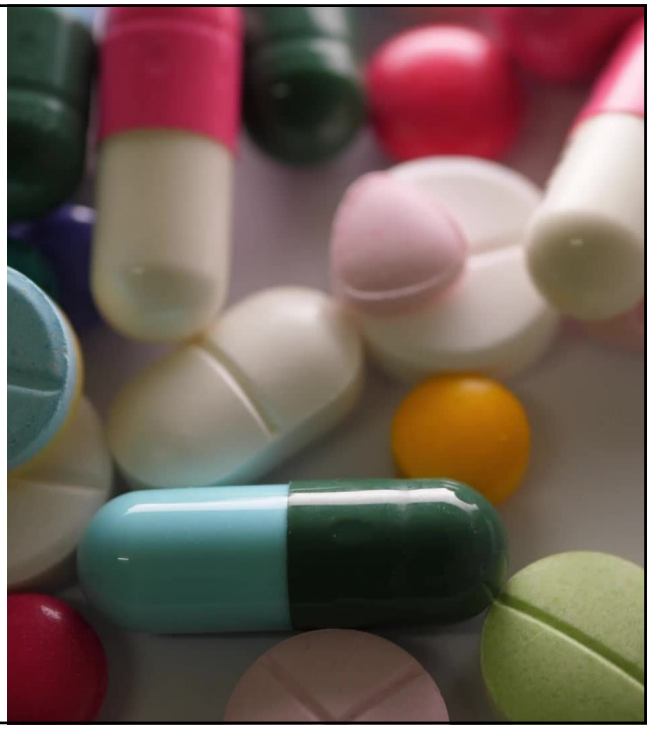
Species-Specific Excipient Limitations

- The prescriber trusts you to choose safe drug products to dispense or excipients to compound the prescribed therapy
- Excipients and inactive ingredients are not featured in most veterinary drug formularies
- Develop a systematic approach to researching if you do not have an approved veterinary product or a verified compounding formula known to be safe and effective in the target species



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Systematic Approach to Excipient Safety

1. Screen for species-specific inactive ingredient/excipient hazards

- **Dogs: xylitol** (contraindicated); avoid chocolate/cocoa, grape and raisin flavors; limit ethanol.
- **Cats:** avoid **propylene glycol orally** (chronic exposure), caution with **benzoic acid derivatives,** avoid concentrated **essential oils;** be wary of strong oxidizers/surfactants.
- **Horses:** avoid ionophore contamination; minimize mucosal irritant solvents/ surfactants; consider metabolic syndrome (limit sugars).
- **Rabbits/small herbivores:** avoid high-sugar/osmotic vehicles (dysbiosis risk).
- **Birds/reptiles/aquatics:** limit ethanol/PG; ensure appropriate osmolality and non-irritant solvents.

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Systematic Approach to Excipient Safety

2. For compounds from human formulas, map the formulation

- List **every component** (API + each excipient), intended **route, strength**, **dose volume,** container/closure
- Verify **source, review COA (eg, impurities such as lead)**, lot, and supplier reliability.
- Review **SDS** (BDS listed as contact irritants or photosensitizers are poor candidates for OTM or transdermal administration)

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Systematic Approach to Excipient Safety

3. Quantify exposure:

- Calculate **per-dose** and **per-day** exposure for each excipient in **mg/kg** (or mL/kg) at **max dose/volume.**
- **Example:**
  - Formula calls for simple syrup
  - Preserved with benzoic acid 1%
  - Rx instructions state 1 mL po q12h daily for 6 weeks for a cat
  - 1% = 10 mg/mL x 2 = 20 mg/day for 6 weeks
  - Limit for chronic exposure is 200 mg/day in cats (*https://doi.org/10.1136/vr.90.3.53*)
  - Probably okay but best to use paraben-preserved simple syrup

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Systematic Approach to Excipient Safety

4. Check route-specific safety limits

- **Ocular:** near-isotonic, pH ~6–8, minimal effective preservative; avoid irritants.
- **Otic:** avoid ototoxic solvents if TM status uncertain; appropriate viscosity.
- **Oral:** palatable; reasonable pH for species; reasonable osmolality; avoid risky sweeteners (xylitol); avoid artificial flavors that mimic toxic foods
- **Parenteral:** parenteral-grade only; suitable pH/osmolality; **endotoxin** controls.
- **Transdermal:** use vehicles with **evidence of dermal delivery** and safety in the **target species;** avoid photosensitizers; avoid contact irritants

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Systematic Approach to Excipient Safety

5. Literature & label corroboration

- Look up the excipient in **veterinary toxicology/formulary sources** for the **target species**.
- Scan **approved product labels** (Animal Drugs @ FDA/FDALabel/ DailyMed/European Medicines Agency) for the **same species & route** to see if the excipient is already used in approved/licensed products

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Systematic Approach to Excipient Safety

6. Consider cumulative & contextual exposure

- Evaluate **all sources:** concurrent meds (eg, multiple propylene glycol-containing liquids), diet/treats, topical/environmental product exposures, foods used to hide pills (eg, xylitol in sugar-free or "light" foods)
- Check **duration** (chronic vs short-term) and **margin of safety**

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Systematic Approach to Inactive Ingredient Safety

7. Document thoroughly

- Record **mg/kg exposure calculations** for each suspect excipient, literature citations, label evidence, and rationale for selections in the Master Formulation and Compounding Records
- Note any **clinical-difference justification** (if avoiding a "copy") and any **shortage/availability** considerations.
- Capture **lot/COA** details for traceability.

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Counseling Pet Owners:

How to give it (route-specific tips)

- **Oral or transmucosal liquids:** Show **how to measure; shake well** if labeled; give slowly into cheek pouch; follow with a treat/water if allowed.
- **Capsules/chews:** Give whole unless told otherwise; do not crush/open unless directed.
- **Transdermal: Wear gloves,** apply to clean, hairless skin (eg, inner ear pinna), **rotate sites,** prevent contact with people/other pets until dry. Thoroughly wash hands afterwards.
- **Eye/ear drops:** Demonstrate drop count/technique; avoid touching tip; wait **≥5 mins** between different drops.
- **Injections (if applicable):** Show dose prep, **needle safety, site rotation,** sharps disposal.

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Counseling Pet Owners

What to watch for & when to call

- Expected effects & **common side effects; red-flag signs** that require calling the vet or urgent care.
- **Unexpected effects;** irritation at administration site; sneezing after administration; may indicate poor compound quality
- **Signs that indicate the therapy is not working** as expected; report to the veterinarian
- Any **lab monitoring** or follow-up visit needed (and when)
- If **vomiting/diarrhea/refusal** persists or a dose is spit out—what to do
- Report any **changes in the compound appearance** or odor back to the pharmacist; contact the pharmacist if the pet refuses the compound after initial acceptance

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Reporting Adverse Events – Mandated for Compounds, Voluntary for Drug Products

Encourage pet owners to report any:

- Expected or unexpected effects (to the veterinarian)
- Difficulty administering the drug or the compound (to both the veterinarian and the pharmacist)
- Changes in compound appearance, odor, consistency, etc (to the pharmacist)
- Problems with administration devices, eg, transdermal applicators, dosing syringes, container closure, etc (to the pharmacist)

All of the above (except expected side effects) **must** be reported by the veterinarian and/or pharmacist on FDA Form 1932a within 15 days of occurrence.

https://www.fda.gov/media/121602/download

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Assessment Question #1:

Which of the following is the MOST appropriate method for verifying that a veterinarian is authorized to prescribe a non-controlled medication for an animal?

A. Verify the veterinarian's National Provider Identifier (NPI) number
B. Verify the veterinarian's state veterinary medical license
C. Verify the veterinarian's DEA registration number
D. Verify the veterinarian's Medicare provider enrollment

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Assessment Question #2:

Which excipient should generally be considered contraindicated in dogs because it may cause severe hypoglycemia and liver injury?

A. Lactose
B. Sorbitol
C. Xylitol
D. Glycerin

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Assessment Question #3:

Which of the following drugs is commonly used in veterinary medicine but is not labeled for human use?

A. Enrofloxacin
B. Amoxicillin
C. Prednisone
D. Levothyroxine

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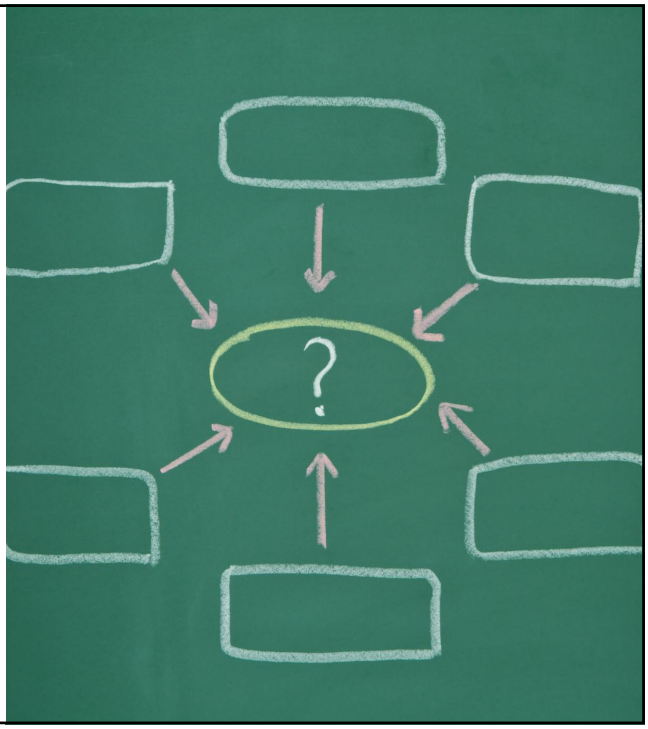
Summary

- Compounding and dispensing considerations for animals are significantly different than for humans
- Stay within the legal boundaries of AMDUCA, GFI #256, USP, and state practice rules
- Excipients and inactive ingredients that are generally recognized as safe in humans are not necessarily GRAS in other species
- Research inactive ingredients in human drugs and in compounded formulations for use/safety in target species
- Document your findings for future root cause analysis if something goes wrong



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2. Click on the "Live CPE" tab
3. Select the webinar from the Live Meetings and Conferences list
4. Enter the session code provided at the end of the webinar
5. Complete the course and speaker evaluations
6. Select the appropriate credit (pharmacist or pharmacy technician)
7. Enter your NABP e-Profile ID and date of birth and certify that the information is correct
8. Click the claim button

Claims must be submitted by noon on September 22, 2026.

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NABP

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