New FDA Guidance on Animal Compounding effective April 1st, 2023

As of April 1st, 2023 the new FDA animal compounding guidelines (GFI #256). We at Village pharmacy want to help you as a Veterinarian navigate these new guidelines.

GFI #256 applies primarily to compounded preparations for:
• Office stock for non-food producing species, like dogs, cats, and horses.
• Food-producing species and free-range wildlife, regardless of whether your request is for a patient-specific prescription or office stock.

Patient Specific Compounding:

Patient-specific compounding for non-food producing species has few restrictions, unless the requested preparation is a copy (same active pharmaceutical ingredient [API] and route of administration) of an FDA approved, conditionally approved, or indexed drug.

Requests for patient-specific compounded products that are considered copies of FDA approved, conditionally approved, or indexed drugs must include your "medical rationale" for why an existing FDA approved, conditionally approved, or indexed drug will not work for your patient (referred to as a "clinical difference"). This "clinical difference" allows for the customized dosage form under the new guidelines and must be documented on the prescription.

Examples of acceptable clinical differences for copies include:
• "Patient is allergic to ingredient [X] in approved product."
• "[Ingredient name] in approved product is toxic to this species."
• "Patient would require too many tablets of the approved product."
• "Patient requires dose that is a fraction of approved tablet, and tablet is not scored to accomplish this fractionated dose."
• "Patient cannot safely be pilled with the approved capsule / tablet."

Examples of unacceptable clinical differences for copies include:
• "The compounded drug is less expensive."
• "Prefer [compounded drug/compounder]."
• "Need half strength" (approved product is 10 mg/ml solution, script written for 5 mg/ml solution)

Compounds for Office Use:

If an office use or office stock product is to be compounded from a bulk drug substance (BDS), compounders will need to first check FDA's approved BDS "list" before compounding for any non-food producing species. Additionally, when compounding for food-producing and free range wildlife species, both patient-specific prescriptions and office stock compounding must adhere to the separate BDS "list" that applies to those animal species groups.

In summary, office use compounds can still be made by a compounder as long as:
• They are made from commercially available, FDA approved, finished pharmaceutical products.
• They are made from ingredients that appear in the GFI #256 list of approved BDS (Bulk Drug Substances).
• They are made within the parameters of the specific BDS "list" for that animal species group.

Scan the QR code below to link to our GFI #256 resources.

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