WHAT YOU NEED TO KNOW

FDA GFI #256, Compounding Animal Drugs from Bulk Drug Substances

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- Compounding in veterinary clinics beginning with FDA approved, conditionally approved, or indexed finished pharmaceuticals as the starting material is outside the scope of GFI #256.
- Patient-specific compounding for nonfood-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").

  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 would require a fraction of the approved tablet, and tablet is not scored to accomplish this fractionated dose."
  - "Patient cannot safely be pilled with the approved capsule."

  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, prescription is written for 10 ml dose of 5 mg/ml solution)

- GFI #256 applies when you request compounded preparations from compounding pharmacies 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.
- If the product is compounded from a bulk drug substance (BDS), compounders will need to check FDA's "lists" before compounding office stock for non-food producing species and either patient-specific or office stock for food-producing and free range wildlife species. FDA's lists include:
  - BDS for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals
  - BDS for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species
  - BDS Currently Under Review
  - BDS Reviewed and Not Listed

FDA Inspections: FDA has indicated it does not intend to inspect veterinary care facilities that do not compound animal drugs from BDS. FDA will also delay inspection of federally registered outsourcing facilities until it clarifies the applicability of GFI #256 to them. A limited number of inspections at state-licensed pharmacies are anticipated. FDA indicates it will "afford individuals and firms an opportunity to voluntarily take appropriate and corrective action prior to the initiation of enforcement action."

For additional information see Axon webinar: Understanding FDA GFI #256; Compounding: FAQs for veterinarians; Compounding from bulk drug substances; FDA releases final guidance on compounding from bulk substances;

Questions? Email compounding@avma.org