PET HEALTH PHARMACY

About the FDA's CVM Draft Guidance for Industry (GFI #256) for Compounding Animal Drugs from Bulk Drug Substances

An informational sheet from Pet Health Pharmacy

The FDA's Center for Veterinary Medicine (CVM) has issued draft guidance (GFI #256) that, if finalized, threatens to have **serious and damaging ramifications** for your practice and your patients.

History:

- **2015** – The FDA introduced a Guidance for Industry (GFI #230) relating to the compounding of animal drugs from bulk drug substances.
- **2017** – The FDA formally withdrew GFI #230 after significant push-back from veterinary and pharmacy communities, as well as from members of Congress.
- **2019** – The FDA issued draft guidance (GFI #256) that threatens to have far-reaching and serious consequences for animal patients and the practices of veterinarians.

The New GFI #256

The new FDA CVM GFI #256 is a draft guidance that would establish the FDA's policies about how and when they would seek enforcement action against veterinarians, state-licensed pharmacies, and federal facilities that compound animal drugs from bulk drug substances. The FDA is creating both a positive and negative list for compounding from bulk ingredients. *The positive list proposed contains a mere seven active pharmaceutical ingredients.*

Repercussions GFI #256 May Have on Veterinary Patients and Veterinarians' Practices:

The FDA is taking this action in the form of a supposed "non-binding" guidance document that places veterinarians and veterinary compounding pharmacies under **extremely burdensome restrictions** that prohibit veterinarians and pharmacies from properly treating patients. It is especially important to note that **Congress has not passed legislation giving the FDA authority to make such a substantial change in animal health.**

In summary, if GFI #256 is finalized,

- Your access to compounded medications for your animals would be severely restricted
- The quality and safety of compounded medications would suffer
- Veterinarians' practices would be burdened by additional FDA regulatory oversight

Restricted Access:

- GFI #256 mandates the development of a **positive list for bulk ingredients for office use**, but there is no statutory basis for this requirement. This list contains only seven items (Apomorphine hydrochloride, Cisapride, Guaifenesin, Metronidazole benzoate, Miconazole nitrate, Potassium bromide, and Tacrolimus). Veterinarians use hundreds of active pharmaceutical ingredients to meet the needs of their patients.
- GFI #256 severely restricts the ability of veterinarians to order any other compounded medication for office use, **requiring a patient-specific prescription and burdensome, yet-to-be-defined, documentation** of the clinical need and medical rationale.
- Often, compounding is in response to FDA manufacturer backorders. Eliminating the ability to start from bulk ingredients will **eliminate access during drug shortages.**
- GFI #256 contradicts existing state law. In most states, veterinarians may exercise their medical judgement to compound or order compounded medications for veterinary office use.
- GFI #256 mandates that compounding, other than the positive list of seven items, begin with FDA-approved drugs—this is not a requirement in human health.
- GFI #256 limits compounding to drugs that "do not present a particular human or animal safety concern." Some examples the FDA gave include "superpotency leading to animal overdose, microbial contamination, and drug formulations that present safety risks for the treated animals or for the people handling or administering the animal drug."
- With no due process, the FDA has also released a negative list, consisting of **11 bulk drug substances that may NOT be used for office use compounding. These currently include:**

  - Amlodipine
  - Budesonide
  - Chloramphenicol
  - Dexamethasone
  - Dipyrone
  - Doxycycline
  - Enrofloxacin
  - Gabapentin
  - Idoxuridine
  - Itraconazole with DMSO
  - Voriconazole

- Many FDA manufacturers will not permit sales of veterinary finished goods to compounding pharmacies, thus oftentimes preventing compounding from FDA-approved sources.

Diminished Accuracy

Providing no scientific reason or rationale, the FDA is taking the position that drugs compounded from bulk drug substances pose an increased risk to patient safety versus drugs compounded from commercially available dosage forms. This view is contrary to the views of many independent scientific experts in many respects. For example:

- Pharmacy quality experts agree that starting with bulk powder ensures purity, consistency, and appropriate potency of compounded medication. Quality standards for ingredients are written into state law, and USP monographs direct pharmacies to begin with bulk active pharmaceutical ingredients. Starting with FDA-finished goods may increase potency variability by as much as +/- 15%.
- Drugs intended for human use may contain ingredients that are toxic to some animal species. Even diluting FDA-approved medications to a lower concentration suitable for an animal could result in potentially deadly outcomes.

Draft GFI Repercussions

Finalizing Draft GFI#256 would:

- Give the FDA new authority over veterinarians and pharmacies that provide compounded preparations.
- Single out veterinarians as the only medical professionals with prescription authority who would have to justify and document for the FDA a clinical effect prior to writing a prescription.
- Hamper veterinatians' ability to use their medical judgement to prescribe or order compounded medication that you believe is best for your patients regarding strength, dosage form and flavoring.
- Force you to use lower quality medication than what is available to human patients due to the requirement to begin most compounding with FDA-approved finished goods.

Take Action!

Prevent the FDA from severely restricting access for veterinarians and animal patients to compounded medication. Ensure that patients benefit from the skills and experience of compounding pharmacists when veterinarians use their professional judgment to prescribe a compounded medication that is the right solution for the unique needs of their patients.

Visit **www.pethealthpharmacy.com/GFI256** to learn more about this draft guidance.

Please take action and let your voice be heard!

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