FDA GFI #256
What you need to know.

01

Compounding guidance is getting tightened up.

Even though the FDA will not come into veterinary hospitals, ordering compounded substances may become more challenging.

02

When does GFI #256 apply?

This guidance applies when ordering compounded animal drugs made from bulk substances for office stock. Additionally, it applies to prescriptions for food-producing species and free-range wildlife, regardless of whether your request is for a patient-specific prescription or office stock.

03

What can be ordered for office-use:

Medications ordered for office stock must be listed on the relevant FDA *List of Bulk Drug Substances for Compounding.* See below:

Nonfood-Producing Animals

Food-Producing Animals or Free-Ranging Wildlife Species

Bulk Drug Substances Currently Under Review

Bulk Drug Substances Reviewed and Not Listed

For additional info:
Compounding: Understanding FDA Final Guidance #256

04

Additional documentation requirements.

Requests for patient-specific compounded products must include your medical rationale. See the next page for more on this.

05

Food-producing species and free-range wildlife.

Regardless of whether your request is for a patient-specific prescription or office stock, the compounded medication must be on the FDA List of Bulk Drug Substances (BDS) for Compounding Drugs for Food-Producing Animals or Free-Ranging Wildlife Species.

GFI #256

Compounding Animal Drugs from Bulk Drug Substances

How does this affect my clients, patients, and prescriptions?

Mrs. Smith's cat Bella was diagnosed with hyperthyroidism 2 years ago. Bella becomes a ferocious tiger when pilled and her veterinarian has prescribed transdermal methimazole through a compounding pharmacy.

How will GFI #256 affect this current prescription that has refills?

For existing prescriptions:

Additional verification

Starting April 1, 2023, pharmacists must call to verify **the medical rationale** with the veterinarian with the VCPR if the rationale is not provided on the prescription.

Examples of medical rationale:

- *Compliance is reduced with the commercial product in this patient and is not effective for achieving the desired medical outcome.*
- *The commercially approved product is not available*
- *Using the commercially available dosage form is not safe for the patient*
- *Patient (or population) has sensitivity, toxicity or aversion to the commercial product*
- *Patient cannot be safely medicated/pilled with the approved product*

TIP: Write your own set of clinical differences that are relevant to your current patients with prescriptions that will be affected.

In Bella's case – the pharmacist sent a form to the prescribing veterinarian who

1) completed the form,
2) documented the form and the medical rationale in Bella's medical record, and then
3) submitted it back to the pharmacist.

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What can I do to help reduce any burden placed on clients or veterinary teams from GFI #256?

01

Pull a report for all patients currently prescribed any of the medications that will be affected by GFI #256.

02

Schedule one or two email informs to go out to the owners of the pets on the report. The key is to inform clients as soon as possible so they know to request a refill a few days early. It's a new process for everyone.

CVM guidance for industry #256. Center for Veterinary Medicine, U.S. Food and Drug Administration.

GFI #256

Applies when you request, from compounding pharmacies, compounded preparations made from bulk substances for:

Office stock
Non-food producing species, like dogs, cats, and horses.

Patient-specific prescription

Food-producing species and free-range wildlife
Regardless of whether your request is for a patient-specific prescription or office stock.

Changes to ordering compounded medications

What can be ordered for office use

Medication ***must*** be on an FDA's Bulk Drug Substances List

- 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 Reviewed and Not Listed

What requires a patient-specific prescription

Additional documentation requirements for veterinarians

- Prescription must include your "medical rationale"
- *Specific reason your patient needs this particular medication compounded*

Compounding Animal Drugs from Bulk Drug Substances

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