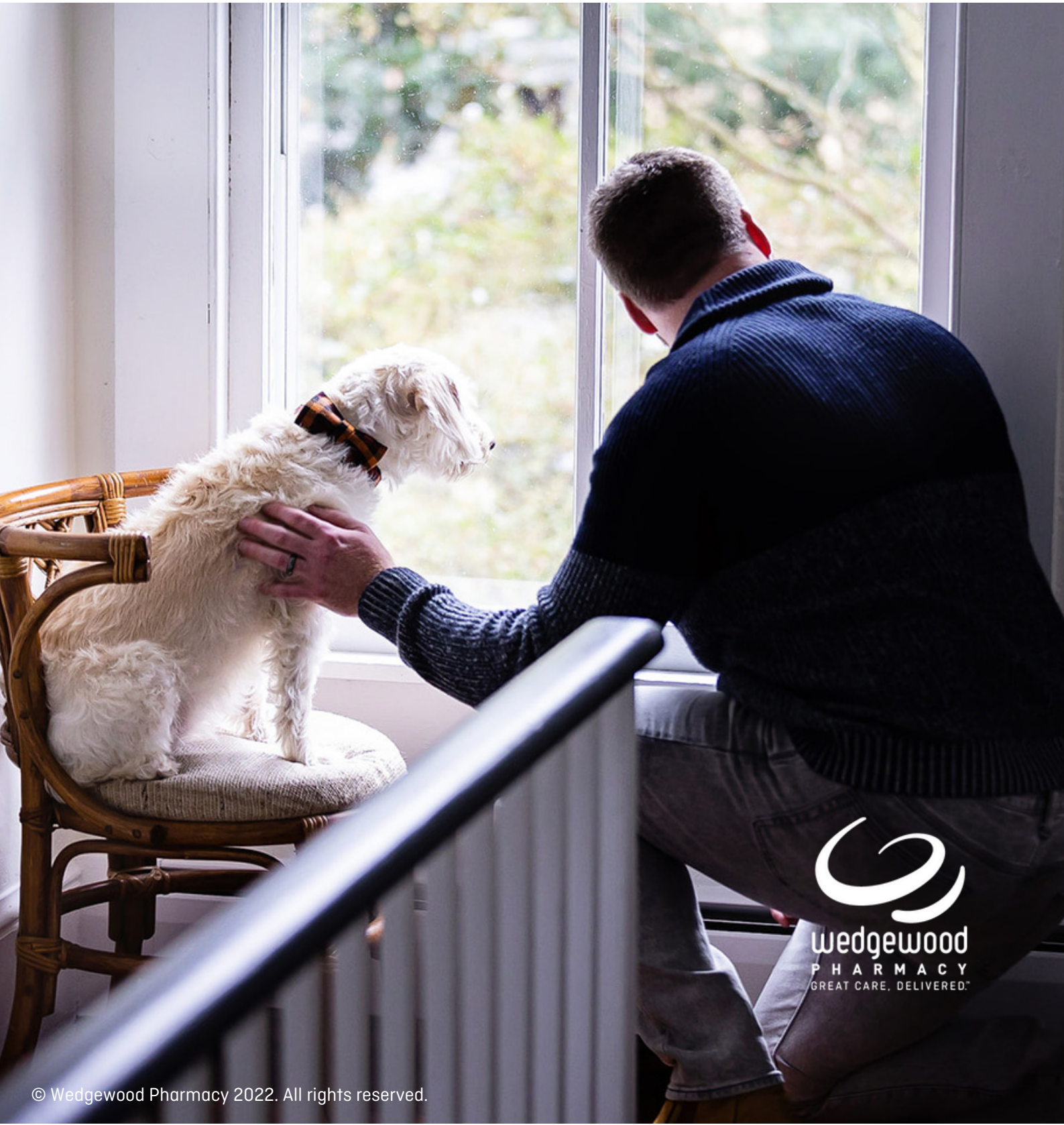
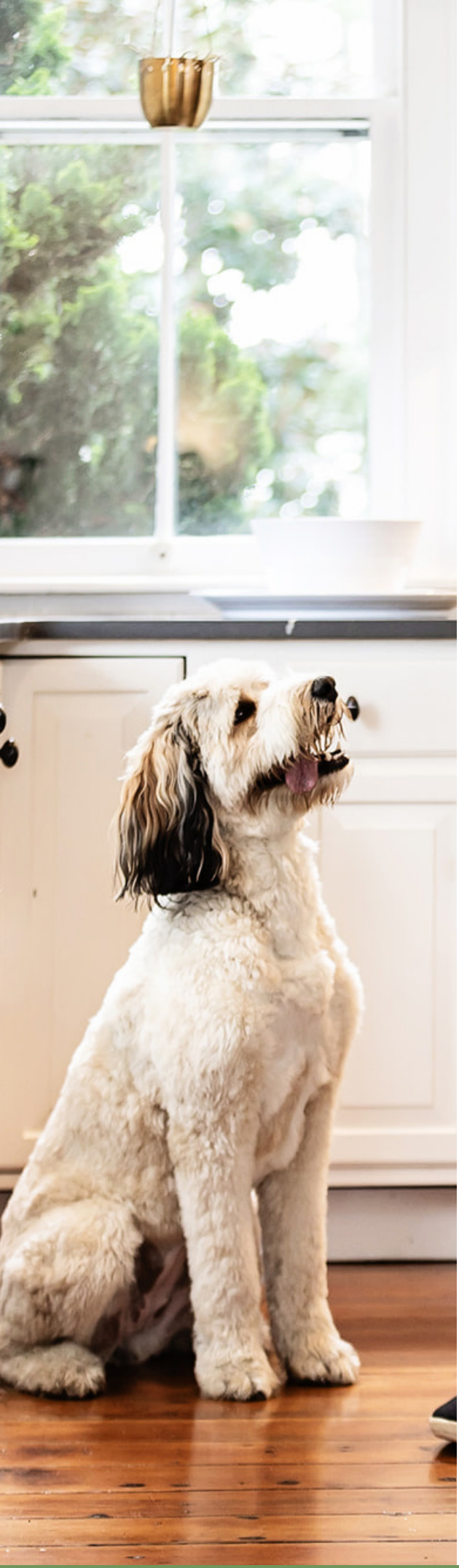
Changes are Coming

How FDA's Guidance For Industry (GFI 256) will affect how you order and prescribe compounded medications

Wedgewood Pharmacy July 13, 2022





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A Brief Introduction

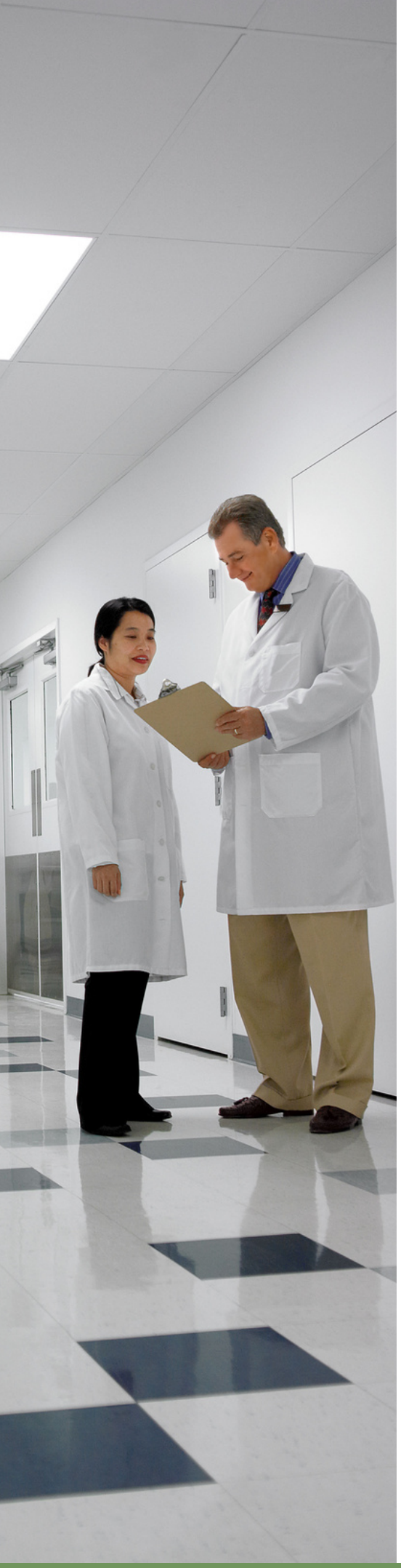
There are transformative changes coming to the regulatory and quality frameworks for compounding in animal health.

With FDA's finalization of the Guidance for Industry for Compounding Animal Drugs from Bulk Drug Substances (GFI 256) issued in April, and the United States Pharmacopeia's upcoming issuance of USP 795 (non-sterile), 797 (sterile), and 800 (hazardous drug) - you can expect transformative changes in the near future.

These changes promise to significantly impact how you prescribe compounded medication for your patients, and they may impact access and requirements for both 503A (state-licensed) pharmacies and 503B outsourcing facilities.

Whatever changes are coming, we promise to work with you to make prescribing and ordering compounded medication as easy and efficient as possible, and to make access to high-quality compounded medication available for those patients you believe have needs that cannot be met by FDA-approved, commercially available drugs.

This white paper is an introduction to these new changes. We hope that its contents will help you understand how GFI 256 will affect your practice and your patients. We look forward to being your partner through these changes, and providing you with new information as the guideposts become clearer.



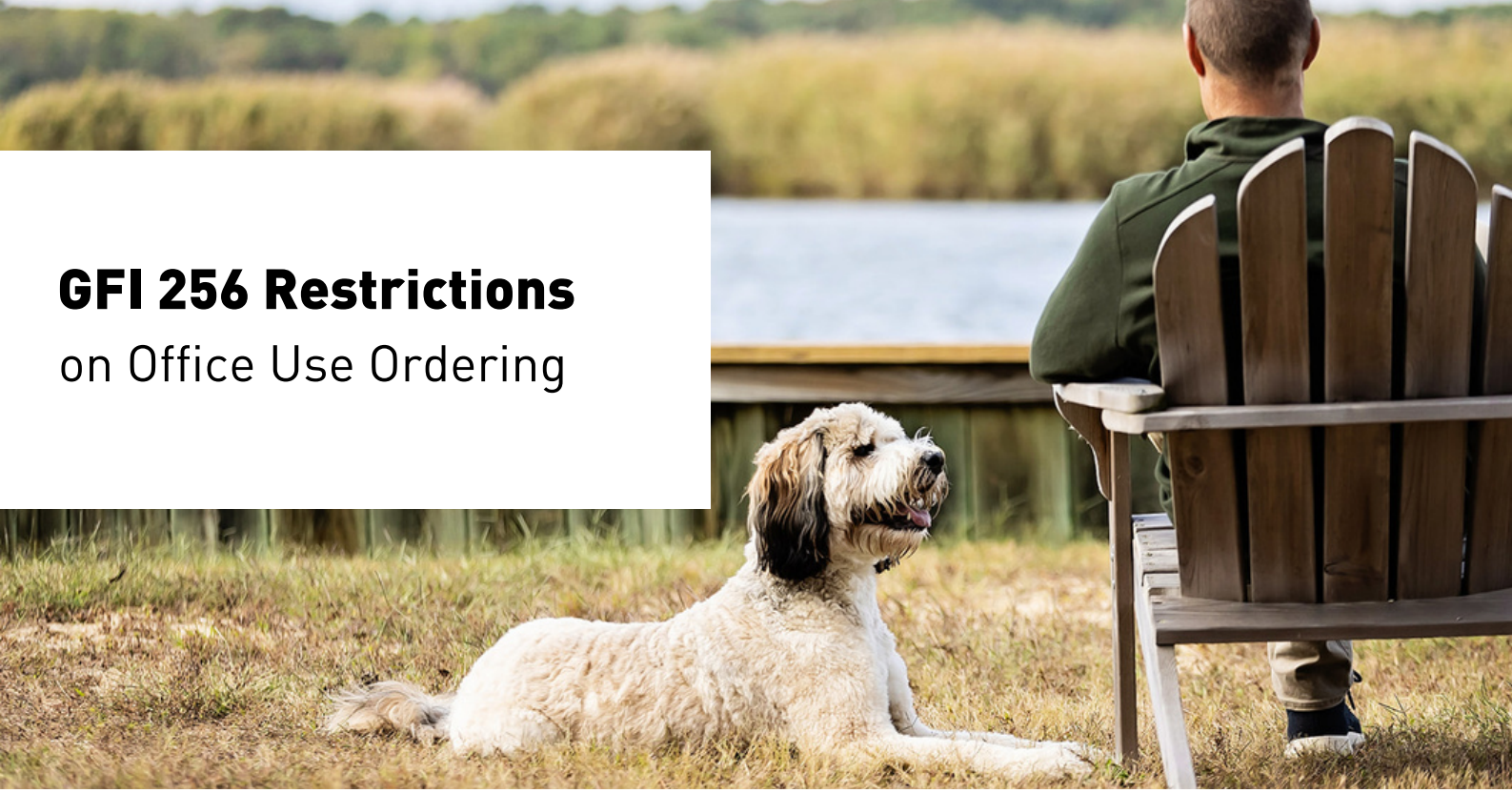
GFI 256 Introduces New Restrictions, Documentation and Requirements

FDA's GFI 256, which on the face states that it is not a law or regulation but the current thinking of the agency, was released on April 13, 2022. FDA announced that enforcement of this Guidance will begin on October 1, 2022.

Although GFI does not align with current standards of practice or state Board of Pharmacy regulations in many ways, we suspect that pharmacies, outsourcing facilities, and veterinary professionals will be expected to comply with both the GFI and conflicting regulations at the state level. For example, while most states allow office use of animal medication, the FDA will restrict office use and require documentation of clinical rationale for patient prescriptions compounded from bulk ingredients although it does not appear that FDA will be auditing veterinarians, only pharmacies with which they do business.

Other elements of FDA's thinking include requiring pharmacies to document why they are compounding with bulk ingredients rather than finished FDA-approved drugs, report adverse events on FDA's website using Form FDA 1932a, and perform compounding under USP quality standards in compliance with all applicable state laws and regulations.

At this time it is unclear what, if any, elements of the GFI 256 apply to 503B outsourcing facilities, which are FDA-registered, cGMP facilities designed to provide office use medications. The 503B construct statutorily applies to human health office use, but numerous outsourcing facilities focus on also providing office use medication for veterinarians, including Wedgewood Connect and others. We are hopeful that FDA will take a definitive stance on this issue prior to October 2022.



GFI 256 Restrictions
on Office Use Ordering

Making the list - and checking it twice.

FDA intends to use enforcement discretion when compounded medication is prepared from bulk ingredients on one of three lists:

1. List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals
2. List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species
3. Nominated Bulk Drug Substances Currently Under Review.

For simplicity, we will call these "positive lists." FDA is accepting nominations for the Bulk Drug Substance lists. Wedgewood Pharmacy has been a leader in nominating medications, with 20 nominations as of mid-July, and many more underway.

Important Notes:

The names of these lists are a bit misleading, because the drugs currently on the list are not limited to "bulk drug substances." FDA has defined the nomination process to require specific finished goods that include the dosage form, active pharmaceutical ingredient (API), strength, indications, and intended species for each drug.

It is unclear how quickly drugs will be placed on the "under review" list, who is making "yes" or "no" decisions about whether or not drugs will be added to one of the positive lists and what the exact criteria is for whether or not a drug will be placed on a positive list.

While the "Bulk Drug Substances Reviewed and Not Listed" (negative list) includes drugs FDA has determined to be inappropriate for office use, these drugs remain available on a patient-specific basis as long as clinical rationale is documented and the other applicable criteria are met.

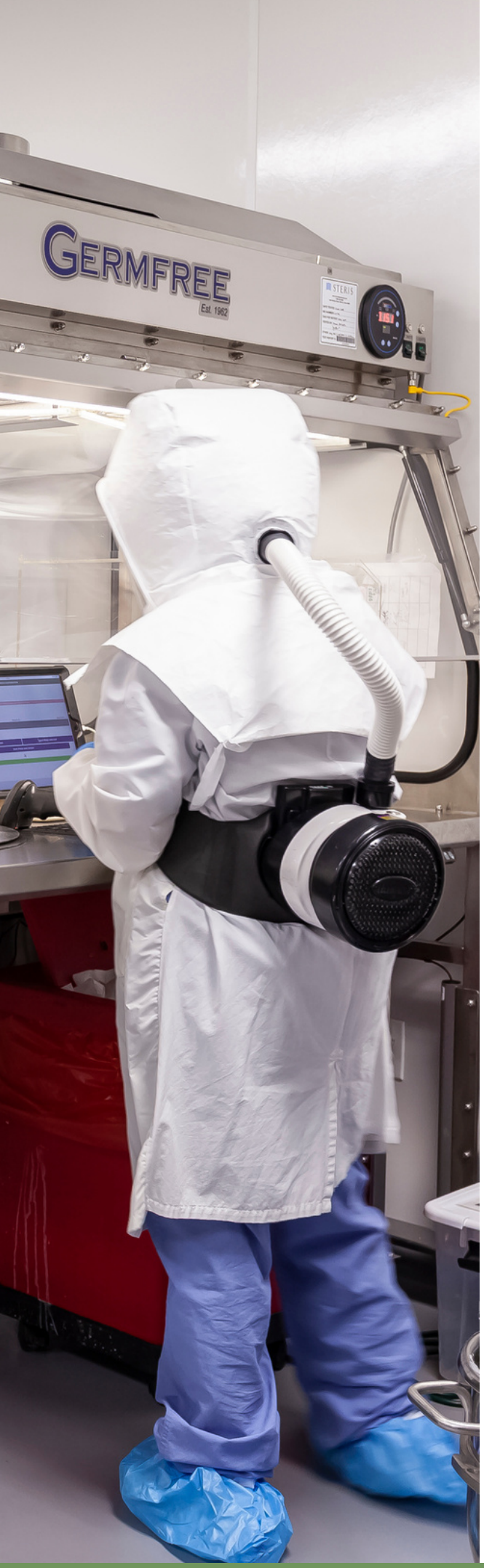
What about In-practice Use and Dispensing to Patients?

GFI 256 seems to permit patient-specific prescriptions being dispensed to a veterinarian or to a pet owner by a pharmacy.

The veterinarian may also dispense to the owner or caretaker of a patient in their practice, or to another veterinarian in their practice located in the same physical location.

While this is a positive element of FDA's current thinking, it does not necessarily align with the regulations of all states, as several states restrict the dispensing of compounded drugs based on a limited number of days supply, and otherwise.

Veterinarians are responsible for understanding all applicable state regulations around dispensing compounded preparations received from 503A state-licensed pharmacies and 503B outsourcing facilities. Regulations for the two may differ.



Compounded Medication Prepared from Bulk Ingredients

for patient prescriptions

If a drug is not on a positive list, it seems FDA is permitting veterinarians to prescribe that medication for specific patients when the veterinarian deems there is a “clinical difference” between the compounded medication and what is available commercially, and that the clinical difference is supported by a medical rationale. Pharmacies are required to keep records of such determinations.

We encourage you to read section III.A.5 (and all) sections of the GFI, as FDA provides several examples of what it considers a valid “clinical difference".

FDA examples of "clinical difference"

Patient is allergic to ingredient X in approved product.

X ingredient in approved product is toxic to this species.

Patient would require too many tablets of the approved product.

Patient cannot safely be pilled with the approved capsule.

Wedgewood Pharmacy's Response

Wedgewood Pharmacy is taking the following actions to ensure continued access to the medication patients need:

1. Requesting a meeting with the FDA to get clarification on the nomination timing, adverse event reporting, and other aspects of GFI 256.
2. Using transactional data to determine what veterinarians most frequently request for office use, along with reference materials (like Plumb's) and the parameters outlined in GFI 256, Wedgewood Pharmacy has an ambitious plan to nominate many substances for consideration for one of the positive lists.
3. We are working with various animal health organizations to support them in their nomination processes.
4. We are re-working prescription intake and making technology changes to enable you to efficiently communicate your clinical rationale for patient-specific prescriptions.

Wedgewood Pharmacy, and its companies Wedgwood Connect and ZooPharm, are committed to working with veterinary practices and patients through these important changes because our vision is to improve the lives of animals and those who love them.

We hope you will be patient as change is always hard, but we are committed to compliance and to communication around these issues, and will do our best to make the transition as easy as possible.

Resources

FDA's Guidance for Industry for Compounding Animal Drugs from Bulk Drug Substances (GFI 256)

Q&A: GFI #256 - Compounding Animal Drugs from Bulk Drug Substances

White Paper: Why Compounding Pharmacies Use Bulk Active Pharmaceutical Ingredients from FDA-Registered Suppliers to Make Custom Medications—and Why That's Best