



Alliance for
Pharmacy
Compounding



July 14, 2022

Steven M. Solomon, D.V.M., M.P.H.
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Pl, HFV-1
Rockville, MD 20855

Re: Request to postpone until FY2024 enforcement of GFI #256

Dear Dr. Solomon:

On behalf of the Alliance for Pharmacy Compounding, the American College of Veterinary Pharmacists, the American Pharmacists Association, the National Community Pharmacists Association, and the Society of Veterinary Hospital Pharmacists, **we write to ask that the Food and Drug Administration postpone until Fiscal Year 2024 any enforcement of GFI #256, "Compounding Animal Drugs from Bulk Drug Substances – Guidance for Industry" (April 22, 2022).**

Collectively, our organizations represent pharmacists practicing in every pharmacy practice setting, including veterinary compounding. The ability of many of those pharmacists to serve animal patients will be affected by this GFI, and we believe there remain too many unanswered questions for pharmacy compounders to have clarity about what constitutes compliance – much less achieve that compliance – in such a short time.

In brief, some of our reasons for this request include:

- Significant portions of GFI #256 are under OMB review, and it is unknown what changes FDA might make to any aspects of GFI #256 because of OMB's review.
- The FDA should allow at least one year for compounders and veterinarians to align with the requirements of GFI #256. Immediate implementation will be disruptive to veterinarians' practice and a deterrent to their patients' health. Some specific circumstances of concern are stated briefly below:
 - Clinical difference: Section III.A.5 imposes new burdens on how veterinarians write prescriptions and communicate with compounders. Sufficient time to create new systems to comply with these requirements is necessary.

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- Compounding from bulk: Section III.A. 6 will require new record keeping practices for compounders and the necessity to put new systems in place to ensure documentation of rationales when bulk drug substances are being used.
- Adverse event reporting: The threshold for “adverse event” is only described generally and needs to be clarified by the agency prior to enforcement. (Section III.A.7, III.B.5, II.C.5)
- FDA’s list for office stock drugs: Until veterinarians and compounders have had an adequate opportunity to nominate products for the list – and CVM has had time to review the nominations – this requirement will likely result in many drugs being immediately unavailable. (Section III.B.2)
- Labeling: Compounded products are not FDA-approved drugs so there is no FDA-approved indication for use; therefore, compounders cannot identify an indication on the label. (Section III.B.6)

This is not an exhaustive list of concerns, but it’s representative of the uncertainty that exists at present and warrants a delay of enforcement. We respectfully request that FDA postpone until FY2024 enforcement of GFI #256.

Thank you in advance for your consideration of this request. Please direct any questions to APC’s Scott Brunner at scott@a4pc.org.

Sincerely,

ALLIANCE FOR PHARMACY COMPOUNDING
AMERICAN COLLEGE OF VETERINARY PHARMACISTS
AMERICAN PHARMACISTS ASSOCIATION
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION
SOCIETY OF VETERINARY HOSPITAL PHARMACISTS

cc: Commissioner Robert Califf