

**Congress of the United States**  
**House of Representatives**  
Washington, DC 20515

August 5, 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 FY 2024 enforcement as described in GFI #256***

Dear Dr. Solomon:

We are aware of serious concerns raised by pharmacy and veterinarian stakeholders about the impact that final GFI #256, “Compounding Animal Drugs from Bulk Drug Substances — Guidance for Industry” (April 22, 2022) will have on animal health care if enforced in its current form. We understand that the Food and Drug Administration (FDA, or Agency) has stated an intention to begin enforcement of GFI #256 on October 1, 2022.

The ability of many veterinarians and pharmacists to serve animal patients will be affected by this GFI, and there remain too many unanswered questions for pharmacy compounders and veterinarians to achieve compliance in such a short time. We therefore respectfully request that CVM and FDA delay enforcement of GFI #256 until at least FY2024 and continue to work with pharmacy and veterinarian stakeholders, including state regulatory agencies, to provide clarification as to how the guidance will be implemented and enforced.

Additional time is needed because we are deeply concerned about immediate patient access barriers once enforcement begins. Indeed, there remains a tremendous amount of uncertainty surrounding the process and timeframe by which substances will be nominated and considered by the agency for inclusion on a positive list for compounding animal drugs from bulk substances for use by veterinarians in clinical settings, a critical component of animal health care. This will likely mean that many compounded drugs currently prescribed and administered to animal patients will become immediately unavailable while under nomination and consideration by the agency.

Additionally, the documentation and reporting requirements in GFI #256 will impose new burdens on how veterinarians communicate with compounding pharmacies and write prescriptions. As well as the development of new processes at pharmacies to meet these new requirements. 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.

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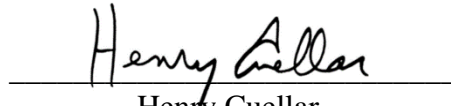
This is not an exhaustive list of concerns, but it is representative of the uncertainty that exists at present and warrants a delay of enforcement. We respectfully request that FDA postpone until FY2024 enforcement of GFI #256.

Thank you in advance for your consideration of this request.

Sincerely,



Diana Harshbarger, Pharm.D.  
Member of Congress



Henry Cuellar  
Member of Congress



Earl L. "Buddy" Carter  
Member of Congress



Donald Norcross  
Member of Congress