

September XX, 2022

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

Re: Request for Congressional Briefing and Delay in Enforcement of GFI#256

Dear Dr. Solomon:

We appreciate the recent announcement that enforcement of GFI #256, “Compounding Animal Drugs from Bulk Drug Substances – Guidance for Industry” will be delayed until the third quarter of fiscal year 2023. However, we remain concerned about the impact that enforcement of GFI #256 will have on patient care.

We are troubled that enforcement of the new processes used in animal compounding could result in delayed access to urgently needed patient care. The House report accompanying the fiscal year 2022 Agriculture Appropriations bill included language stating that “*(t)he Committee expects that any finalized guidance on compounding for animal health will preserve treatment options available to veterinarians, will reflect public input, and will recognize the need for compounded medications by pet owners, animal shelters, zoos and other stakeholders.*” It is disappointing that the Center for Veterinary Medicine (CVM) largely ignores the concerns that Congress and pharmacy and veterinarian stakeholders have raised about the impact this guidance will have on animal patient access to compounded drugs.

We respectfully request that CVM and the Food and Drug Administration continue to work with pharmacy and veterinarian stakeholders, including state regulatory agencies, over the next six months to provide clarification as to how the guidance will be implemented and enforced. Additionally, we request that CVM provide a briefing to Members of Congress and our staff within 60 days about how stakeholder concerns are being addressed and how the agency will implement and enforce GFI #256 in a manner that will not disrupt veterinarians’ practices and be detrimental to their patients’ health.

We understand the many priorities your agency must balance and we appreciate your consideration of this request. If you have questions, please have your staff contact [insert name].

Sincerely,