



Center for Veterinary Medicine (CVM)
Food and Drug Administration (FDA)
7500 Standish Pl, HFV-1
Rockville, MD 20855

February 2, 2023

RE: Request for Extension for Implementation of GFI #256

Dear Drs. Flynn and McCoig:

Thank you for the opportunity to meet with your team this past week to discuss [CVM GFI #256, Guidance for Industry for Animal Compounding](#). On behalf of APhA, we appreciate the time and look forward to continued discussions on the guidance and its implementation.

During the meeting, Dr. Flynn indicated that answers to the numerous questions would be issued soon. These questions have been submitted either individually, or from pharmacist associations to help bring clarity for our nation's compounding pharmacists who are working hard to care for their veterinary patients.

Many of our members have indicated their planning for the implementation of this guidance has been put on hold pending the answers to the questions submitted over these last several months. Once clarity is provided, our members can fully consider the scope and impact of the guidance for their practices. However, many pharmacists have indicated that use of the guidance will require technical infrastructure and additional in-depth education with veterinary practitioners on their ability to access and use compounded medications as a therapeutic tool in their practices.

As such, APhA respectfully requests a six-month (until October 2023) extension of the ongoing outreach and education period that was previously announced for GFI #256. An extension will enable pharmacists time to better understand the FDA's intent once they have more answers to the questions that have been posed. During this time APhA members can also educate the veterinary community on how these changes will have an impact on their practices. An extension will also aid in working towards minimal disruption to the care of animal patients which would be an unintended consequence of CVM holding to the April 1, 2023 date. While we appreciate FDA does not intend to take immediate action, some state board inspectors and third-party certification and accreditation organizations will require full compliance by April 1, 2023. In summary, an extension until October 2023 would enable compounding pharmacies time to consider



FDA's responses to the questions that have been raised. Provided these answers give clarity, it will also allow for adjustments to operations and to work with veterinary practitioners to implement these changes to meet the needs of our veterinary patients.

Respectfully,

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CC: Tracey H. Forfa J.D., Acting Director, CVM