

January 27, 2023

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 for additional postponement of enforcement as described in GFI #256

On behalf of the Alliance for Pharmacy Compounding, the American Pharmacists Association, and the National Community Pharmacists Association, 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 from our perspective, nothing has changed since we asked for the previous delay – no elaboration or clarification. Now we find ourselves a little over two months away from enforcement set to begin on April 1, 2023, with very little to tell veterinary compounders on what compliance looks like.

We are sincerely grateful for the open communication in which the agency has engaged. Our aim all along has been to help the agency implement guidance that works, that is understandable, and that is uniformly enforceable. During the period since the announcing the current delay of enforcement, CVM has not shared any clarification or further update that would equip pharmacy compounders to comply with the guidance. From our perspective, the purpose of that enforcement delay has not been achieved.

We await your release of answers to the questions we submitted last summer, which we are told are coming soon. When we have those questions, we'll need time to prepare compounders, veterinarians, and state boards of pharmacy for enforcement. That alone will require 9-12 months in our estimation. This includes sufficient time to socialize a compliance framework or rubric. The guidance currently doesn't provide that framework which will be essential for consistency in practice and enforcement.

Members of Congress wrote to the agency last autumn to request a briefing on progress in clarifying what compliance looks like. To our knowledge, that has not occurred.

As the April 1 enforcement deadline approaches, we are concerned that there's just not enough known yet – particularly by state boards of pharmacy – to initiate enforcement.

For these reasons, we respectfully request that FDA CVM postpone for at 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 PHARMACISTS ASSOCIATION

NATIONAL COMMUNITY PHARMACISTS ASSOCIATION