February 8, 2023

Dr. William Flynn, DVM
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Pl, HFV-1
Rockville, MD 20855

Re: Request for clarification on 2023 enforcement of GFI #256

Dear Dr. Flynn:

On behalf of the Alliance for Pharmacy Compounding and the National Community Pharmacists Association, thank you for the update on GFI 256 you and your team provided us last Friday. We appreciate your continued attentiveness to our concerns. As we stated again on that call, the result we seek is a GFI that we can all support – one that creates reasonable framework for the safety and effectiveness of compounded animal drugs while providing a compliance standard for veterinarians and compounding pharmacies and facilities that does not infringe on access to essential compounded animal drugs.

From our perspective, the agency has still not provided necessary clarity regarding compliance with the GFI, and as we mentioned on Friday's call, nothing has changed since we sought – and were granted – a delay of enforcement of the GFI last autumn. We continue to seek bright-line compliance standards that pharmacies can discern and adhere to – and more importantly, that state boards of pharmacies can discern and enforce. Absent that clarity, our inclination is to advocate for another delay of CVM's stated enforcement date.

However, we understand from you that the agency will soon be providing answers to the numerous questions we submitted late last summer, and we're hopeful those responses can provide some of the needed clarity. Even so, time is short between our receipt of those answers and the April 1 enforcement date the agency has publicly announced. Presuming CVM's answers will provide the additional direction we seek, it will take time for pharmacies to come into full compliance and for state boards to develop and/or adjust inspection standards in line with the GFI and your responses to our specific questions.

You indicated in the conversation last Friday that the April 1 enforcement deadline was not ironclad and that the agency views the April date *as only a target to begin phasing-in inspection activities*. You indicated that the agency anticipates a limited number of inspections for remainder of FY2023. We further understood you to say that those inspections that do occur will be *informational* in nature, with emphasis on the agency advising the inspected pharmacy/facility on observed areas of noncompliance.

If this is an accurate summary of your statements to us, we request that the agency issue a public statement to that effect. Further, if there are specific policies within the GFI that you believe are relatively clear and will likely begin enforcing on April 1 – the office-use positive list, for instance – it would be helpful for you to mention those in that statement.

Such a statement about your planned phase-in of enforcement will have a three-fold benefit:

1. It will provide some confidence to compounding pharmacies and facilities that they are being provided adequate time to bring their operations into compliance.
2. It will telegraph to state boards of pharmacy the agency's plans regarding enforcement and reduce the likelihood that state boards will begin their own version of enforcement on the April 1 date – enforcement that may well overreach or not comport with CVM's own views of compliant veterinary compounding practice.
3. It will indicate to those Members of Congress who wrote to the agency last autumn (to request a briefing on progress in clarifying what GFI 256 compliance looks like) that the agency takes seriously their concerns about assuring that compliance clarity precedes enforcement.

If the agency is willing to issue such a statement to stakeholders and to provide us answers to our submitted questions by February 28, 2023, we will certainly stand down on our intention to advocate for another delay of enforcement.

Additionally, as was discussed on our call on Friday, **there is a growing sense of urgency for the agency to provide clarification as to the application of GFI 256 to outsourcing facilities registered with FDA under Section 503B of the FDCA, particularly as it relates to compounding animal drugs from bulk ingredients for office stock**, as some state boards of pharmacy have recently moved to amend their regulations or policies on the issue in ways that may not align with GFI 256.

We also urge that the agency not limit its state regulator outreach to NABP only, but also reach out *directly* to state boards of pharmacy to assure the most complete and accurate communication of the agency's intentions on GFI 256 compliance and enforcement.

Again, we are sincerely grateful for the open communication in which the agency has engaged. Our aim has been and is to help the agency implement guidance that works, that is understandable, and that is uniformly enforceable.

Thank you in advance for your consideration of these requests. Please direct any questions to APC's Scott Brunner at scott@a4pc.org.

Sincerely,

ALLIANCE FOR PHARMACY COMPOUNDING
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION