Scott Brunner
President
Alliance for Pharmacy Compounding
100 Daingerfield Road, Suite 100
Alexandria, Virginia 22314

March 10, 2023

Dear Mr. Brunner:

Thank you for your letter on behalf of the Alliance for Pharmacy Compounding and National Community Pharmacists Association dated February 8, 2023, asking that the agency release a public statement on our intentions regarding phasing in inspectional activity in relation to the policy in the guidance document [GFI #256, Compounding Animal Drugs from Bulk Drug Substances].

As we discussed with you on February 3rd, 2023, FDA intends to shift our resources toward routine inspectional activities in April 2023. We will continue to engage stakeholders to address questions and clarify certain aspects of the guidance as we transition into this new inspectional phase.

FDA anticipates a limited number of inspections at State-licensed pharmacies through September 2023. As we transition into inspections in April 2023, FDA's initial emphasis will be to gather facts about compounding operations in relation to the policies and priorities in GFI #256 and then discuss them with the inspected pharmacy/facility. Information obtained during animal drug compounding inspections will be evaluated in accordance with FDA's prior notice policy. For situations that do not present human or animal safety concerns, this policy describes "FDA's practice to afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action" (see Regulatory Procedures Manual, 10-2).

With respect to inspections of federally registered outsourcing facilities, FDA does not intend to conduct routine inspections relating to the enforcement priorities for animal drugs described in GFI 256 until we provide clarification regarding how the policy in GFI 256 applies to these facilities. However, FDA may choose to conduct non-routine inspections at outsourcing facilities related to animal drugs, for instance, in response to evidence of insanitary conditions or to reports of adverse events or product defects associated with animal drugs compounded by these facilities that may present particular human or animal safety concerns.

FDA has made this information publicly available on our website. We appreciate the ongoing discussions with APC and NCPA and we will continue our outreach with you and other

stakeholders throughout this transitional period. Please let us know if you have any other questions.

Sincerely,

William T. Flynn -S Digitally signed by William T. Flynn -S
Date: 2023.03.10 15:31:08 -05'00'

William Flynn, DVM, MS
Deputy Director- Science Policy
Center for Veterinary Medicine