U.S. FOOD & DRUG ADMINISTRATION

September 9, 2022

Scott Brunner
Chief Executive Officer
100 Dangerfield Road,
Suite 100
Alexandria, VA 22314

Dear Mr. Brunner:

Thank you for your letter on behalf of Alliance for Pharmacy Compounding, American College of Veterinary Pharmacists, American Pharmacists Association, National Community Pharmacists Association, and Society of Veterinary Hospital Pharmacists dated July 14, 2022, regarding GFI #256, "Compounding Animal Drugs from Bulk Drug Substances-Guidance for Industry."

Since publication of the final guidance on animal drug compounding (GFI #256), FDA has engaged with a variety of stakeholders. We recognize that some pharmacies may need additional time to review the recommendations described in the guidance or make suggested changes to their processes, as well as to submit nominations for BDS for compounding office stock. Therefore, we are extending the ongoing outreach and education period that we previously announced. At this time, we do not intend to shift our resources toward routine inspectional activities until April 2023 (third quarter of fiscal year 2023). Nonetheless, as is currently the case, we will continue to take appropriate actions when we become aware of compounding practices that threaten human or animal health before we begin routine inspectional activities related to the new policy.

We will continue to engage stakeholders to address questions and clarify certain aspects of the guidance. This includes those issues that were raised in your letter. Please note that OMB completed their review of GFI #256 under the Paperwork Reduction Act on June 1, 2022; GFI #256 posted on the web CVM GFI #256 - Compounding Animal Drugs from Bulk Drug Substances | FDA reflects OMB clearance.

FDA's goal is to be transparent about the BDS that are submitted for review for use in compounding office stock by having them submitted to Docket No. FDA-2018-N-4626. This allows stakeholders to see what nominations are already made so that duplication of effort is avoided. Once a BDS is submitted for review and during the review process, that BDS will be added to the List of Nominated Bulk Drug Substances Currently Under Review and can continue to be used, thus keeping those substances available for use during FDA's review. Once a determination is made, the BDS will be removed from the List of Nominated Bulk Drug Substances Currently Under Review, and either added to the BDS to List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species or to the Bulk Drug Substances Reviewed and Not Listed.

We currently have 122 bulk drug substances included on the List of Nominated Bulk Drug Substances Currently Under Review posted on our website. FDA intends to provide enforcement discretion throughout the duration of the review of the BDS on this list so that veterinarians can continue to have access to BDS. The BDS lists remain open for nominations and will be updated as other nominations are submitted and reviews are completed. Please note that patient specific prescriptions are not limited to a BDS list.

We appreciate your willingness to continue to engage with the agency to ensure that your members are included in our ongoing outreach and educational efforts to support FDA's new animal drug compounding guidance.

Sincerely,

Steven Solomon -S

Digitally signed by Steven Solomon -S
Date: 2022.09.09 16:23:00 -04'00'

Steven M. Solomon, DVM, MPH
Director, Center for Veterinary Medicine