100 Daingerfield Road, Suite 401
Alexandria, VA 22314
www.a4pc.org

Alliance for Pharmacy Compounding

May 5, 2020

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

RE: Draft Guidance for Industry #256, Compounding Animal Drugs from Bulk Drug Substances (FDA-2018-D-4533)

Dear Dr. Solomon:

Thank you very much for your presentation to the Alliance for Pharmacy Compounding (APC) online educational conference this past Sunday. Your remarks were informative, and our members greatly appreciate the open line of communication you have established with our organization and your willingness to listen to our concerns about Draft GFI #256, Compounding Animal Drugs from Bulk Drug Substances.

We would also like to thank you for extending the original comment period on Draft GFI #256 for an additional 120 days to June 17, 2020. Because many of our members and other pharmacy stakeholders have been focused on working with the hospitals, physicians and other front-line responders treating COVID-19 patients, we have been unable to receive and process the level of input necessary to provide substantive comments into the docket on this draft guidance. Unfortunately, we anticipate this to be the case for the next few months until infection rates flatten and decline**. For this reason, we respectfully request an extension of another 180 days of the comment period on Draft GFI #256 until December 16, 2020.**

Below are a few of the questions submitted by participants at your Sunday session that we unfortunately did not have time to get to. If you are willing, we would appreciate answers to the following at your convenience. We're presenting them here in the form and syntax in which they were submitted.

1. The Index of Legally Marketed Unapproved New Animal Drugs was established almost 25 years ago, yet to date contains only 14 items, 2 of which are buprenorphine preparations and 4 of which are benzalkonium based topical antiseptics. Why does CVM think there has been so little utilization of this list, and do you think it is truly a viable mechanism for bringing MUMS drugs to market?

2. How might compounders and veterinarians obtain more clarity around FDA's expectations for what is acceptable rationale for their decision to use bulk API when prescribing and compounding individual patient prescriptions? Understanding the Agency's expectations will help guide the feedback our members provide in their comments to the Guidance.

3. How does the bulk API list and nomination process for office use veterinary compounds described in this guidance align with other FDA guidance related to the use of bulk API by both

100 Daingerfield Road, Suite 401
Alexandria, VA 22314
www.a4pc.org

Alliance for Pharmacy Compounding

503A and 503B compounders? In other words- are bulk API's listed on the positive list for use in animal health automatically approved for use by 503As and 503Bs compounding animal health medication regardless of whether or not these API's have been nominated and/or approved for use in accordance with current guidance for bulk API use in 503As or 503Bs?

4. The nomination process seems to hinge upon data that are very challenging to obtain when medications are made for individual patients on patient-specific prescriptions. How do we reconcile the requirement for these data with the rules that make it impossible to obtain the data?

5. Since 2013, pharmaceutical manufacturers have released at least four FDA-approved animal drug products per year, all based on preparations being compounded by pharmacies from bulk drug substances. This leads us to question the concern with compounding from BDS disincentivizing manufacturers from going through the new drug approval process. Furthermore, as you must be aware, most manufacturers of animal drugs refuse to sell to pharmacies, so, how are we supposed to compound from approved product if we cannot obtain it?

Thank you again for your participation in APC's EduCon2020, and for your continued willingness to engage with APC and other pharmacy stakeholders on animal drug compounding issues. We look forward to continuing to work with you and your team at CVM on these important issues.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer