March 9, 2022

The Honorable Earl L. "Buddy" Carter
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Carter:

Thank you for your letter of January 19, 2022, cosigned by seven of your colleagues, regarding the Food and Drug Administration's (FDA or the Agency) draft Guidance for Industry (GFI) #256, *Compounding Animal Drugs from Bulk Drug Substances*. Your letter requests that FDA issue another round of draft guidance before publishing the final version of GFI #256. We would like to provide some additional information in response to your letter.

FDA's Center for Veterinary Medicine's mission is to protect human and animal health. Although compounding an animal drug from bulk drug substances results in an unapproved new animal drug, we recognize that compounded drugs are an important tool in veterinary medicine because they allow veterinarians to treat a wide variety of animal species with varying conditions when approved drugs to treat those animals are unavailable. When finalized, GFI #256 will help protect animal health by recognizing the need for veterinarians to access animal drugs compounded from bulk drug substances when FDA-approved drugs are not available.

FDA understands the significance of this topic for animal health and has engaged a wide variety of affected stakeholders, including veterinarians, pharmacists, and animal owners. To further foster collaboration with stakeholders on the draft guidance, FDA provided two back-to-back extensions to the deadline to allow more than 212 days to submit comments to the public docket for the draft guidance. During this time, FDA held a public webinar and engaged directly with affected stakeholder groups through discussions, briefings, presentations, and educational webinars. FDA developed and implemented a rigorous process to carefully consider the more than 2,200 comments received to our draft guidance. Based on the feedback received, we have substantially modified the guidance to address many of the concerns that were raised. At this time, we do not believe that issuing another round of draft guidance is warranted. However, consistent with FDA's Good Guidance Practices regulations, we note that interested stakeholders can submit comments on any FDA guidance document at any time.

After the final guidance is issued, FDA is planning an extensive outreach and education period to further engage affected stakeholders, including the veterinary, pharmaceutical, and compounding pharmacy communities. During this period, FDA will meet with interested stakeholders, host webinars, and otherwise engage veterinarians and compounding pharmacists to discuss the new guidance and address questions about content and implementation. FDA intends to have an

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extended timeframe to focus on education and stakeholder engagement for the new animal drug compounding policies and will work flexibly and cooperatively with stakeholders during this period. We will take appropriate actions, as we currently do, when compounding practices threaten human or animal health.

We plan to follow up with you to confirm the timing of publication and to provide additional information regarding our phased-in implementation strategy. We would also be happy to meet with you to discuss in detail our revised guidance and our outreach and education activities after the final guidance is published.

Thank you again for your interest in animal drug compounding, an issue of high importance for veterinary medicine. The same letter has been sent to your cosigners.

Sincerely,

Steven Solomon -S

Digitally signed by Steven Solomon -S
Date: 2022.03.09 17:39:07 -05'00'

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