Congress of the United States
Washington, DC 20515

January 19, 2022

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

We write to you today regarding our concerns with the Food and Drug Administration's (FDA) Guidance for Industry #256, "Compounding Animal Drugs from Bulk Drug Substances" ("GFI #256). This draft guidance was published in the Federal Register on November 20, 2019 and has faced serious concerns from pet owners and the animal caretaker community since then. I urge you to ensure that any next steps the FDA takes on GFI #256 are published in draft – not final – form due to the following concerns.

GFI #256 proposes drastic changes in the way compounded animal drugs are produced and sold that would have the harmful impact of increasing the price and reducing the safety of these drugs. The FDA guidance would require veterinary compounders to use finished drug products, as opposed to bulk substances, in their compounded medications. The cost of finished products is significantly greater than the cost of bulk substances, increasing the price of medications by up to 300%. Additionally, using finished drugs in compounded medications introduces unnecessary and potentially unsafe excipients into compounded medications, impacting their administration and the animals' health outcomes.

In response to GFI #256, over 2,500 comment letters and were submitted to the agency from veterinary, pharmacy, research, zoo, wildlife, shelter, and other organizations detailing their concerns over cost and safety. Dozens of Representatives have also shared their concerns regarding the statutory authority of the agency to implement GFI #256 in letters to the agency, most recently on October 15, 2020. Lastly, Congress has raised similar concerns regarding the need for any guidance documents related to animal compounding to be grounded in statute in final appropriation conference reports for FY2017, FY2018, and FY2019.

The issues addressed in GFI #256 are complex and warrant further input from stakeholders yet, despite congressional requests, we understand that there have not been significant stakeholder meetings during the one-year period since the comment period ended. GFI #256 presents too significant of a barrier in access to medications for pets, companions, and exotic animals for the agency to move forward with final guidance at this time. Therefore, it is necessary for the FDA to issue another round of draft guidance to ensure there is fair evaluation

of any new proposal or changes made to accommodate the overwhelming concerns from pet owners and the animal caretaker community. Thank you for your consideration of this request.

Sincerely,

Mark Pocan
Member of Congress

Kurt Schrader
Member of Congress

Bill Posey
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

Debbie Lesko
Member of Congress

Bruce Westerman
Member of Congress

Henry Cuellar
Member of Congress

David Schweikert
Member of Congress