# Congress of the United States
Washington, DC 20515

Stephen Hahn, M.D
Commissioner
United States Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20903

October 15, 2020

Dear Commissioner Hahn:

We are writing to express our concern with FDA's draft Guidance for Industry #256, "Compounding Animal Drugs from Bulk Drug Substances" ("GFI #256). This draft guidance was published in the Federal Register on November 20, 2019, and is very similar to GFI #230, which the Agency issued on May 19, 2015 and withdrew in 2017 following serious objections from the veterinary and pharmacy community as well as from pet owners.

We are concerned that GFI #256 would single out veterinarians as the only medical professionals with prescription authority required to document in writing a clinical need and medical rationale before they can provide certain patient specific prescriptions from a traditional pharmacy made from bulk active pharmaceutical ingredients (API). The proposed GFI #256 also limits office stock medications made from API to a positive list developed at the sole discretion of FDA. Since veterinary clinics serve as emergency rooms and hospitals for animals, this restrictive regulation of office stock medications may lower the standard of care for animal patients and limit access to important medications.

As you may know, the cost of medication for animals can be a barrier to care. We are concerned that the proposed guidance requires that finished pharmaceutical ingredients be used as a starting point for compounding may lead to a massive increase in the cost of commonly used animal medications. In fact, veterinarians and animal compounding pharmacists have reached out to our offices to notify us that these new rules will significantly increase the cost of the most commonly used animal drugs.

We are concerned that no existing statute gives FDA the authority to implement the provisions set forth in GFI #256. 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.

We therefore ask, unless FDA can identify the specific statutory authority that supports the provisions of GFI #256, that this draft guidance be modified or withdrawn so that it is in

compliance with existing laws, does not increase the cost of animal health care, or restrict safe pharmaceutical options available for veterinarians treating their animal patients. We also ask that FDA engage all stakeholders, including pet owners, zoos, rescue shelters, veterinarians, compounding pharmacists and others as this process moves forward.

Thank you for your attention to this matter. Please do not hesitate to contact our offices if you require any further information.

Sincerely,



Ted S. Yoho, D.V.M.
Member of Congress



Mark Pocan
Member of Congress



Donald Norcross
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

Michael F.Q. San Nicolas
Member of Congress

Henry Cuellar
Member of Congress

Bill Posey
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John R. Carter
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Bruce Westerman
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Eleanor Holmes Norton
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Bonnie Watson Coleman
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