Congress of the United States
Washington, DC 20515

February 4, 2020

Commissioner Stephen M. Hahn, M.D.
Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hahn,

We write today regarding FDA's draft Guidance for Industry (GFI) #256, "Compounding Animal Drugs from Bulk Drug Substances" ("GFI #256"), which was published in the Federal Register on November 20, 2019. GFI #256 is very similar to GFI #230, which was released in April of 2015 and rescinded in 2017. In the final appropriations bills for FY2017 and FY2018, Congress included report language expressing concerns that the previous guidance on animal drug compounding, GFI #230, exceeded FDA's statutory authority. Given these concerns and others, we seek clarification on the new draft guidance and ask that FDA extend the public comment period by 90 days to allow for sufficient stakeholder input.

Draft GFI #256 asserts that animal drugs may only be compounded from approved products, citing the Agency's extra-label regulations that state that their scope pertains to "any approved new animal drug or approved new human drug". The draft guidance also establishes criteria for when the agency will exercise enforcement discretion and allow for the use of bulk active pharmaceutical ingredients when necessary to meet the medical needs of a particular animal patient. Often, the FDA product is in a dosage or strength that is not suited to treat animals of varying breeds and sizes. FDA has suggested that FDA-approved human and animal drugs be used as a starting point for compounding, and if smaller or larger doses are needed, the caregiver should fractionalize or multiply the dose. Given the lack of accuracy in compounding from finished drug product and the potential hazards of doing so, what is the scientific rationale for this recommendation and what consideration has been given to possible safety risks from this process?

If finalized, the guidance would represent, for the first time, the current thinking of the FDA on medications compounded from bulk drug substances for animals without patient-specific prescriptions (or "office stock"). The rationale for providing oversight of these products may be well-intended, but we have questions about the process FDA will undertake for adding bulk drug substances to the list of ingredients that can be used for compounding preparations for office stock. Despite previous submissions of many ingredients for inclusion on this list, only a woefully insufficient eight ingredients are listed. Veterinary clinics often serve as emergency rooms and hospitals for animals, and certain compounded medications must be immediately available in order to ensure proper patient outcomes. Please detail FDA's proposed process and timeline for evaluating bulk ingredients for inclusion on the proposed positive list. As the sheer number of bulk ingredients currently used for compounding in animal health is a robust list of over 450, how many nominations do you anticipate that you will be able to evaluate and approve and in what timeframe? What restrictions on bulk ingredients does FDA intend to enforce during this review process?

We would also note that there is an atypical need for compounded preparations to be maintained as office stock for minor species, such as exotic, zoo and wildlife animals. We are concerned that the few ingredients available to be used for compounding preparations for office stock will leave a gap in the life-saving medical care that we provide to animals. There is a lack of transparency in who is making the decisions about the substances and how these decisions are being made. What is the FDA's rational for setting narrow limits on species, dosage form and strength of medications even from APIs that are currently prescribed more broadly? We request additional information on who is reviewing submissions and how FDA intends to review substances that are critical for treating patients but where all of the information FDA is requesting for substance nominations does not exist. Veterinarians should be involved in the decision-making process for determining permissible ingredients to ensure the list will meet the needs of their practices.

Veterinarians commonly document medical rationale for choosing any treatment for their patient, however, the guidance requires that a medical rationale be documented for choosing compounded products when FDA approved products are available for use. The guidance does not indicate what will meet this requirement, including where the documentation must be submitted. Medical providers with prescription authority evaluate patients and write prescriptions as necessary which document clinical need. Veterinarians are no different. Please clarify the reasoning for this new requirement on veterinarians and whether providing an explanation in the animal's medical record would meet the intent of this requirement and, if not, what is being required of veterinarians.

We appreciate that the FDA's intended purpose of the new guidance is to ensure safety and effectiveness of animal drugs compounded from bulk drug substances. Significant work has been done since the withdrawal of GFI #230 in 2017 but given the significant departure from current practices, we urge additional scrutiny and evaluation of any recommendations that move forward. We request a 90 day extension to the comment period past the February 18, 2020 deadline to allow ample time for interested parties to provide feedback and a written response to the concerns we have outlined in this letter, and those you may receive from stakeholders, prior to finalizing any form of this draft guidance on animal drug compounding from bulk drug substances.

Thank you for your attention to this matter. We look forward to receiving a response from you within fourteen business days, and please do not hesitate to contact our offices if you require any further information.

Sincerely,

Kurt Schrader, DVM
Member of Congress

Ted S. Yoho, DVM
Member of Congress