American Pharmacists Association

FDA Drug Compounding Annual Listening Session –
Pharmacy, Consumer, and Industry Organizations
Compounding SIG Coordinator Natalie Young, PharmD, FACVP
June 17, 2022

- Thank you for the opportunity to represent our nation's pharmacists at today's compounding listening session.

- Today, I will be addressing the FDA's Center for Veterinary Medicine's Guidance for Industry (GFI) #256 - Compounding Animal Drugs from Bulk Drug Substances – which is of particular concern to our members' veterinary pharmacists.

- Additional written comments from APhA will also be submitted separately.

- I would like to stress that it's important for the veterinary community to continue to have open dialogue with the FDA about the impact of this guidance. While GFI #256 is "guidance," from the FDA, and even by the FDA's own statements is not legally binding and is to provide the FDA's current policy on whether or not they would take enforcement action or not, GFI #256 has the effect of creating regulations that must be followed. We are already experiencing numerous third-party accreditation bodies requiring documentation of compliance with the guidance. And we expect state regulatory bodies to also formally reference the guidance in their enforcement actions.

- To be clear, pharmacists appreciate the efforts of the FDA to issue the guidance and the time they took to consider all of the comments and incorporate a number of the concepts received from stakeholders in the final document.

- Compounding, particularly in the veterinary space, meets an important need to provide personalized medicines for a wide variety of species as well as the individual breeds within those species.

- With such a variety of patient needs, it is often difficult to find commercially available products in the dose or dosage form that enables proper administration of medications to animals.

- Veterinarians need compounded medications in specific doses or dosage forms to administer in-clinic or to provide at least initial dosing to their pet patients until the pet owner may have the prescription filled at a pharmacy. The current list of substances approved does not fully address the clinical needs of all species. Companion animals (namely canine and feline patients) are well represented, but equine is glaringly disregarded.

- Doxycycline, a justifiable office medication, is a particular example of concern. For an equine patient, it will require an exorbitant amount of approved product to make the dosage needed. To be clear, this is not a concern of cost, but of the ability to accurately manipulate so many tablets or capsules to make a final product.

- While the FDA has made statements that it is their intention to have an orderly and expeditious process to nominate and review bulk substances for the various lists created under the guidance, there is still concern about the process and how it will impact the ability of veterinarians to provide care in-clinic.

- It is our hope that the process to nominate and review bulk substances for office use will take into account the needs of veterinarians and their pet patients and can be done in a timely manner so as to not impact emergent treatment needs of the pet patients.

- We find it difficult to understand why this guidance is built on the idea that compounding from active pharmaceutical ingredients for non-food producing animals is inappropriate in so many situations. The FAQ for GFI 256 states: "Although the resulting compounded drug is not considered FDA-approved, the process starts with a substance that has been evaluated by FDA, which provides some assurance of safety and effectiveness." This is refuted by data from USP showing that some formulations fail when compounded from manufactured products. In addition, the excipients in veterinary medications are not disclosed meaning it would not be possible to verify if any of the excipients are problematic to formulations or specific species.

- Finally, FDA's list of compounds for office use is specific to the point of providing indications for specific compounds and routes of administration. This would seem to be a departure from the Agency's typical approach to say that only FDA approved drugs could have indications.

- Thank you for the opportunity to address you today. We hope that the FDA continues to consider these impacts and contacts APhA as a resource when considering bulk substance nominations in the future.