American Pharmacists Association

FDA Drug Compounding Annual Listening Session –
Pharmacy Groups
Representing the American Pharmacists Association:
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- Esteemed FDA staff, pharmacy colleagues, and other attendees. It is a privilege to address you today on behalf of the American Pharmacists Association on behalf of our nation's pharmacists at today's compounding listening session

- We are grateful for this opportunity to engage in an open discussion about the pressing issues in pharmaceutical compounding, which are critical not only to patient care but also to the integrity of our practice.

- Here are the issues we would like to highlight for you at the session, which includes issues related to veterinary compounding. We would like you to share with your CVM colleagues and we intend to request a separate meeting with them to discuss those issues.

- Thank you for the opportunity to provide our perspective to the FDA. We hope FDA considers these points as it crafts future policy and contacts APhA as a resource to ensure patients have appropriate access to compounded medications.

Drug Shortages

- The potential for 503A facilities to help mitigate drug shortages, particularly for small, rapidly needed orders, underscores the necessity of a clearer regulatory framework. We would like FDA to further collaborate with state boards of pharmacy on the intent of FDA policy. In last year's listening session, we commented on the challenges that patients and caregivers faced in obtaining ibuprofen and acetaminophen oral suspensions.

- Unfortunately, those medications were never added to the FDA's drug shortage list despite not being on store shelves and numerous media reports reporting the shortages. While FDA did ultimately issue immediately in effect guidance on 503Bs producing ibuprofen there was limited uptake of the model at that time. Since last year's listening session, we have become aware of boards of pharmacy that have taken action against pharmacies that chose to serve the needs of those patients. FDA's FAQ on the 503B guidance noted that 503A pharmacies can make copies of commercial products provided that they do not do so regularly or inordinate amounts. FDA's view on

inordinate amounts as expressed in the 503A copies guidance is no more than 4 copies in a month. One pharmacy was penalized by its board of pharmacy for serving the needs of 5 patients in a month. It remains challenging to consider denying needed care to a patient because they are number 5 as opposed to number 4 in a given month. This demonstrates the strict and literal reading of FDA guidance by boards of pharmacy, despite that it is FDA's current thinking and stakeholders can take different approaches.

- APhA would like to further explore FDA policies that would permit 503A pharmacies to serve the needs of their patients in a shortage. We strongly urges FDA to consider alternate approaches for future drug shortages. The model of having 503Bs providing medications to 503A pharmacies can be helpful for shortages. However, it is not sufficient for all situations and continues to provide challenges from some state boards of pharmacy as they apply FDA's draft guidance. APhA requests FDA to collaborate with state boards of pharmacy to help address these gaps in care to meet the needs of patients.

- FDA's guidance suggests 503B outsourcing facilities could produce the ibuprofen suspension and then provide it to 503A pharmacies for dispensing to patients with prescriptions. This approach is challenging on multiple levels. Pharmacies do not commonly purchase compounded products from 503B outsourcing facilities for dispensing and they found it difficult to determine which of the approximately 75 outsourcing facilities to contact for ibuprofen suspension during that shortage.

- In addition, Section 503B of the Food Drug and Cosmetic Act (FDCA) also has a prohibition on wholesaling and the law requires labeling on all products produced by 503B facilities to include the statement "Not for resale." Many pharmacists would regard the sale of the compounded drug product by a 503B outsourcing facility to a 503A pharmacy as wholesaling, and the label on that product would instruct the pharmacy not to resell it to the patient. Boards of pharmacy may also have questions or concerns regarding the interpretation of wholesaling by outsourcing facilities.

- In addition to the 503A and 503B issues – another barrier is requiring a prescription for what is typically available as an over-the-counter (OTC) drug product. FDA guidance on the prescription requirement under Section 503A of the FDCA states that a prescription for a human compounded drug is required for products compounded by 503A pharmacies. Understandably, this was a logistical burden on prescribers to write for what is otherwise an OTC drug.

- In summary, while it may be viable for 503B outsourcing facilities to provide compounded medications to 503A pharmacies for dispensing, this model is relatively new and was challenging to implement during a shortage. 503A pharmacies should be

utilized to compound these medications in shortages as they are readily accessible to patients and caregivers in their communities to meet these needs. It may be of value to FDA to confer with Health Canada to learn more about their decision to allow pharmacies in Canada to compound both ibuprofen and acetaminophen suspensions due to the shortages experienced in Canada.

Stability Studies

- Regarding the requirement under USP <797> that sterile compounding pharmacies have completed stability studies for Compounded Sterile Preparations in Category 3, testing laboratories are experiencing unprecedented backlogs and considerably longer turnaround times. APhA urges FDA to use enforcement discretion for sterile compounders to have completed stability studies under USP category 3 to allow compounders the ability to continue to serve patients during the required time to receive stability testing results. APhA also requests that FDA work with the boards of pharmacy to understand and provide some transition time for compliance with this new requirement.

Veterinary Compounding

CVM's GFI #256

- APhA expresses our appreciation for the FDA's efforts in veterinary compounding, especially concerning CVM's Guidance for Industry #256. This guidance marks a significant advancement in curbing practices that endanger patients and undermine the foundation of compounding. The veterinary compounding community has increasingly noticed a rise in the egregious practice of redispensing office stock medications for profit, an action that compromises the safety and well-being of many animals. Such practices, along with the creation of extensive product lines that resemble mass manufacturing, distort the essence of compounding. We commend the FDA's initiative in addressing these harmful behaviors, reflecting our mutual commitment to patient safety and ethical compounding practices.

- However, despite the progress GFI #256 represents, there remains a level of confusion that we urge the FDA to clarify promptly. Despite some 503B facilities claiming that GFI #256 does not apply to them, FDA guidance suggests otherwise. This misinterpretation or misapplication of guidelines can create a regulatory gray area, jeopardizing compliance as well as the safety and efficacy of veterinary compounds. Clear and explicit guidance from the FDA is urgently needed to ensure that these facilities operate legally, protecting both animal and human health.

API

- Another significant challenge in veterinary compounding is the absence of publicly available quality standards for active pharmaceutical ingredients in the field. This

deficiency hampers our capacity to guarantee the safety, efficacy, and quality of medications tailored for veterinary use. A concerted effort involving pharmacists specializing in this niche, and regulatory authorities is essential to develop and enforce stringent quality criteria. Establishing and implementing USP monographs for veterinary APIs would make substantial progress, providing the necessary guidelines to ensure the highest level of care for animal patients.