

## VIA ELECTRONIC SUBMISSION

January 27, 2020

Food and Drug Administration  
Division of Dockets Management  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2018-D-4533 for “Compounding Animal Drugs from Bulk Drug Substances” Draft Guidance for Industry**

Dear Sir/Madam,

The United States Pharmacopeia (USP)<sup>1</sup> appreciates the opportunity to provide comments on FDA’s draft guidance, “Compounding Animal Drugs from Bulk Drug Substances.” Through the development of public quality standards, USP shares FDA’s goal of ensuring the quality and safety of compounded preparations both for human and animal patients. We laud the Agency’s reissuance of draft guidance specific to the compounding of animal drugs.

USP’s public standards are developed through an open, transparent process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology. The process utilizes the work of independent experts in close collaboration with stakeholders and government agencies, such as FDA.

USP compounding standards are developed by independent experts from industry, academia, and healthcare fields. USP is committed to the continued development of public standards for animal drug products, whether they are drug substances, conventionally manufactured products, or compounded preparations.

We appreciate FDA’s sustained efforts to support public quality standards for animal health products, including recognition of the role of USP’s compounding chapters and monographs. In particular, we note FDA’s statement in the draft guidance that the Agency does not intend to take enforcement action where drugs for nonfood-producing animals are compounded from bulk substances in accordance with the current *USP-NF* Chapter <795> “Pharmaceutical Compounding – Nonsterile Preparations” or <797> “Pharmaceutical Compounding – Sterile Preparations” and in compliance “with the standards of all applicable *USP-NF* monographs (e.g., a monograph for a bulk drug substance or a monograph for a compounded finished product).”

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<sup>1</sup> USP is an independent, scientific, nonprofit organization dedicated to improving health through the development of public standards for medicines, foods, and dietary supplements. Through a longstanding collaboration with FDA, we have worked continuously to benefit public health through accessible quality medicines.

USP's drug standards are made applicable to articles in commerce by express recognition in the Federal Food, Drug, and Cosmetic Act (FD&C Act).<sup>2</sup> USP monographs for drug articles include standards of identity, quality, purity, strength, packaging and labeling and are applicable to both human drugs and animal drugs. There are more than 190 veterinary-specific monographs for drug substances and FDA-approved drug products. USP currently has more than 220 monographs for compounded preparations, with more than 20 veterinary-specific compounded formulations.

With respect to the practice of pharmacy compounding, USP's General Chapters <795> and <797> are made applicable to human drugs under section 503A of the FD&C Act, as elaborated further in guidance documents. Both chapters contain provisions that are intended to be relevant and useful in animal health. The Compounding Expert Committee (CMP EC) previously noted that it will consider the development of a veterinary-specific chapter in the 2020-2025 revision cycle.<sup>3</sup> The CMP EC continues to commit to thorough evaluation and deliberation regarding the development of a veterinary-specific compounding chapter. USP welcomes input on the development of the chapter from stakeholders, including FDA.

Thank you for the opportunity to comment. We appreciate FDA's recognition of USP standards for use in the compounding of animal drugs and look forward to continued collaboration with the Agency and other stakeholders in this area.

For more information, please contact Elizabeth Miller, Pharm.D., Vice President, U.S. Public Policy and Regulatory Affairs, at [ehm@usp.org](mailto:ehm@usp.org); (240) 221-2064.

Sincerely yours,



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<sup>2</sup> See "Recognition of USP Compounding Standards," at <https://www.usp.org/compounding/legal-considerations>.

<sup>3</sup> See, e.g., Response to Commentary Summary #6 and #7, page 3, at [https://www.uspnf.com/sites/default/files/usp\\_pdf/EN/USPNF/usp-nf-commentary/commentary-gc-795-20190531.pdf?\\_ga=2.212844116.197934846.1577110715-90430730.1570817712](https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/commentary-gc-795-20190531.pdf?_ga=2.212844116.197934846.1577110715-90430730.1570817712) (June 1, 2019); and Response to Commentary Summary #11 and #13, pages 4-5, at [https://www.uspnf.com/sites/default/files/usp\\_pdf/EN/USPNF/usp-nf-commentary/gc-797-commentary-20190628.pdf?\\_ga=2.212844116.197934846.1577110715-90430730.1570817712](https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/gc-797-commentary-20190628.pdf?_ga=2.212844116.197934846.1577110715-90430730.1570817712) (June 28, 2019).