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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852

Subject: Comments of USP on FDA's "Request for Quality Metrics Draft Guidance for Industry," Docket No. FDA-2015-D-2537

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) "Request for Quality Metrics Draft Guidance for Industry" (Quality Metrics Draft Guidance). We have consistently supported FDA's quality initiative, "Pharmaceutical cGMPs for the 21<sup>st</sup> Century: A Risk-Based Approach," since its launch in 2002. We recognize the value of quality metrics as part of FDA's overall quality initiative and appreciate the efforts the Agency has undertaken to engage stakeholders on this issue. USP commits to working with you and other stakeholders to help advance these important efforts.

USP is a nongovernment, nonprofit organization with a mission to improve global health through public standards and related programs. We offer a trusted source of science-based information and set public standards for the identity, strength, quality, and purity of medicines, working through scientific experts who volunteer their time and expertise to the standard-setting process. USP standards are published in the *United States Pharmacopeia - National Formulary*, an official compendium of the United States, and are legally enforceable by FDA. USP's longstanding collaboration with FDA has worked continuously to benefit public health, whether it has been updating quality standards for heparin and glycerin, or more recent compendial modernization efforts. Building on this partnership, USP is significantly investing over the next five years in new approaches with FDA and industry to ensure that our quality standards for medicines are current and represent the best state of science and today's practices.

Since 1820, when USP was founded with the objective of bringing uniformity to medicine and pharmacy in the United States through the establishment of a compendium of drug standards, much has changed, including the globalization of the pharmaceutical industry, scientific advancements, multi-sourced products, and orientation towards a quality culture. There have also been increased challenges in the supply chain, including drug shortages caused by quality concerns that pose significant health risks to patients and increase costs to the healthcare system. Throughout these changes, we have evolved, and USP's public standards have continued to play a key role as part of the safety net that protects patients in the US and assures access to high quality medicines. We commend FDA for seeking opportunities to reduce these public health risks.

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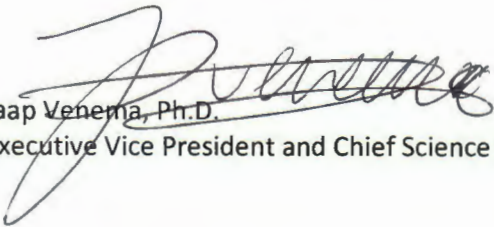
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USP supports FDA's quality initiatives, as included in the Quality Metrics Draft Guidance, and the corresponding effort to ensure that pharmaceutical manufacturing—and the manner in which quality is measured and achieved—advances continuous innovation and delivery of high quality medicines to patients. A risk-based approach, combined with a commitment to the welfare of patients, is essential in helping all of us meet the demands of the modern global supply chain and ensure optimal use of resources for this important enterprise. Ultimately, we support risk-based quality approaches which are balanced in terms of demands on stakeholders to enable implementation, but also effective in improving overall quality of public health and reducing potential impact of manufacturing quality deficiencies, including drug shortages.

Like FDA, USP envisions a world in which all patients have access to high-quality, safe and effective medicines and we look forward to continuing our partnership with FDA and industry towards this shared vision. Thank you for your consideration of these comments. If you have any questions please do not hesitate to contact me.

Sincerely,



Jaap Venema, Ph.D.  
Executive Vice President and Chief Science Officer