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To enhance pharmaceutical quality and patient safety, USP announces expanded access to the *USP-NF* online platform

Over 5,000 medicine monograph standards to help keep patients safe

Rockville, MD, November 21, 2019 — As the global pharmaceutical supply chain becomes more complex, adherence to public quality standards is especially important because they provide transparent, publicly available requirements for medicines and their ingredients. To address concerns raised during recent Congressional hearings to safeguard pharmaceutical supply chains, the United States Pharmacopeia (USP) is providing complimentary access to the *United States Pharmacopeia-National Formulary (USP-NF)* online platform to global drug manufacturers that are not currently subscribed. USP's quality standards set specifications for identity, purity, potency, and performance quality attributes in prescription drugs and their ingredients.

"While there are many components to the regulatory framework to safeguard medicine quality, adherence to USP standards remain foundational. For this reason, we are making the online platform of *USP-NF* available for free for six months to new subscribers," said Ronald Piervincenzi, Ph.D., Chief Executive Officer, USP.

According to the U.S. Food and Drug Administration (FDA), over 70 percent of all active pharmaceutical ingredient (API) manufacturers for the US market are outside the United States. USP's API monographs outline the quality requirements of 82 percent of the single active ingredient medicines Americans rely upon to sustain and improve their health. These standards are based on the work done by scientific and healthcare experts that volunteer their time and are an integral part of the foundation of the system, which helps to ensure patient safety.

"We also deliver education courses detailing dosage form quality, including specifications, analytical method validation, and pharmaceutical quality practices," stated Salah Kivlighn, Ph.D., Senior Vice President, Global Strategic Marketing and Program Operations, USP. "Courses are provided online and in person in 36 countries, including the U.S., India, China, and other locations where medicines are manufactured."

USP will continue to develop and train on adherence to standards and collaborate with FDA and stakeholders to leverage our scientific expertise to help address new medicine quality and patient safety challenges as we have done for 200 years.

About the USP-NF



The *USP-NF* includes more than 5,000 monographs for finished drug products (both chemical and biologic), as well as active pharmaceutical ingredients (APIs) and excipients. Specifically, the *USP-NF* includes more than 1,500 API monographs, covering 50 therapeutic classes including oncology, cardiovascular, endocrine, infectious disease, and mental health drugs.

Manufacturers interested in six months complimentary access to *USP-NF* should contact <u>uspnf-info@usp.org</u>. Offer is limited to manufacturers that are not current online subscribers to the *USP-NF*. After the 6-month period, participants will have the option to purchase an online subscription.

About USP

USP is an independent scientific organization whose mission is to improve public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. Through our standards, advocacy, and capability-building, USP helps increase the availability of quality medicines, supplements, and food in the United States and for billions of people worldwide. USP has offices in the United States, Asia, Africa, Latin America, and Europe, including five state-of-the-art laboratories, full-scale training facilities in Ghana and India, online and in person training courses, and partnerships with national quality control laboratories around the world. For more information about USP, visit www.usp.org.

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