

FOR IMMEDIATE RELEASE

Media Contact

Claudia Costabile: cac@usp.org

Office: +1-301-816-8314

Mobile: +1-240-274-0678

U.S. Pharmacopeia (USP) Extends Standards Implementation Dates and Comment Period for *USP–NF* and *FCC* Publications

Rockville, MD, March 30, 2020 – The U.S. Pharmacopeia (USP) is taking actions to help stakeholders currently facing numerous challenges with maintaining normal operations during, and responding to, the Coronavirus disease (COVID-19) global pandemic. In light of these circumstances, the USP Council of Experts (CoE) has adjusted the upcoming official/effective dates for the *U.S. Pharmacopeia* and *National Formulary (USP–NF)* and *Food Chemicals Codex (FCC)* publications as follows:

- *United States Pharmacopoeia and National Formulary*
 - ***USP 43–NF 38 (published November, 2019)***: Official date has been extended by 6 months from May 1, 2020 to November 1, 2020
 - ***USP 43–NF 38, First Supplement (published February, 2020)***: Official date has been extended by 3 months from August 1, 2020 to November 1, 2020

Per the *USP–NF General Notices and Requirements*, Section 3.10 *Applicability of Standards*, early adoption of revised standards in advance of the official date is allowed by USP, unless specified otherwise at the time of publication.

- *Food Chemicals Codex*
 - ***FCC, Twelfth Edition (published December, 2019)***: Effective date has been extended by 6 months from June 1, 2020 to December 1, 2020

In addition, USP is extending the comment period deadlines for *Pharmacopeial Forum (PF)* 46(2) [Mar.–Apr.] 2020 by 2 months from May 31, 2020 to July 31, 2020.

In addition to proactively adjusting official dates and comment timelines for USP publications, USP may facilitate rapid compendial actions, if necessary, to prevent supply disruptions and ensure the availability of existing/new treatments.

The unfolding Coronavirus disease (COVID-19) outbreak is placing unprecedented burdens on the public health infrastructure, including the drug supply chain. The above actions are being taken to support industry and regulators while continuing to promote quality and public health during this difficult time.

To learn more about USP's comprehensive program to support the public health response to the COVID-19 pandemic, visit: <https://www.usp.org/about/public-policy/covid-19>.

#

About USP

U.S. Pharmacopeia (USP) is an independent, nonprofit, scientific organization that sets quality standards for medicines, dietary supplements and food ingredients worldwide. USP's quality standards are enforceable in the United States by the Food and Drug Administration and integrated into law in more than 40 countries. These standards, which are continuously developed and revised by more than 800 volunteer experts in science, industry, healthcare and academia, are also used in more than 150 countries.

Since its founding in 1820, USP has helped ensure the quality of the American drug supply. Building on its 200-year legacy, USP today works with scientists, practitioners and regulators of many nations to protect and improve global health. From the standards USP creates to the partnerships it fosters, USP continually works to build a world where everyone can trust in the quality of medicine and healthcare. 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.

The United States Pharmacopeia–National Formulary (*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. The first printing of the *U.S. Pharmacopeia* was in 1820. Since then, 43 editions have been published. USP published the last printed edition of the *USP–NF* in November 2019. The *USP–NF* is now available to subscribers online and via a mobile app.

For more information, visit www.usp.org