Extended Implementation and Comment Period Extension for USP and FCC Publications

Type of Posting: Publication Announcement

Posting Date: 27-Mar-2020; updated 31-Mar-2020; updated 24-Apr-2020; updated 29-Apr-20; updated 01-May-2020*

USP recognizes that stakeholders are 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 has adjusted the upcoming official/effective dates for the *USP–NF* and *FCC* as follows:

- United States Pharmacopoeia and National Formulary
 - USP 43-NF 38: Official date has been extended by 6 months from May 1, 2020 to November 1, 2020
 - USP 43–NF 38, First Supplement. 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: Effective date has been extended from June 1, 2020 to December 1, 2020

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

The unfolding Coronavirus disease (COVID-19) outbreak is placing unprecedented burdens on the public heath 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.

At this time USP does not intend to broadly adjust official dates for accelerated revisions (i.e., Errata, Revision Bulletins, or Interim Revision Announcements for the *USP-NF* and Errata, Immediate Standards and Expedited Standards for the *FCC*). USP will also consider additional requests for delayed implementation and comment period extensions on an as-needed basis.

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

Extending the official dates is a direct response to the COVID-19 crisis. USP worked expeditiously to obtain and communicate this decision to our stakeholders and customers. However, we request and appreciate your patience while we update our online platform to accurately reflect the extended dates. We hope to implement these updates as soon as possible, prior to May 1, 2020.

Click here to learn more about USP's comprehensive program to support the public health response to the COVID-19 pandemic.

Should you have any questions, please contact Jessica Simpson, Senior Manager Compendial Operations at execsec@usp.org.

For a list of FAQs related to the extended implementation, please <u>click here</u>.

*This Notice was updated on March 31, 2020 to refer to the timeline for updates in the online product. This Notice was further updated on April 24, 2020 to add the FAQ section and again on April 29, 2020 to update the FAQ. The FAQ was updated and move to a dedicated page on May 1, 2020.

CN-20-046-04