Extension of USP-NF and FCC implementation periods and PF 46(2) comment period

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Agenda

- Decision to extend implementation dates
- Review of implementation dates for effected publications
- PF comment period extension
- Implementation in platforms
- Questions
Decision to extend implementation dates

USP-NF and FCC

- Part of the multi-pronged approach USP is taking to respond to Covid-19

- Response to stakeholder resource constraints during Coronavirus pandemic

- Convened the USP Council of Experts March 26, 2020
  - Approved decision to extend implementation dates
  - Posted Publication Announcement to communicate extension March 27, 2020
Updated official/effective dates and comment period

Uspnf.com/notices

- Extended Implementation dates:
  - USP 43–NF 38
    - Original official date: May 1, 2020
    - Extended official date: Nov 1, 2020
  - USP 43–NF 38 First Supplement
    - Original official date: Aug 1, 2020
    - Extended official date: Nov 1, 2020
  - Food Chemicals Codex 12th edition
    - Original effective date: June 1, 2020
    - Extended effective date: Dec 1, 2020

- PF 46(2)
  - Original comment close: May 31, 2020
  - New comment close: July 31, 2020

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

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 Pharmacopeia 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 *Pharmaceutical 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 health infrastructure.
Implementation in platforms

- **USP 43–NF 38 and USP 43–NF 38 1S**
  - At this time, it is expected that extended the implementation date update will go live in the USP-NF platform April 24, 2020
  - Banner will change to Nov 1, 2020

- **FCC 12th edition**
  - Will go live in May 2020
  - Banner will change to Dec 1, 2020

- **PF 46(2) comment period extension**
  - Comment box will remain active (green) until July 31, 2020
  - 46(2) proposals will still target USP 2021 Issue 2
Thank You