Monographs Affected by Revision to <1195> Significant Change Guide for Bulk Pharmaceutical Excipients

Type of Posting: Notice of Intent to Revise

Posting Date: 02-Oct-2020

Targeted Official Date: 01-May-2021

Expert Committee: Various

In accordance with the 2020–2025 Rules and Procedures of the Council of Experts, this is to provide notice that USP and its Expert Committees, as applicable, intend to revise multiple monographs in response to the revision of General Chapter <1195> Significant Change Guide for Bulk Pharmaceutical Excipients.

General Chapter <1195> was proposed for comment in *Pharmacopeial Forum* 45(6) and will appear in *USP–NF* 2021, *Issue 1*. USP has identified General Chapters that reference General Chapter <1195> and thus require revision to modify these references. These references will be updated when the General Chapter appears in *USP–NF* 2021, *Issue 1*. A list of the General Chapters that will be modified can be found here.

All modifications will become official on May 1, 2021, to coincide with the official date of revised General Chapter <1195>.

Please also see the Compendial Notice: <u>New Revision Markup for Reference Changes in *USP–NF* for details on the revision markup used to identify the reference updates.</u>

Interested stakeholders are encouraged to alert USP staff to any impact they may recognize related to the update of those monographs.

Should you have any questions or comments, please contact Galina Holloway, Senior Scientific Liaison, (gvh@usp.org), or the affected monograph's liaisons.

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