Monographs Affected by Revision to <161> Medical Devices—Bacterial Endotoxin and Pyrogen Tests

Type of Posting: Notice of Intent to Revise

Posting Date: 05-Oct-2018

Targeted Official Date: 01-May-2019

Expert Committee: Various

In accordance with section 7.05(c) of the 2010–2015 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 <161> Medical Devices—Bacterial Endotoxin and Pyrogen Tests.

A retrospective review was conducted on cross references to General Chapter <161>, and a need to update several monographs was identified. The updates are incorporated in the *USP* 42–*NF* 37 publication, official as of May 1, 2019. A list of the monographs that will be modified can be found here.

All modifications will become official on May 1, 2019, to coincide with the official date of revised General Chapter <161>.

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 Radhakrishna S. Tirumalai, Principal Scientific Liaison (301-816-8339 or rst@usp.org), or the affected monograph's liaisons.

CN-19-014-00

