General Notices: References to General Chapters <659> Packaging and Storage Requirements, <232> Elemental Impurities—Limits, and <233> Elemental Impurities—Procedures

Type of Posting: Notice of Intent to Revise

Posting Date: 27-Apr-2012; updated 18-May-2012* and 21-Nov-2012

The USP Council of Experts Executive Committee is considering revisions for General Notices, which are expected to appear as an in-process revision in Pharmacopeial Forum (PF) 39(1) [Jan. – Feb. 2013]. If, after review of the comments received, the Council of Experts Executive Committee approves these revisions, they will be published in *USP 37–NF 32*, with an official date of May 1, 2014.

While a number of revisions are expected to be included in the PF proposal, two planned changes are being highlighted in this Notice of Intent to Revise. First, the packing and storage provisions of General Notices, sections 10.10-10.30.100 and 10.50, will be largely omitted, other than a brief remaining provision in section 10.10 calling out and applying new General Chapter <659> Packaging and Storage Requirements. General Chapter <659> was published in USP 35, and will become official May 1, 2012. Second, a new provision will be added to General Notices regarding new General Chapters <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures. This new General Notices provision will make these General Chapters applicable to all official articles recognized in *USP* and/or *NF*. General Chapters <232> and <233> were approved for publication in the Second Supplement to USP 35 published June 1, 2012, with an official date of December 1, 2012 (postponed). Because the General Notices provision making these general chapters applicable to articles in *USP* and *NF*, if approved by the Council of Experts Executive Committee, would be published in USP 37, the date on which users would need to meet the requirements of the Elemental Impurities general chapters would be May 1, 2014.

Should you have any questions regarding General Notices, please contact Mario Sindaco, Director, Compendial Affairs and Executive Secretariat (301-816-8246 or mys@usp.org). For questions related to General Chapter <659>, contact Desmond Hunt, Ph.D., Senior Scientific Liaison to the General Chapters—Packaging Storage and Distribution Expert Committee (301-816-8341 or dgh@usp.org). For General Chapters <232> and <232>, contact Kahkashan Zaidi, Ph.D., Senior Scientific Liaison to the General Chapters—Chemical Analysis Expert Committee (301-816-8269 or kxz@usp.org).

* References to "General Chapters <659> Packaging Components and Storage Conditions" changed to "General Chapter <659> Packaging and Storage Requirements on 18–May–2012.
For further information see <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures Postponement.