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Prescription/Non-Prescription Stakeholder Forum
Meeting #5 for 2010-2015
Friday, March 7, 2014

General Notices Update

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Director, Compendial Affairs

- ▶ Presents the basic assumptions, definitions, and default conditions for the interpretation and application of the USP and NF
- ▶ Apply to all articles recognized in the USP and NF and to all general chapters unless specifically stated otherwise
- ▶ Monograph requirements, when different, apply and supersede the requirements of the General Notices or the general chapter
- ▶ Revised every two years (usually)
- ▶ Currently official General Notices is in USP 36-NF 31
- ▶ Subsequent revisions:
 - *USP 37-NF 32* (official May 1, 2014)
 - *Supplement 2 to USP 37-NF 32* (official December 1, 2014)

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USP-NF General Notices

Special Update related to 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements

Updated: 27-Dec-2013

The most recent update of General Notices occurred with the USP 37-NF 32 version, which will become official on May 1, 2014. At the time of balloting, the Council of Experts (CoE) Executive Committee, the body responsible for approving General Notices, decided to defer the proposed section 5.60.30 so that further deliberation could occur related to the date of applicability of General Chapters <232> Elemental Impurities—Limits and <2232> Elemental Contaminants in Dietary Supplements. That deliberation has occurred (see the [Elemental Impurities Key Issues](#), and the CoE Executive Committee has approved section 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements, with an official date of **December 1, 2015**. Links to these and previous recent versions of General Notices can be found below.

- [General Notices in the Second Supplement to USP 37-NF 32](#) (posted 27-Dec-2013; publishing in Second Supplement to USP 37-NF 32 on June 1, 2014; official 01-Dec-2014). This version contains section 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements, which has a delayed official date of December 1, 2015.
 - [Commentary for section 5.60.30 \[proposed in PF 39 \(1\)\]](#)
- [General Notices in USP 37-NF 32](#) (posted 08-Aug-2013; official 01-May-2014)
- [General Notices in USP 36-NF 31](#) (published 01-Nov-2012; official 01-May-2013). This is the currently-official version as of the December 27, 2013 posting.
- [General Notices in USP 35-NF 30](#) (published 01-May-2011; official 01-May-2011)

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- ▶ Considerations include from among the following:
 - ▶ Cancellations from previous revision
 - ▶ Pending/suggested requests for revision
 - ▶ General Notices Project Team proposals
 - ▶ Expert- and staff-initiated proposals
- ▶ Timeline:
 - ▶ PF 41(1) [Jan-Feb 2015] for public comment (pre-post to website)
 - ▶ USP 39-NF 34 (publish November 1, 2015; official May 1, 2016)
- ▶ GN PT, FDA, and the CoE EC engaged throughout revision process

- ▶ Official text: Whether and how to make the online version “official”?
- ▶ Indicating Conformance: To label as “USP” or “NF,” an article must...
- ▶ Other Impurities: Make clear the application of impurities standards*

*Project Team proposal

Some Revisions Under Discussion...(other)

- ▶ Hierarchy of monographs, general chapters, and General Notices: does it require clarification?*
- ▶ Applicability of dosage form general chapters*
- ▶ Calling out <7> *Labeling*
- ▶ Review for criteria or requirements related to compounded preparations
- ▶ Reagents and solutions: can they be harmonized? Can General Notices help?*
- ▶ Potency: update regarding biologics, IUs
- ▶ Consideration of laboratory temperature*

*Project Team proposal

GN PT Members:

1. Gina Marsee, Co-chair
2. Neil Schwarzwald, Co-chair
3. Joe Albanese
4. Susan Beavis
5. Hong Du
6. Robert Johnson
7. Elisabeth Kovacs
8. Herman Lam
9. Pallavi Nithyanandan
10. Danita Scott
11. Saji P. Thomas
12. Yan-Bo Yang



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A light gray world map is centered in the background of the slide, showing the continents of North America, South America, Europe, Africa, Asia, and Australia.

Thank You