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U.S. Pharmacopeial Convention

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

General Notices Update

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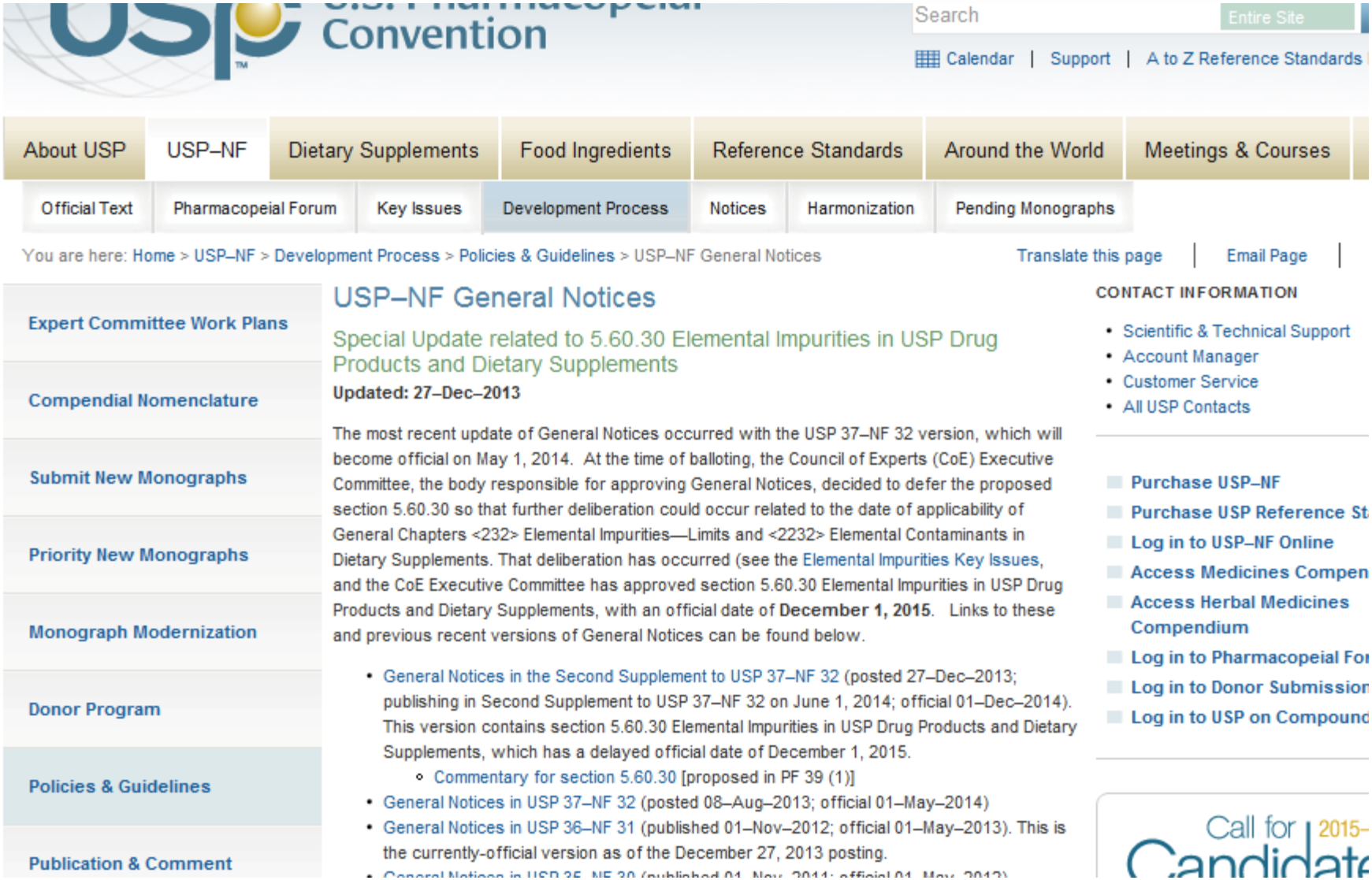
Background

- 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)

General Notices on www.usp.org



Next Revision

- 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

Some Revisions Under Discussion…(cancellations)

- 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

General Notices Project Team

GN PT Members:

1. Gina Marsee, Co-chair
2. Neil Schwarzwalder, 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

Thank You