Role of USP General Chapters and Compliance

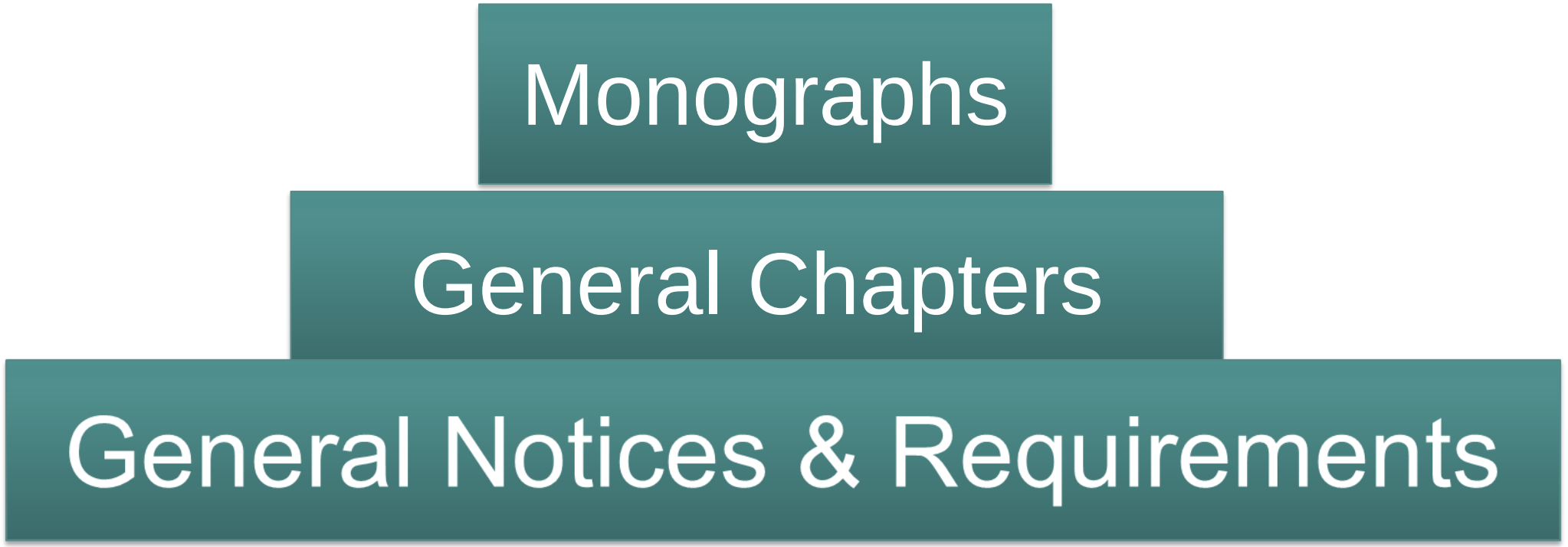
Kit Goldman, Ph.D.
Senior Director, Dietary Supplements and Herbal Medicines

April 21, 2022

Outline

- USP Documentary standards- Compendial Hierarchy
- General Notices
- General Chapters
- USP Dietary Supplement Monographs
- General Chapters- Requirements for Compliance

USP Documentary Standards – Compendial Hierarchy



General Notices

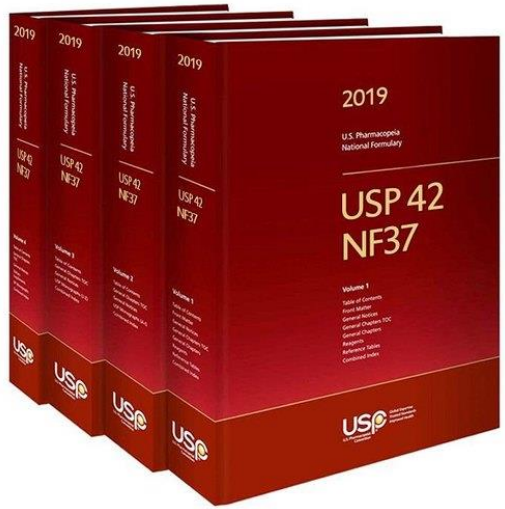
- Presents basic assumptions, definitions, and default conditions for interpretation and application of *USP-NF*
- Applies to all articles recognized in *USP-NF* and to all general chapters unless specifically stated otherwise.
- Monograph requirements supersede General Notice and General Chapter requirements in case of conflict

General Chapters

- General chapters provide guidelines on activities related to tests and procedures in monographs
- General chapters may contain descriptions of tests and procedures, general information on interpretation of compendial requirements, or general guidance on official substances or official products
  - <1> to <999>: General tests & Assays
  - <1000> to <1999>: General Information, Non-Mandatory
  - >=<2000>: Dietary Supplements

USP Dietary Supplement Monographs

- For a specific Dietary Ingredient or Dietary Supplement Product
  - A list of official and validated tests
  - Their analytical procedures
  - Their acceptance criteria
  - Together these define specifications for
    - *Identity*
    - *Purity/Limits for Contaminants*
    - *Content (Strength/Composition)*
    - *Quality (Performance and Other Requirements)*



General Chapters – Requirements for Compliance

- <1> - <999> General Tests and Assays
  - Compliance with chapters is required if chapters are cited in monograph or General Notices and compliance with monograph is required (e.g., for APIs and finished drug products in the U.S.) Compliance with Residual Solvents <467> and Elemental Impurities <232> is always required per GN 5.60.20
- <1000> - <1999> Informational Chapters
  - Provide information about standards, assays etc.
  - Non-Mandatory
- Above <2000> Chapters specifically related to dietary supplement ingredients/products
  - Required ONLY if cited in monograph or General Notices when claiming compliance to USP (compliance with residual solvents and elemental contaminants <2232> is always required when applicable per GN 5.60.20 if claiming compliance with USP)
- Dietary Supplement monographs may also cite chapters below <2000>
- <2760> is intended to provide information for industry – not mandatory

Thank You

The standard of trust

Stay Connected

Kit Goldman, Ph.D. | Senior Director, Dietary Supplements and Herbal Medicines |
kit.goldman@usp.org

The standard of trust