Update on USP Monographs and General Chapters

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Topics

• Update on monographs for PET drugs
• Progress on general chapters pertinent to nuclear medicine
Monographs for PET Drugs

• On June 1, 2014, USP announced the omission of monographs for non-FDA approved PET drugs
• Based on recommendations of the SNMMI Committee on Pharmacopeia (see: JNM, 2013, vol. 54, no. 3, pp 472-475)
• Official on December 1, 2014
• USP will continue to maintain monographs for FDA-approved PET drugs
• This is the final step in a series of USP activities related to PET drug monographs.
• More information available on the USP website in the **Key Issues** section
**Reminder**

- USP general chapters with numbers less than a \(<1000\)> are enforceable.
- GCs with numbers \(<1000\)> or greater are informational.
- Note: a GC numbered \(<1000\)> or greater may become enforceable if it is referenced in a GC with a number less than \(<1000\>.
- For some time, the USP has been updating enforceable GCs to remove content that is informational.
<821> Radioactivity

- First appeared in 1975
- Has not been revised since then
- Contains an extensive amount of informational content
- A USP Expert Panel is currently working on a revision
- Will remove informational content and create a new informational GC numbered <1821>
Table of contents for revised chapter
1. Introduction
2. Personnel Training and Documentation
3. Qualification of Instruments
4. Ongoing Performance Tests of Instruments
5. Identification of Radionuclides
6. Assay of Radionuclides
7. Glossary

Revision will appear in Pharmacopeial Forum on Sep 01, 2015.
Public comment period ends on Nov 30, 2015.
Table of contents for new chapter
1. Introduction
2. Types of Decay
3. General Considerations
4. Instrumentation for Detection and Measurement of Radioactive Emissions and Applications
5. Glossary
6. References

Revision will appear in Pharmacopeial Forum on Sep 01, 2015.
Public comment period ends on Nov 30, 2015.
General Chapters

<823> PET Drugs and <1015> Apparatus

- First appeared in mid-1990s
- <823> was revised starting in 2011 and the revision became official in 2013
- <1015> has not been revised since original appearance
- A USP Expert Panel is currently working on a new informational chapter <1823>
- Will include informational content from the original <823> and the existing <1015>
- <1015> will be omitted from USP
Table of contents for new chapter
1. Introduction
2. Techniques for Production and Quality Control
3. Quality Assurance
4. Production
5. Quality Control
6. Analytical Methodology
7. Quality Attributes
8. Sterility Assurance
9. Labeling
10. Glossary

Revision will appear in Pharmacopeial Forum on Sep 01, 2015.
Public comment period ends on Nov 30, 2015.
• Sally Schwarz
• Steve Zigler
• Paula Jacobs
• Jonathan Fitzsimmons
• James Brodack *(resigned due to personal reasons)*
• James Ponto
• Jerome Lewis
• Roger Moroney
• Thijs Kroon
• Cathy Cutler
• Duann Thistlewaite
Thank You
Update on USP Activities

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USP
Topics

• Review USP Expert Committee structure
• Standards pertinent to nuclear medicine
• Review current cycle (2010-2015)
• Describe anticipated work in new cycle (2015-2020)
• Public involvement
Monographs for radioactive drugs (SPECT and PET)

General chapters for radioactive drugs (<821>, <823>, etc.)
Standards for Radioactive Drugs in USP

**General Chapters**
- <821> Radioactivity
- <823> PET Drugs
- <1015> Automated Radiochemical Synthesis Apparatus
- Others based on requirements of the dosage form (e.g., Bacterial Endotoxins <85>, etc.)

**Monographs**
- About 100 monographs for various SPECT and PET products
General Chapters
- Expert Panel completed revision of <823> to reflect the changing role of the FDA in the post-FDAMA era
- <823> revision official since May 1, 2013
- New Expert Panel formed to revise <821> Radioactivity and to develop new informational chapters on radioactivity and PET drugs

Monographs
- Omitted monographs for non-approved PET drugs (based on recommendations from PET community)
- Aligns PET drug monographs with monographs for non-radioactive drug products
Anticipated Activities (2015 to 2020)

2015–2020 Council of Experts
Expert Committees and Collaborative Groups

- **Healthcare Quality Standards Collaborative Group**
  - Nomenclature & Labeling
    - Stephanie Y. Crawford
  - Compounding
    - Gigi S. Davidson
  - Healthcare Quality
    - Dennis E. Doherty

- **Chemical Medicines Monographs Collaborative Group**
  - Chemical Medicines Monographs 1
    - Richard A. Blessing
  - Chemical Medicines Monographs 2
    - Ernest Parente
  - Chemical Medicines Monographs 3
    - Bernard A. Olsen
  - Chemical Medicines Monographs 4
    - Kim C. Huynh-Ba
  - Chemical Medicines Monographs 5
    - Amy J. Karran
  - Chemical Medicines Monographs 6
    - David A. Fay

- **Biologic and Biotechnology (B&B) Collaborative Group**
  - B&B Peptides
    - Michael K. Du Filippedis
  - B&B Proteins
    - Michael G. Mulkern
  - B&B Complex Biologicals
    - Edward K. Chess
  - B&B Biological Analysis
    - Wesley J. Walkow

- **Excipient Monographs Collaborative Group**
  - Excipient Monographs 1
    - Eric J. Munson
  - Excipient Monographs 2
    - Mary C. Houck

- **Dietary Supplements/Herbal Medicines/Foods Collaborative Group**
  - Non-botanical Dietary Supplements
    - Dennis K.J. Gornicki
  - Botanical Dietary Supplements & Herbal Medicines
    - Robin J. Marles
  - Food Ingredients
    - Jonathan W. Davies

- **General Chapters Collaborative Group**
  - Chemical Analysis
    - Timothy J. Wozniak
  - Physical Analysis
    - Xiaorong He
  - Statistics
    - Robert R. Singer
  - Microbiology
    - David Husson
  - Dosage Forms
    - James E. DeMuth
  - Packaging & Distribution
    - Mary G. Foster
Anticipated Activities (2015 to 2020)

**General Chapters**
- Expert Panel completes revision of <821> Radioactivity
- Expert Panel completes new informational chapters <1821> and <1823>

**Monographs**
- Revise monographs for approved PET drugs as needed
- Create Expert Panel to review and revise (as needed) monographs for SPECT drugs
Public Involvement

**Pharmacopeial Forum**
- Free online publication
- Published 6 times each year (Jan, Mar, May, Jul, Sep, and Nov)
- Visit [http://www.usp.org/usp-nf/pharmacopeial-forum](http://www.usp.org/usp-nf/pharmacopeial-forum) to get your own free subscription
- All you need to provide is your email address

**USP Website**
- **Key Issues** page will continue to announce revisions and updates pertinent to the nuclear medicine community
Thank You