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Plastic Packaging Standards: Grandfathering Exemption

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Overview: <661> Plastic Packaging Systems and their Materials of Construction

General Notices and Requirements



<659> Packaging and Storage Requirements



<661> Plastic Packaging Systems and their Materials of Construction



<661.1>

Plastic Material of Construction

- Identification
- Biological Activity
- Physico-chemical Tests
- Extractable Metals
- Plastic Additives

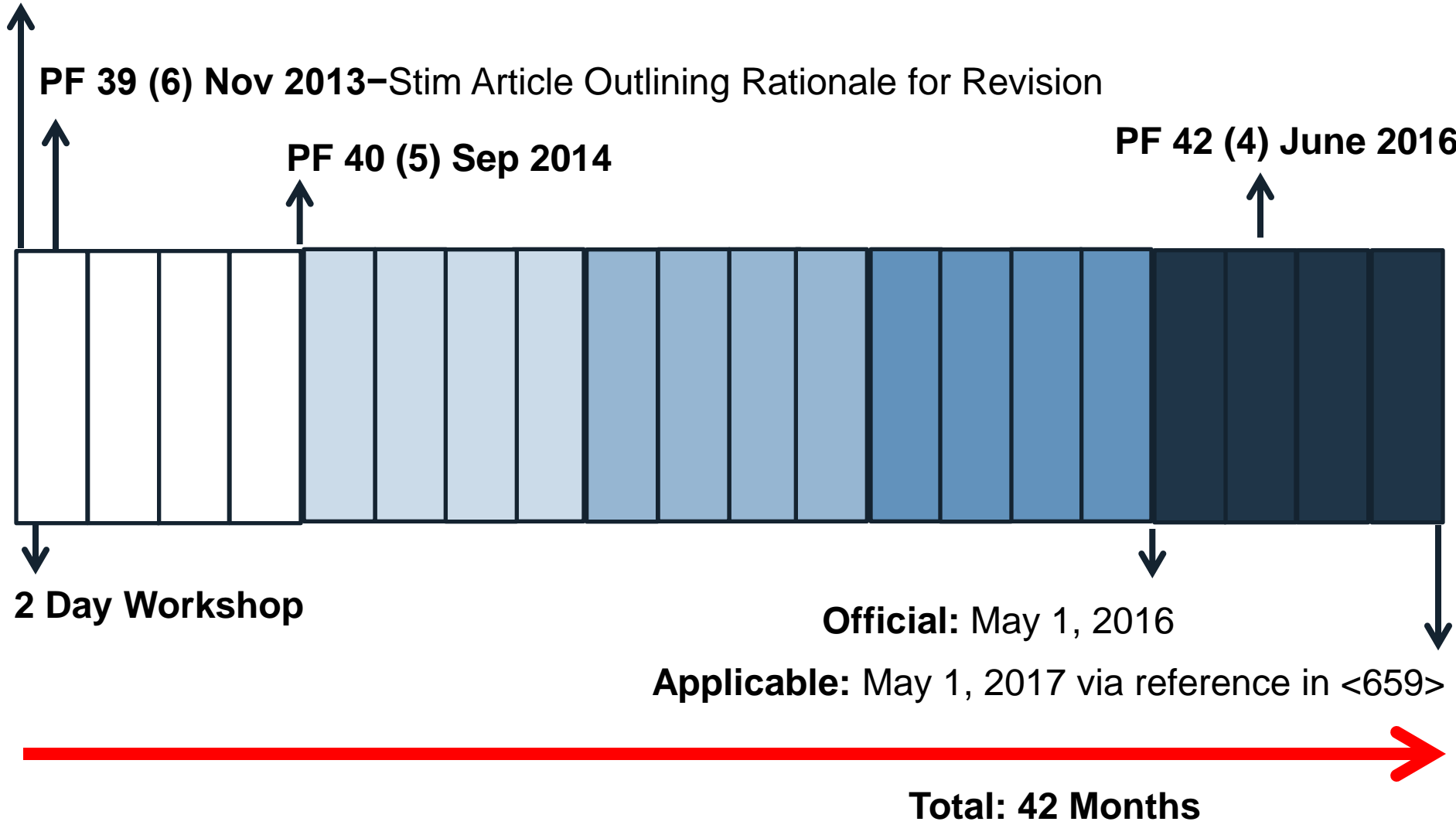
<661.2>

Plastic Packaging Systems for Pharmaceutical Use

- Biological Activity
- Physico-chemical Tests
- Safety Assessment (Extractables/Leachables)

Revision Timeline

PF 39 (5) Sep 2013—<661>, <661.1> and <661.2>



Revision Impact

- ▶ 50 year old standard was revised
- ▶ Added new polymers
- ▶ Added new testing procedures and specifications
- ▶ Currently approved drug products that uses a plastic component in it's packaging system could be impacted.

Scope:

... Alternatively, individual plastic materials of construction are deemed to be well characterized and appropriate for use if they are used in a packaging system that meets the requirements in (661.2) or if the packaging system has been deemed appropriate for pharmaceutical use by the appropriate regulatory authority.

- ▶ They considered removing the grandfathering provision from the chapters
 - **However, the concerns that led to including the grandfather language are still a point discussion**
 - Industry impact
 - Currently approved products where packaging system can't meet new standard
 - Material and component suppliers (market withdrawal)
 - Timeline for removal
 - What is a realistic timeline for the removal of the provision
 - Communication plan
 - Best way to communicate this change to effected stakeholders

Can we alleviate the uncertainty regarding the implementation?

OPTION 1:

... Alternatively, individual plastic materials of construction are deemed to be well characterized and appropriate for use if they are used in a packaging system that meets the requirements in <661.2> or if the packaging system has been deemed appropriate for pharmaceutical use by the appropriate regulatory authority. (Official until xxx)

OPTION 2:

... Alternatively, individual plastic materials of construction are deemed to be well characterized and appropriate for use if they are used in a packaging system that meets the requirements in <661.2> For currently marketed articles, the implementation date for the requirements in this chapter will be XXX.

Delayed Implementation vs Grandfathering

- ▶ Delayed implementation is the preferred option. Several examples:
 - <467> Organic Volatile Impurities and <467> Residual Solvents
 - <61> Microbial Examination, <61> Microbial Enumeration and <62> Tests for Specified Microorganisms
 - <231> to <232>/<233>
 - Harmonization: <711>/<724>; <905>

- ▶ Grandfathering clause, not commonly used:
 - <1226> Verification of compendial procedures:
 - “ *This chapter is not intended for retroactive application to already successfully established laboratory procedures.*”

- ▶ In accordance with section 7.05(c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the Packaging and Distribution Expert Committee intends to revise the following General Chapters:
 - <659> Packaging and Storage Requirements
 - <661> Plastic Packaging Systems and Their Materials of Construction
 - <661.1> Plastic Materials of Construction
 - <661.2> Plastic Packaging Systems for Pharmaceutical Use

The purpose of the revisions are:

- ▶ to provide a three-year period for implementation of the requirements specified in General Chapters <661.1> and <661.2>,
- ▶ to reinstate requirements previously expressed in General Chapter <661> during this three-year period;
- ▶ to enable early adoption of the requirements in General Chapters <661.1> and <661.2> at any time during the three-year period in lieu of meeting the reinstated <661> requirements;
- ▶ to remove the exemptions to General Chapters <661.1> and <661.2.> for previously approved packaging systems.

661.1 and 661.2

- ▶ This chapter will become official on May 1, 2020 . Early adoption of the requirements in this chapter and its companion chapter <661.2> are permitted by USP. When early adoption is not used, <661> will apply and must be met wherever <661.1> or <661.2> is referenced in the USP-NF.



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Thank You