Plastics Packaging
Working Group Update
Purpose

• To present the perspective of the pharmaceutical industry with respect to the following revised General Chapters
  – <659>/<661>/<661.1>/<661.2>/<1661>
  – Describe impact of the chapter revisions to various functions in industry
  – Provide a case study industry impact to implementation

• Create a collaborative dialog between industry, FDA, & USP

Danita Broyles
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<th>Members</th>
<th>CoE Observers</th>
<th>FDA</th>
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Is May 1, 2020 the right implementation date?
- To explore this question the Plastic working group was formed to discuss if the current implementation date is appropriate and if not what should be it.

Plastic Working Group
- Composition
  - FDA
  - Industry
  - USP
- Scope
  - To review the implementation timeline of the revision for Chapters <659>, <661>, <661.1>, and <661.2>.
- Objective
  - Make recommendations for an implementation date to the USP.
    - This recommendation will be based upon requirements for regulatory filing and pre-approval and to set an implementation date in consideration of regulatory implications and processes.
The working group has met twice since it formation

- May 1, 2018
- June 7, 2018
- Next meeting August 23rd

Discussion Topic

- questions need to be discussed/answered to make the appropriate recommendation?
  - For USP
  - For Industry
  - For FDA
Questions

Empowering a healthy tomorrow
Thank You

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