<1381> Evaluation of Elastomeric Components Used in Pharmaceutical Packaging/Delivery Systems

Type of Posting: General Chapter Prospectus

Posting Date: 30–Dec–2016

Expert Committee: General Chapters—Packaging and Storage

Input Deadline: January 30, 2017

Suggested audience: Suppliers of elastomeric materials and components used for packaging systems (primary packaging components) and drug product manufacturers using elastomeric component and system primary containers.

Estimated proposal Pharmacopeial Forum: *PF* 43(3) [May–Jun. 2017].

Description of scope and application: The scope of this chapter is to: a) to describe elastomeric components and their materials of construction for use in pharmaceutical packaging systems; b) provide a high level introduction to elastomer chemistry, manufacturing technology and the post processing of components; c) explain basic functional characteristics of components; d) designate baseline requirements and; e) discuss identification testing.

Elastomeric components are comprised of multiple materials which have unique attributes for each configuration, application and changes resulting from any treatment that occurs after formation (post processing). This can be a challenge for establishing elastomeric baselines due to multiple combinations of materials and post processing treatments by the component manufacturer and the drug product manufacturer. Since it can be difficult to assess the elastomeric formulation, guidance on the responsibilities of the supplier and applicant are provided under Test Procedures section of this chapter. The chapter is meant to support <381> and the major revision to be proposed for that chapter.

Anticipated proposed design phase activities (stimuli article, workshop, etc.): To initiate an open dialog with stakeholders regarding this

revision, the Expert Committee will host a Workshop at USP Headquarters in Rockville, MD on June 19–20, 2017. The input received during this Workshop will provide input to the revision of the General Chapter.

Anticipated implementation timing (routine, extended, etc.): To be determined

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