General Chapter Prospectus: Metal Packaging Components and their Materials of Construction

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Expert Committee: General Chapters—Packaging and Storage

Input Deadline: 29-Mar-2016

Proposed Title: <662> Metal Packaging Components and their Materials of Construction

Suggested audience: Suppliers of metal materials and components used for packaging systems (primary packaging components) and drug product manufacturer using metal primary containers

Estimated proposal PF: 44

Background and objective(s): A metal packaging system was first used to package pharmaceutical products in the early 1900s due to its lightness and its impermeability to light and moisture. Common metal packaging components include aluminum and its alloys, stainless steel, tinfree steel, and tinplate. Within the pharmaceutical industry, primary metal packaging systems can include aerosols, blister packs, canisters, collapsible tubes, drums and gas cylinders, and secondary packaging systems such as overwraps and seals. Currently there are no compendial standards for metal packaging systems. Thus, to help ensure the safety and suitability of metal packaging system for pharmaceutical products, the USP will develop a new chapter that will provide test methods and standards for metal materials of construction and packaging system.

Description of scope and application: Metal materials and components that make up a primary packaging system. The chapter is to be used in

helping determine the safety and suitability of metal packaging system for pharmaceutical products

Anticipated proposed design phase activities: To initiate the work of the Expert Committee, a teleconference will be held to discuss the scope and goals of the General Chapter with interested parties. The intent is to have dialogue regarding practices that are currently used by suppliers and product manufacturers to ensure safety, suitability and compatibility. The input received during this call will provide a foundation for the first draft of this new General Chapter.

Anticipated implementation timing: Extended

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