<1168> Compounding for Phase I Investigational Studies

Type of Posting: Notice of Intent to Revise

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In accordance with section 7.05 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Compounding Expert Committee intends to republish General Chapter <1168> *Compounding for Phase I Investigational Studies* for public comment. The chapter was previously published in *Pharmacopeial Forum* 39(5) [Sep.-Oct. 2013] for public comment and has been revised based on stakeholder input received. The revised chapter is being published for another round of public comment.

Public comments can be submitted by using the electronic form available at www.surveymonkey.com/r/1168PublicComments. When submitting your comments, please note the line number(s) relevant to your comments in the electronic form. After completion of the form, you will receive a confirmation email with a copy of your comments.

General Chapter <1168> was developed to provide guidance on compounding for investigational preparations for Phase I clinical studies. Compounding of investigational preparations requires additional considerations because it is likely that the agents in these preparations have never been administered to humans.

Major changes from the previous chapter published in *PF* 39(5) include:

1. Clarification of information that a compounder should know as part of participating in a study involving the compounding of investigational preparations
2. Clarification of personnel responsibilities on materials management

Should you have any questions, please contact the Healthcare Quality Standards team at CompoundingSL@usp.org.