Comment Submission Template for:
General Chapter <797> *Pharmaceutical Compounding—Sterile Preparations*

Revision proposed in *Pharmacopeial Forum* 41(6) Nov/Dec 2015

Send completed template to CompoundingSL@usp.org by January 31, 2016

Commenter's Name:	Position:	Full Contact Details:
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General Comments:

On behalf of the Asthma and Allergy Foundation of America (AAFA, www.aafa.org) I am pleased to submit comments in response to the Compounding Expert Committee's proposed revisions to General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. AAFA, a not-for-profit organization founded in 1953, is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. AAFA is dedicated to improving the quality of life for people with asthma and allergic diseases through education, advocacy, and research. As we indicate in our comments below, AAFA does not support the proposed changes. Furthermore, our constituents tell us that their lives depend on timely access to and ongoing availability of allergen immunotherapy.

Allergen immunotherapy is an important treatment for allergic diseases that has improved the quality of life for many allergy patients: reducing symptoms, decreasing medication costs, and diminishing the number of hospitalizations and emergency room visits. While the newly introduced regulations may aim to increase the safety and hygiene standards of this treatment, AAFA believes the proposed changes will have a deleterious effect and severely limit patient access to immunotherapy in the United States. We are extremely concerned that there is also no scientific data in the peer-reviewed medical literature to support the need for these more stringent requirements.

The more extensive procedures for mixing allergen extracts under the new regulations will make it highly unlikely that allergists would be able to continue to mix allergen extracts for their patients in the office setting. Non-healthcare system-employed physicians will have very limited options for securing allergy immunotherapy prescriptions for their patients. Having to use outside facilities to obtain immunotherapy extracts will have a number of consequences. The timeline of a patient's treatment could be interrupted, limited, or otherwise negatively impacted. Also, Medicare currently does not cover allergen immunotherapy manufactured by a third party vendor; thus, Medicare recipients would no longer have allergen immunotherapy as a covered service.

Additionally, restricting the beyond use date (BUD) for extracts to 28 days will drastically increase the cost of the treatment, as extracts

will meet their expiration date very rapidly.

AAFA is greatly concerned about the effect these proposed regulations will have on patient access to immunotherapy. To implement the regulations would enact enormous barriers to a major component of allergy research and treatment. We strongly urge USP to keep the existing guidelines for immunotherapy treatment preparation in place so that allergy patients in the United States can continue to receive treatment, and so that researchers and clinicians can continue to learn more about treating allergic diseases.

Specific Comments:

Section(s)	**Line Number(s)**	**Existing text:** (Provide the proposed text.)	**Suggested change:** (Provide the revised suggestion to replace the existing text.)	**Comment**	**Rationale / Scientific Evidence**

(Add additional lines to the table as necessary.)