

How to Submit Comments on <797> Revisions (July 2018)

1. Visit: <http://www.usp.org/compounding/general-chapter-797>
 - a. Download the [Proposed Revision](#) with line numbers
 - b. Click on the “[Submit Comments](#)” link to submit public comments

General Chapter <797> Pharmaceutical Compounding – Sterile Preparations

Millions of medications are compounded each year in the US to meet the unique needs of patients. Compounding provides access to medication for patients who may not be able to use commercially available formulations due to dosing requirements, allergies or rare diseases. Medications that are required to be sterile include those administered through injection, intravenous infusion (IV), intraocular (injection in the eye) or intrathecal (injection in the spine).

Understanding the risks inherent in sterile compounding and incorporating established standards are essential for patient safety. Compounded drugs made without the guidance of standards may be sub-potent, super potent or contaminated, exposing patients to significant risk of adverse events or even death.

USP develops standards for preparing compounded sterile drugs to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing.

USP General Chapter <797> describes a number of requirements, including responsibilities of compounding personnel, training, facilities, environmental monitoring, and storage and testing of finished preparations.

Important Updates

- July 27, 2018 - The proposed General Chapter <797> is now posted for public comment.



Download the
Proposed GC <797>

Submit Comments to the
Proposed GC <797>



- [Instructions on how to submit comments to the proposed General Chapter <797>](#)

2. Read the welcome page and select **NEXT** to enter the electronic form
3. Enter your information
 - Enter your [contact information](#)
 - Select the [job function](#) that most closely represents your current position
 - Select the type of [organization](#) that most closely represents where you work
4. Select the type of comments you would like to submit on General Chapter <797>
 - **General Comments**
Select [General Comments](#) if you have a general comment that does not have a corresponding line number.
 - **Specific Comments**
Select [Specific Comments](#) if you have specific line numbers corresponding to your comments.
 - **General Comments & Specific Comments**
If you have both general and specific comments, please select both options.
You will be prompted to enter your general comments first, followed by your specific comments.

5. For General Comments that do not have a corresponding line number:

- Please enter the comment or specific change requested.
- Please enter the rationale for your comment or change requested.

Please enter only one comment per page. If you have additional specific comments, select yes to enter them on the next page.

6. For Specific Comments that have corresponding line numbers.

- Please enter the line number(s) corresponding to your comment.
- Please enter the specific change requested.
- Please enter the rationale for the specific change requested above.

Please enter only one comment per page. If you have additional specific comments, select yes to enter them on the next page.

7. Once you are done entering your comments, select No to indicate that you don't have additional comment.

- Click Next to finish

You will receive an email from USP within 5-7 business days confirming receipt of your comments. If you have any questions, please email CompoundingSL@usp.org.