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EXHIBIT 6



INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS

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New Requirements for Sterile Compounding; Request for Comments

IACP has submitted comments to USP regarding USP Proposed Chapter <797> Pharmaceutical Compounding—Sterile Preparations. The USP is proposing to renumber Chapter 1206, which provides guidelines on sterile product preparation making its provisions mandatory. These guidelines are in need of much revision before becoming mandatory.

How You Can Help

IACP is asking its members to submit comments to USP. Comments should be sent to Dr. Claudia Okeke at the USP, cco@usp.org. Please provide a copy of your comments to IACP. Feel free to use IACP's comments and attach a short cover letter expressing your concerns. If you have any suggested changes to IACP's comments, or if you would like a copy of the proposed chapter with which to comment to USP, please contact L.D. King at ldking@iacprx.org or fax 281-495-0602.

- IACP's Introduction to Scientific Comments to USP
- IACP's Draft of Scientific Comments to USP (PDF FORMAT)
- Excerpts from IACP's comments on FDA's proposal to make USP Chapter 1206 mandatory

Among the possible problems with USP proposed chapter 797:

1. All compounded sterile products would need to meet extensive requirements for purity and particulate matter.
2. It is implied multiple times that stability testing would need to be performed on compounded sterile products
3. Sterility testing, including bacteriostasis and fungistasis testing, would be required for all high-risk sterile products. Extensive sampling protocols are required. This level of sterility testing is currently not performed in pharmacy practice. There is no exception for emergency or single-use, single formulation products.
4. Endotoxin testing would be required for all high-risk compounded products. In-house testing would not be allowed. There is no exception for emergency or single-use, single formulation products.

5. Extensive policies and procedures would need to be developed for the transit of each type of sterile product. Delivery personnel would be required to provide written assurance of the capability of fulfilling extensive requirements as spelled out by the pharmacists.
6. Pharmacists must develop a patient-monitoring plan which includes written outcome measures and systems for routine patient assessment.

If you are unable to read Adobe .pdf documents, please contact IACP at 281-933-8400 or by email at ldking@iacprx.org and we will fax the documents to you.

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