In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 4 Expert Committee has revised the Vigabatrin Tablets monograph. The purpose of this revision is to add Dissolution Test 2 to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test. Labeling information has been incorporated to support the inclusion of Dissolution Test 2. Existing references to reagents have been updated for consistency with the reagent entry.

- Dissolution Test 2 was validated using the Partisil 10 SCX brand of column with L9 packing. The typical retention time for vigabatrin is about 5 min.

The Vigabatrin Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or yanyin.yang@usp.org).