OTC Compounding Policy and Procedure # 133

The minimum guidelines for pharmacists who are doing over-the-counter (OTC) compounding upon receipt of valid prescription are:

- 1. Component products used in OTC compounding should be available to the public.
- 2. Compounded product should be made on a patient-specific need and kept behind the pharmacy counter under supervision of the pharmacist.
- 3. Compounded product labels should include: active ingredients; strength; dosage; directions for use; expiration date; and one of the following: a) lot number b) batch number c) control number, or d) identification number; as well as, appropriate auxiliary labels.
- 4. Patients should receive detailed written or verbal information and counseling with all compounded products.
- 5. Records of products provided to patients must be maintained in a readily retrievable manner.