Appendix VII Labeling and Packaging Standards

1. A PET drug product must be suitably labeled and packaged to protect the product from alteration, contamination, and damage during the established conditions of shipping, distribution, handling, and use.
2. The following information should appear on the label attached to the final PET drug container:
   - 2.1 The name of the PET drug product, including the dosage form and add substances(e.g. stabilizer or preservative).
   - 2.2 The assigned batch number.
   - 2.3 The date and time of calibration.
   - 2.4 The total radioactivity in MBq (or mCi) at time of calibration.
   - 2.5 The strength in MBq/mL (or mCi/mL) of the final product.
   - 2.6 Expiration time and date.
   - 2.7 Any required radioactive symbols.
   - 2.8 Other applicable warning statements (e.g. “Do not use if cloudy or if it contains particulate matter”).
3. Labels must be legible and applied so as to remain legible and affixed during the established conditions of processing, distribution, handling, and use.
4. All information stated on each label must be contained in each batch production record, and be kept.
5. Labeling and packaging operations must be controlled to prevent labeling and product mix-ups.