APPENDIX II

133.5 Personnel

The key personnel involved in the manufacture and control of the drug shall have a background of appropriate education and/or appropriate experience for assuming responsibility to insure that the drug has the safety, identity, strength, quality, and purity that it purports to possess.

133.6 Components

Components used in the manufacture and processing of drugs, regardless of whether they are intended to appear in the finished product, shall be identified, handled, and otherwise controlled in a manner to insure that they conform to appropriate standards of identity, strength, quality, and purity, and are free of contaminants at time of use. Adequate measures shall be taken to prevent mixups and cross-contamination affecting drugs and drug products. Components shall be withheld from use until they have been identified, sampled, and tested for conformance with established specifications and are released by a materials approval unit.

133.7 Master and batch production and control records

For each drug product, master production and control records shall be prepared, endorsed, and dated by a competent and responsible individual and shall be independently checked, reconciled, endorsed, and dated by a second competent and responsible individual. These records shall include specified information concerning, among other things, identity of the product; dosage; labeling; identity and weight and measure of ingredients; containers, closure, packaging, and finishing materials; and manufacturing and control instructions, procedures, specifications, special notations and precautions to be followed.