§ 133.5 Personnel.

The key personnel involved in the manufacture and control of the drug shall have a background of appropriate education or appropriate experience or combination thereof for assuming responsibility to assure 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, stored, examined, tested, inventoried, handled, and otherwise controlled in a manner to assure that they conform to appropriate standards of identity, strength, quality, and purity, and are free of contaminants at time of use, and are so stored and handled as to assure that dust or particles resulting from such storage or handling does not contaminate other substances or preparations on the premises, and to provide that appropriate records are maintained of their origin, receipt, examination, testing, disposition, and use in drug manufacture or processing.

§ 133.7 Master-formula and batch-production records.

(a) For each drug product, master-formula 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. The record shall include:

(1) The name of the product, a description of its dosage form, and a specimen or copy of the label and each other portion of the labeling contained in a retail package of the drug.

(2) The weight or measure of each ingredient per dosage unit or per unit of weight or measure of the finished drug, and a statement of the total weight or measure of any dosage unit.

(3) A complete batch formula for each batch size to be produced from the master-formula record, including a complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic; an accurate statement of the weight or measure of each ingredient, regardless of whether it appears in the finished product, except that reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form, provided that the variations are stated in the master formula; an appropriate statement concerning any calculated excess of an ingredient; appropriate statements of theoretical weight or measure at various stages of processing; and a statement of the theoretical yield.

(4) A description of the containers, closures, packaging, and finishing materials.

(5) Manufacturing and control instructions, procedures, specifications, special notations, and precautions to be followed.

(b) A separate batch-production and control record shall be prepared for each batch of drug produced and shall be retained for at least 2 years after distribution has been completed. The batch-production and control record shall include:

(1) An accurate reproduction of the appropriate master-formula record, checked and endorsed by a competent responsible individual.

(2) Records of each step in the manufacturing, processing, packaging, labeling, and controlling of the batch, including dates, specific identification of each batch of components used, weights or measures of components and products in course of processing, in-process and laboratory-control results, and the endorsements of the individual actively performing or the individual actively supervising or checking each step in the operation.

(3) A batch number that permits determination of all laboratory-control procedures and results on the batch and all lot or control numbers appearing on the labels of drugs from the batch.

§ 133.8 Production and control procedures.

Production and control procedures shall include all reasonable precautions, including the following, to assure that the drugs produced have the identity, strength, quality, and purity they purport to possess.

(a) Each critical step in the process, such as the selection, weighing and measuring of components; the addition of active ingredients during the process; weighing and measuring during various stages of the processing; and the determination of the finished yield shall be performed by a competent, responsi-