APPENDIX II

133.10 Packaging and labeling

Packaging and labeling operations shall be adequately controlled to insure that only those drugs that have met the standards and specifications established in their master production and control records shall be distributed; to prevent mixups between drugs during the filling, packaging, and labeling operations; to insure that correct labeling is employed for the drug; and to identify finished products with lot or control numbers that permit determination of the history of the manufacture and control of the batch of drug.

133.11 Laboratory controls

Laboratory controls shall include the establishment of adequate specifications and test procedures to insure that components, drug preparations in the course of processing, and finished products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include the establishment of master records containing appropriate specifications for the acceptance of each lot of each component used in drug production and a description of the sampling and testing procedures used to check them. Samples shall be representative and adequately identified. Such records shall also provide for appropriate retesting of materials subject to deterioration. In addition, a reserve sample of at least twice the quantity of the drug necessary to perform most of the required tests and stored under conditions consistent with product labeling shall be retained at least 2 years after the drug distribution has been completed or at least 1 year after the drug's expiration date, whichever is longer. Also, the controls shall include the establishment of a master record of appropriate finished-product specifications and a description of sampling procedures to check them. In addition, the controls should include adequate provision to check the reliability, accuracy, precision, and performance of laboratory test procedures and laboratory instruments used.

133.12 Distribution records

Complete records shall be maintained of the distribution of each batch of drug in a manner that will facilitate its recall if necessary. Such records shall be retained for at least 2 years after distribution of the drug has been completed