

APPENDIX II

or 1 year after the expiration date of the drug, whichever is longer, and shall include the name and address of the consignee, the date and quantity shipped, and the lot or control numbers identifying the batch of drug.

133.13 Stability

Adequate provision shall be made to insure the stability of finished drugs.

133.14 Expiration dating

Labels of all drug products liable to deterioration shall have suitable expiration dates which relate to stability tests performed on the product to insure that such drug products meet appropriate standards of identity, strength, quality, and purity at the time of use.

133.15 Complaint files

Records shall be maintained of all written or verbal complaints for each product. Complaints shall be evaluated by competent and responsible personnel and, where indicated, appropriate action shall be taken. The record shall indicate the evaluation and action.