

the manufacturing process and the individual who checked each key step. Such control numbers and documentation should also relate to records of the packaging operations and the final audit for the total number of packages produced. The control number and documentation also provide a means to facilitate recalls, if necessary.

ADDENDUM

In the application of these general principles, consideration should be given, but not necessarily limited, to all of the items mentioned in the P.M.A. Statement on Control of Quality dated May 3, 1961, which are listed below.

1. Buildings for manufacturing, testing, and storage operations are of adequate design, size and construction to :
 - (a) provide for proper receipt and storage of raw materials.
 - (b) allow proper segregation and identification of material during manufacturing and packaging.
 - (c) provide for ease in maintaining cleanliness and for avoiding contamination.
 - (d) provide suitable sampling facilities.
 - (e) provide adequate laboratory facilities.
 - (f) provide proper storage for final products.
2. Equipment is :
 - (a) properly located.
 - (b) adequate for the required operations.
 - (c) constructed to facilitate cleaning.
 - (d) properly maintained.
3. Raw materials are controlled by :
 - (a) establishment of suitable specifications.
 - (b) development of adequate test procedures.
 - (c) specific identification markings.
 - (d) proper storage conditions.
 - (e) adequate sampling.
 - (f) appropriate testing.
 - (g) requiring compliance with specifications.
 - (h) providing for Quality Control release.
 - (i) maintaining records and samples whenever appropriate.
4. Manufacturing operations are controlled by :
 - (a) use of a suitable batch numbering system.
 - (b) preparation of formula or batch records.
 - (c) checking of ingredients; identity, weight and measure.
 - (d) maintaining identity during processing.
 - (e) checking quality during processing.
 - (f) checking yield against theory.
 - (g) adequate sampling and testing.
 - (h) requiring compliance with specifications.
 - (i) maintaining appropriate records and samples.
5. Packaging and finishing are controlled by :
 - (a) establishment of specifications for packaging and packaging operations.
 - (b) a formal procedure providing for the inspection and issuance of packaging materials including labels and labeling.
 - (c) providing for the proper disposition of unused labels and labeling.
 - (d) use of suitable batch, lot or control numbers.
 - (e) maintaining identity of product before and during packaging.
 - (f) checking yield against theory.
 - (g) sampling and checking for compliance with specifications.
 - (h) providing for release by Quality Control.
 - (i) maintaining appropriate records and samples.
6. Finished stock quality is maintained by :
 - (a) providing proper storage conditions.
 - (b) collection and review of stability data.
 - (c) investigation of all significant complaints concerning quality of products.
 - (d) providing for the disposition of returned goods.