standards of identity, strength, quality, and purity at the time of use.

(e) Adequate provision to check the reliability, accuracy, and precision of any laboratory test procedure used. The official methods in ''Methods of Analysis of the Association of Official Analytical Chemists,''[1] methods described in an official compendium, and any method submitted as a part of a food additive petition or new-drug application that has been accepted by the Food and Drug Administration shall be regarded as meeting this provision.

(f) Provisions for the maintenance of the results of any assays, including dates and endorsement of analysts. Such records shall be retained in the possession of the manufacturer and shall be maintained for a period of at least 2 years after distribution by the manufacturer of the Type A medicated article(s) has been completed.

[40 FR 14031, Mar. 27, 1975, as amended at 55 FR 11577, Mar. 29, 1990; 55 FR 23703, June 12, 1990; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

Subpart D—Packaging and Labeling

§ 226.80 Packaging and labeling.

(a) Packaging and labeling operations shall be adequately controlled:

(1) To assure that only those Type A medicated article(s) that have met the specifications established in the master-formula records shall be distributed.

(2) To prevent mixups during the packaging and labeling operations.

(3) To assure that correct labeling is employed for each Type A medicated article(s).

(4) To identify Type A medicated article(s) with lot or control numbers that permit determination of the history of the manufacture and control of the batch of Type A medicated article(s).

(b) Packaging and labeling operations shall provide:

(1) For storage of labeling in a manner to avoid mixups.

(2) For careful checking of labeling for identity and conformity to the labeling specified in the batch-production records.

(3) For adequate control of the quantities of labeling issued for use with the Type A medicated article(s).

(c) Type A medicated article(s) shall be distributed in suitable containers to insure the safety, identity, strength, and quality of the finished product.

Subpart E—Records and Reports

§ 226.102 Master-formula and batch-production records.

(a) For each Type A medicated article(s) 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 Type A medicated article(s) and a specimen copy of its label.

(2) The weight or measure of each ingredient, adequately identified, to be used in manufacturing a stated weight of the Type A medicated article(s).

(3) A complete formula for each batch size, or of appropriate size in the case of continuous systems 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 characteristics; an accurate statement of the weight or measure of each ingredient, except that reasonable variations may be permitted in the amount of ingredients necessary in the preparation of the Type A medicated article(s), provided that the variations are stated in the master formula; an appropriate statement concerning any calculated excess of an ingredient; and a statement of the theoretical yield.

(4) Manufacturing instructions for each type of Type A medicated article(s) produced on a batch or continuous operation basis, including mixing steps and mixing times that have been determined to yield an adequately mixed Type A medicated article(s); and in the case of Type A medicated article(s) produced by continuous production run, any additional manufacturing

[1] Copies may be obtained from: AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877.