Kansas Administrative Regulations

Department of Health and Environment

Article 21.—Food, Drugs and Cosmetics

28-21-262. Master production and control records.

(a) Batch production and control records. (1) To assure uniformity from batch to batch, a master production and control record for each drug product and each batch size of amygdalin (laetrile) shall be prepared, dated, and signed or initialed by a competent and responsible individual and shall be independently checked, reconciled, dated, and signed or initialed by a second competent and responsible individual. The master production and control record shall include: (A) The name of the product, description of the dosage form, and a specimen or copy of each label and all other labeling associated with the retail or bulk unit, including copies of such labeling signed or initialed and dated by the person or persons responsible for approval of such labeling.

(B) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the finished product and a statement of the total weight or measure of any dosage unit.

(C) 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 provisions for such variations are included in the master production and control record; an appropriate statement concerning any calculated excess of an ingredient; an appropriate statement of theoretical weight or measure at various stages of processing; and a statement of the theoretical yield.

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

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

(2) The batch production and control record shall be prepared for each batch of amygdalin (laetrile) produced and shall include complete information relating to the production and control of each batch. These records shall be retained for at least two (2) years after the batch distribution is complete, or at least one (1) year after the batch expiration date, whichever is longer. These records shall identify the specific labeling and lot or control numbers used on the batch and shall be readily available during such retention period. The batch record shall include: (A) An accurate reproduction of the appropriate master formula checked, dated, and signed or initialed by a competent and responsible individual.

(B) A record of each significant step in the manufacturing, processing, packaging, labeling, testing, and controlling of the batch, including: Dates; individual major equipment and lines employed; specific identification of each batch of components used; weights and measures of components and products used in the course of processing; in-process and laboratory control results; and identifications of the individual(s) actively performing and the individual(s) directly supervising or checking each significant step in the operation.

(C) A batch number that identified all the production and control documents relating to the history of the batch and all lot or control numbers associated with the batch.

(D) A record of any investigation made.

(Authorized by K.S.A. 1978 Supp. 65-6b06 and 65-6b07; effective May 1, 1979.)