Kansas Administrative Regulations

Department of Health and Environment

Article 21.—Food, Drugs and Cosmetics

28-21-261. Packaging and labeling.

(a) Packaging and labeling operations shall be adequately controlled, to assure that only those products that have met the standards and specifications established in their master production and control records shall be distributed; to prevent mixups between products during filling, packaging, and labeling operations; to assure that correct labels and labeling are employed for the product; and to identify the finished product with a lot or control number that permits determination of the history of the manufacture and control of the batch. An hour, day, or shift code is appropriate as a lot or control number for all products manufactured or processed in continuous production equipment. Packaging and labeling operations shall: (1) Be separated (physically or spatially) from operations on other drugs in a manner adequate to avoid mixups and minimize cross-contamination. Two (2) or more packaging or labeling operations having amygdalin (laetrile) and other drugs, containers, or labeling similar in appearance shall not be in process simultaneously on adjacent or nearby lines unless these operations are separated either physically or spatially.

(2) Provide for an inspection of the facilities prior to use to assure that all drugs and previously used packaging and labeling materials have been removed.

(3) Include the following labeling controls: (A) The holding of labels and package labeling upon receipt pending review and proofing against an approved final copy by a competent and responsible individual to assure that they are accurate regarding identity, content, and conformity with the approved copy before release to inventory.

(B) The maintenance and storage of each type of label and package labeling representing different products, strength, dosage forms, or quantity of contents in such manner as to prevent mixups and provide proper identification.

(C) A suitable system for assuring that only current labels and package labeling are retained and that stocks of obsolete labels and package labeling are destroyed.

(D) Restriction of access to labels and package labeling to authorized personnel.

(E) Avoidance of gang printing of cut labels, cartons, or inserts when the labels, cartons, or inserts are for different products or different strengths of the same products or are of the same size and have identical or similar format or color schemes. If gang printing is employed, packaging and labeling operations shall provide for added control procedures. These added controls should consider sheet layout, stacking, cutting, and handling during and after printing.

(4) Provide strict control of the package labeling issued for use with amygdalin (laetrile). Such issue shall be carefully checked by a competent and responsible person for identity and conformity to the labeling specified in the batch production record. Said record shall identify the labeling and the quantities issued and used and shall reasonably reconcile any discrepancy between the quantity of amygdalin (laetrile) finished and the quantities of labeling issued. All excess package labeling bearing lot or control numbers shall be destroyed. In event of any significant unexplained discrepancy, an investigation should be carried out.

(5) Provide for adequate examination or laboratory testing of representative samples of finished products after packaging and labeling to safeguard against any errors in the finishing operations and to prevent distribution of any batch until all specified tests have been met.

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