Kansas Administrative Regulations

Department of Health and Environment

Article 21.—Food, Drugs and Cosmetics

28-21-258. Laboratory controls.

(a) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, and test procedures to assure that components, in-processed drugs, and finished products conform to appropriate standards of identity, strength, quality and purity. Laboratory controls shall include:

(1) The establishment of master records containing appropriate specifications for the acceptance of each lot of the components, product containers, and their components used in the production and packaging and description of the sampling and testing procedures used for them. Said samples shall be representative and adequately identified. Such record shall also provide for appropriate retesting of the components, product containers, and their components subject to deterioration.

(2) A reserve sample of all active ingredients is required.

(3) The establishment of master records, when needed, containing specifications and a description of sampling and testing procedures for in-process amygdalin (laetrile) preparations. Such samples shall be adequately representative and properly identified.

(4) The establishment of master records containing a description of sampling procedures and appropriate specifications for finished products. Such shall be adequately representative and properly identified.

(5) Adequate provisions for checking the identity and strength of amygdalin (laetrile) for all active ingredients and for assuring:

(A) Sterility of amygdalin (laetrile) purported to be sterile and freedom from objectionable micro-organisms for those products which should be so by virtue of their intended use.

(B) The absence of pyrogens for those products purporting to be pyrogen-free.

(C) That the release pattern of sustained release products is tested by laboratory methods to assure conformance to the release specifications.

(6) Adequate provision for auditing the reliability, accuracy, precision, and performance of laboratory test procedures and laboratory instruments used.

(7) A properly identified reserve sample of the finished product (stored in the same immediate container-closure system in which the product is marketed) consisting of at least twice the quantity necessary to perform all the required tests, except those for sterility and determination of the absence of pyrogens, and stored under conditions consistent with product labeling shall be retained for at least two (2) years after distribution has been completed or one (1) year after the product's expiration date, whichever is longer.

(8) Provision for retaining complete records of all laboratory data relating to each batch or lot of amygdalin (laetrile) to which they apply. Such records shall be retained for at least two (2) years after distribution has been completed or one (1) year after the product's expiration date, whichever is longer.

(9) Provision that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and appropriate records maintained to determine the history of use.

(10) Provision that firms which manufacture non-penicillin products (including certifiable antibiotic products) on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may reasonably be regarded as conducive to contamination of other products by penicillin, shall test such non-penicillin products to determine whether any have become cross-contaminated by penicillin. Such products shall not be marketed if intended for use in man and the product is contaminated with an amount of penicillin equivalent to 0.05 (five one hundredths) unit or more of penicillin G per maximum single dose recommended in the labeling of a product intended for parenteral administration, or an amount of penicillin equivalent to 0.5 (five one tenth) unit or more of penicillin G per maximum single dose recommended in the labeling of a product intended for oral use. (Authorized by K.S.A. 1978 Supp. 65-6b06 and 65-6b07; effective May 1, 1979.)