Kansas Administrative Regulations

Department of Health and Environment

Article 21.—Food, Drugs and Cosmetics

28-21-250. Definitions.

(a) The term "laetrile" (with a small l) is a generic term which is used interchangeably with "Laetrile," "nitriloside," "amygdalin," "vitamin B-17" and related compounds of unknown number. The term is also used to include a number of these compounds, in which case it may appear as "laetriles."

(b) "Laetrile" (with a capital L) is a specific chemical entity with a specific chemical formula of 1-mandelonitrile-beta-glucuronic acid. This is a registered trade name.

(c) "Amygdalin" is a specific chemical entity having a specific chemical formula of D-mandelonitrile-beta-D-glucoside-6-beta-D-glucoside. Mandelonitrile is a chemical in which cyanide is combined with benzaldehyde. Amygdalin is a laetrile compound but is not "Laetrile." Only amygdalin (laetrile) has been authorized to be manufactured and used in the state of Kansas and is hereafter referred to in these regulations.

(d) The term "component" means any ingredient intended for use in the manufacture of amygdalin (laetrile) in dosage form, including those that may not appear in the finished product.

(e) The term "batch" means a specific quantity of amygdalin (laetrile) that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(f) The term "lot" means a batch or any portion of a batch of amygdalin (laetrile) or, in the case of amygdalin (laetrile) produced by a continuous process, an amount of the substance produced in a unit of time or quantity in a manner that assures its uniformity, and in either case which is identified by a distinctive lot number and has uniform character and quality within specified limits.

(g) The terms "lot number" or "control number" means any distinctive combination of letters, or numbers, or both, from which the complete history of the manufacture,

control, packaging, and distribution of a batch or lot of amygdalin (laetrile) can be determined.

(h) The term "active ingredient" means any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of man or other animals. The term shall include those components which may undergo chemical change in the manufacture of amygdalin (laetrile) and be present in the finished product in a modified form intended to furnish the specified activity or effect.

(i) The term "inactive ingredient" means any component other than an "active ingredient" present in the product.

(j) The term "materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

(k) The term "strength" means the concentration of the amygdalin (laetrile).

(l) The term "potency" means the therapeutic activity of amygdalin (laetrile) as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data.

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