

Kansas Administrative Regulations

Department of Health and Environment

Article 21.—Food, Drugs and Cosmetics

28-21-267. Registration and renewal of registration.

(a) Any pharmaceutical firm desiring to manufacture amygdalin (laetrile) in the state of Kansas shall file an application for a permit with the secretary of health and environment. Such application shall be accompanied by a fee of \$2,500 (two thousand five hundred dollars) for the purpose of paying for the costs involved in administering this program. The permit shall be effective for one (1) year after the date of its issuance and may be renewed annually by the permit holder for a fee of \$1,000 (one thousand dollars). No permits or renewal of permits shall be issued unless such fees have been collected. In addition to the permit fee the manufacturer shall be responsible for all costs incurred by the state department of health and environment for laboratory analysis and testing of each lot number of amygdalin (laetrile) submitted to the department for its approval and certification by the secretary of health and environment.

(b) The secretary of health and environment, after giving notice and holding a hearing, may revoke, suspend, or refuse to renew the permit of any person who violates any rule or regulation adopted by the secretary of health and environment or who is subject to applicable civil or criminal sanctions under the federal food, drug, and cosmetic act.

(c) No person, other than a physician, may sell, offer for sale, distribute, or dispense to the public within this state amygdalin (laetrile) unless said person is currently licensed to dispense by the Kansas board of pharmacy and first obtains a permit from the secretary of health and environment authorizing the permit holder to sell, offer for sale, distribute, or dispense amygdalin (laetrile) to the public. Selling, offering for sale, or distributing amygdalin (laetrile) to the public without a valid prescription of a physician to do so shall constitute a class B misdemeanor.

(d) Application for a permit to sell, offer for sale, or dispense amygdalin (laetrile) to the public must be filed with the secretary of health and environment and shall be

accompanied by a fee of \$10 (ten dollars) for the purpose of paying for the costs in administering this program. The permit shall be effective for one (1) year after the date of its issuance and may be renewed annually by the permit holder for a fee of \$10 (ten dollars). No permits or renewal of permits shall be issued unless such fees have been collected.

(e) Any person who sells, dispenses, or administers amygdalin (laetrile) to the public shall maintain complete records of same on forms provided by the secretary of health and environment.

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

***** Authenticated Kansas Administrative Regulation *****