2021 Kansas Statutes

65-669a. New drugs; selling, offering or giving away, restrictions; investigational uses. (a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved and such approval has not been withdrawn under 21 U.S.C.A. 355, or (2) when not subject to the federal act, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the secretary an application setting forth (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the secretary may require; and (F) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subsection (a)(2) of this section shall become effective 180 days after the filing thereof, except that if the secretary finds, after due notice to the applicant and giving the applicant an opportunity for a hearing, that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof, the secretary shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective. Hearings under this subsection shall be conducted in accordance with the provisions of the Kansas administrative procedure act.

(c) An order refusing to permit an application under this section to become effective may be revoked by the secretary.

(d) This section shall not apply to: (1) A drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug is plainly labeled in compliance with regulations issued by the secretary or pursuant to 21 U.S.C.A. 355 or 21 U.S.C.A. 357; or (2) a drug sold in this state at any time prior to the enactment of this act or introduced into interstate commerce at any time prior to the enactment of the federal act; or (3) any drug which is licensed under the virus, serum, and toxin act of July 1, 1902 (U.S.C. 1958 ed. title 42, chapter 6A, sec. 262); or (4) any drug which is subject to subsection (1) of K.S.A. 65-669 and amendments thereto.

(e) The provisions of subsection (n) of K.S.A. 65-656 and amendments thereto shall not apply to any drug which was, on October 9, 1962, or on the date immediately preceding the enactment of this subsection, (1) commercially sold or used in this state or in the United States, (2) not a new drug as defined by subsection (n) of K.S.A. 65-656 and amendments thereto as then in force, and (3) was not covered by an effective application under this section or under 21 U.S.C.A. 355, when such drug is intended solely for use under conditions prescribed, recommended or suggested in labeling with respect to such drug.

History: L. 1965, ch. 377, § 7; L. 1974, ch. 352, § 109; L. 1988, ch. 356, § 187; July 1, 1989.