217.075 Restrictions on handling of new drugs.

(1) No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless:

(a) An application with respect thereto has become effective under the federal act; or

(b) When not subject to the federal act unless such drug has been tested and has not been found to be unsafe for 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 cabinet an application setting forth: full reports of investigations which have been made to show whether or not such drug is safe for use; a full list of the articles used as components of such drug; a full statement of the composition of such drug; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; such samples of such drug and of the articles used as components thereof as the cabinet may require; and specimens of the labeling proposed to be used for such drug.

(2) An application provided for in subsection (1)(b) of this section shall become effective on the sixtieth day after the filing thereof, except that if the cabinet finds after due notice to the applicant and giving him an opportunity for a hearing, conducted in accordance with KRS Chapter 13B, that the drug is not safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, it shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(3) This section shall not apply:

(a) To a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety in drugs provided the drug is plainly labeled "For investigational use only"; or

(b) To a drug sold in the state at any time prior to the enactment of KRS 217.005 to 217.215 or introduced into interstate commerce at any time prior to the enactment of the federal act; or

(c) To any drug which is licensed under the Virus, Serum, and Toxin Act of July 1, 1902, and any amendments thereto. (42 U.S.C. secs. 262 et seq., and amendments thereto).

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

Effective: July 15, 1996

History: Amended 1996 Ky. Acts ch. 318, sec. 122, effective July 15, 1996. -- Created 1960 Ky. Acts ch. 247, sec. 8.