217.065 When drug or device deemed misbranded.

Except for violations of KRS 218A.350, a drug or device shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any particular;

(2) If in package form unless it bears a label containing:

(a) The name and place of business of the manufacturer, packer, or distributor, except that, in the case of a prescription drug, it shall bear the name and place of business of the manufacturer, and the name and place of business of the packer, or distributor, if other than the manufacturer; and

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided that reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the secretary;

(3) If any word, statement, or other information required by or under authority of KRS 217.005 to 217.215 to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, synthetic drugs, salvia, morphine, opium, paraldehyde, peyote, or sulfonmethane, or any chemical derivative of such substance, which derivative has been by the secretary after investigation, found to be, and by regulations under KRS 217.005 to 217.215 designated as, habit forming; unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning -- May be habit-forming";

(5) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears:

(a) The common or usual name of the drug, if such there be; and

(b) In case it is fabricated from two (2) or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including whether active or not the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein; provided that to the extent that compliance with this subsection is impracticable, exemptions shall be established by regulations promulgated by the secretary;

(6) Unless its labeling bears:

(a) Adequate directions for use; and

(b) Such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; provided that where any requirement of subsection (a) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the secretary shall promulgate regulations exempting such drug or device from such requirements;

(7) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; provided that the method of packing may be modified with a consent of the cabinet. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia;

(8) If it has been found by the cabinet to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the secretary shall by administrative regulations require as necessary for the protection of public health. No such administrative regulation shall be established for any drug recognized in an official compendium until the secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements;

(9) (a) If it is a drug and its container is so made, formed, or filled as to be misleading; or

(b) If it is an imitation of another drug; or

(c) If it is offered for sale under the name of another drug;

(10) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

(11) If:

(a) It is a drug intended for use by man which is a habit forming drug to which subsection (4) of this section applies; or because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioner, and is not dispensed upon a prescription unless prior to dispensing its label bears the statement "Caution: Federal law prohibits dispensing without prescription"; or

(b) It is a drug or device and its label (as originally packed) directs that it is to be dispensed or sold only on prescription, unless it is dispensed or sold on a prescription of an authorized practitioner and its label (as dispensed) bears the name and place of business of the dispenser or seller, the serial number and

date of such prescription, and the name of such licensed practitioner. Such prescriptions shall not be refilled except on the specific authorization of the prescribing practitioner; provided that where any requirement of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the secretary shall promulgate regulations exempting such drug or device from such requirement;

(12) A drug sold on a prescription of a practitioner (except a drug sold in the course of the conduct of a business of selling drugs pursuant to diagnosis by mail) shall be exempt from the requirements of this section if:

(a) Such practitioner is licensed by law to administer such drug; and

(b) Such drug bears a label containing the name and place of business of the seller, the serial number and date of such prescription, and the name of such practitioner.

(13) It is not the intention of subsection (2)(a) of this section as amended herein to require the name and place of business of the wholesaler to appear upon the label of the package unless otherwise required by this section.

Effective: April 11, 2012

History: Amended 2012 Ky. Acts ch. 108, sec. 2, effective April 11, 2012. -- Amended 2011 Ky. Acts ch. 45, sec. 5, effective March 16, 2011. -- Amended 2010 Ky. Acts ch. 149, sec. 6, effective April 13, 2010.; and ch. 160, sec. 6, effective April 26, 2010. -- Amended 1982 Ky. Acts ch. 419, sec. 2, effective July 15, 1982. -- Amended 1978 Ky. Acts ch. 322, sec. 1, effective January 1, 1979. -- Amended 1974 Ky. Acts ch. 74, Art. VI, sec. 107(1), (11), (22). -- Amended 1972 Ky. Acts ch. 208, sec. 11. -- Created 1960 Ky. Acts ch. 247, sec. 7.