

2012 Kansas Statutes

65-669. Same; drugs or devices deemed misbranded, when. A drug or device shall be deemed to be misbranded:

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing: (1) the name and place of business of the manufacturer, the packer or the distributor, except that in the case of a prescription drug it shall bear the name and place of business of the person responsible for the production of the finished dosage form of the drug, the packer and the distributor; except that nothing in clause (1) of this paragraph shall be construed to apply to wholesalers and the requirement of clause (1) shall be satisfied by stating such information on the label of the drug and filing a statement with such information with the secretary which shall be made available by the secretary on request to local, public and private health agencies, poison control centers, licentiates of the healing arts, the state board of pharmacy, consumers and others to promote the purposes of this act; in no event, however, shall the label contain less information than required under federal law; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under clause (2) of this paragraph reasonable variations shall be permitted and exemptions as to small packages shall be allowed, in accordance with regulations prescribed by the secretary, or issued under the federal act.

(c) If any word, statement, or other information required by or under authority of this act 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.

(d) If it is for use by man and contains any quantity of narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substance, which derivative has been by the secretary after investigation, found to be, and by regulations under this act, or by regulations issued pursuant to 21 U.S.C. 352 (d), 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."

(e) (1) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be; and (ii) in case it is fabricated from two or more ingredients, the established name of each active ingredient, including the kind and quantity of proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, 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. The requirements for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs. To the extent that compliance with the requirements of clause (ii) of this subparagraph is impracticable, exemptions shall be allowed under regulations promulgated by the secretary, or under the federal act.

(2) As used in this paragraph (e), the term "established name," with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to 21 U.S.C. 358, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient. Where clause (B) of this subparagraph applies to an article recognized in the United States pharmacopoeia and in the homeopathic pharmacopoeia under different official titles, the official title used in the United States pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the homeopathic pharmacopoeia shall apply.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warning 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. Where any requirement of clause (1) of this paragraph, 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. Articles exempted under regulations issued under 21 U.S.C. 352 (f) may also be exempt.

(g) 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. The method of packing may be modified with the consent of the secretary, or if consent is obtained under the federal act. 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 the 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. In the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the secretary or under the federal act to be a drug liable to deterioration, unless it is packed in such form and manner, and its label bears a statement of such precautions, as the regulations adopted by the secretary require as necessary for the protection of public health. No such regulations 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.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

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

(k) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to 21 U.S.C. 356, and (2) such certificate or release is in effect with respect to such drug.

(l) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof,

unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to 21 U.S.C. 357, and (2) such certificate or release is in effect with respect to such drug. This paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under 21 U.S.C. 357 (c) or (d). For the purpose of this subsection the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).

(m) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of K.S.A. 65-667 or of the federal act.

(n) In the case of any prescription drug distributed or offered for sale in this state, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name, as defined in subsection (e) (2) of this section, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under 21 U.S.C. 352 (e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issued under the federal act.

(o) If a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.

(p) Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling or packaging requirements of this act if such drugs and devices are being delivered, manufactured, processed, labeled, repacked or otherwise held in compliance with regulations issued by the secretary or under the federal act.

(q) A drug intended for use by man which (A) is a habit-forming drug to which K.S.A. 65-668 applies; or (B) 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 licensed by law to administer such drug; or (C) is limited by an approved application under 21 U.S.C. 355 or K.S.A. 65-669a to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug or upon the written prescription of a mid-level practitioner as defined in subsection (ii) of K.S.A. 65-1626 and amendments thereto, or (ii) upon an oral prescription of such practitioner or mid-level practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling, any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in a drug being misbranded while held for sale.

(r) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug or by filling or refilling a written or oral prescription of a mid-level practitioner as defined in subsection (ii) of K.S.A. 65-1626 and amendments thereto shall be exempt from the requirements of this section, except subsections (a), (i) (2) and (3), (k), and (l), and the packaging requirements of subsections (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (q) of this section.

(s) The secretary may, by regulation, remove drugs subject to subsection (d) of this section and K.S.A. 65-669a from the requirements of paragraph (q) of this section when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the federal act by regulations issued thereunder may also, by regulations issued by the secretary, be removed from the requirements of paragraph (q) of this section.

(t) A drug which is subject to paragraph (q) of this section shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "caution: federal law prohibits dispensing without prescription," or "caution: state law prohibits dispensing without prescription." A drug to which paragraph (q) of this section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(u) Nothing in this section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs or marijuana as defined in the applicable federal and state laws relating to narcotic drugs and marijuana.

History: L. 1953, ch. 286, § 15; L. 1965, ch. 377, § 6; L. 1972, ch. 230, § 1; L. 1974, ch. 352, § 108; L. 1977, ch. 215, § 1; L. 1999, ch. 115, § 8; Apr. 1, 2000.