Session of 2008

SENATE BILL No. 490

By Joint Committee on Administrative Rules and Regulations

1-28

AN ACT relating to food, drug and cosmetic act; concerning prohibited procedure of administering phosphatidylcholine and sodium deoxycholate by injection; amending K.S.A. 65-656 and 65-657 and repealing the existing sections.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 65-656 is hereby amended to read as follows: 65-656. For the purpose of this act: (a) The term "secretary" means the secretary of health and environment.

(b) The term "person" includes individual, partnership, corporation, and association.

(c) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(d) The term "drug" means (1) articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; and (2) articles intended for use in diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts or accessories. The term "drug" shall not include amygdalin (laetrile).

(e) The term "device," except when used in paragraph (k) of this section and in K.S.A. 65-657 (j), 65-665 (f), 65-669 (c) and (o), and 65-671 (c) means instruments, apparatus and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(f) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleaning, beautifying, promoting attractiveness, or altering the appearance; and (2) articles intended

for use as a component of any such articles, except that such term shall not include soap.

(g) The term "official compendium" means the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, official national formulary, or any supplement to any of them.

(h) The term "label" means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this act that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(i) The term "immediate container" does not include package liners.

(j) The term "labeling" means all labels and other written, printed or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying such article.

(k) If any article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or in any combinations thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or materials with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

(l) The term "advertisement" means all representations disseminated in any manner or by any means other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(m) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(n) The term "new drug" means (1) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or (2) any drug the composition of which is such that such drug, as a result of

investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions. The term "new drug" shall not include amygdalin (laetrile).

(o) The term "contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

(p) The provisions of this act regarding the selling of food, drug, devices, or cosmetics, shall be considered to include the manufacture, production, processing, packaging, exposure, offer, possession, and holding of any such articles for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment.

(q) The term "pesticide chemical" means any substance which, alone, in chemical combination, or in formulation with one or more other substances is an "economic poison" within the meaning of the agricultural chemicals act, K.S.A. 2-2202 as now enacted or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include: (1) A pesticide chemical in or on a raw agricultural commodity; or (2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to the enactment of the food additive amendment of 1958, pursuant to the federal act.

(t) (1) The term "color additive" means a material which — (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source, or (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting color thereto; except that such term does not include any material which has been or hereafter is exempted under the federal act. (2) The term "color" includes black, white and intermediate grays. (3) Nothing in clause (1) (t) shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "imitation" shall mean any article made in the semblance of another, consisting of similar or dissimilar ingredients and being capable of being substituted for the imitated article without the knowledge of the consumer.

(v) The term "federal act" means the federal food, drug and cosmetic act (title 21 U.S.C. 301 et seq.; 52 Stat. 1040 et seq.).

(w) The term "PCDC" means phosphatidylcholine and sodium deoxycholate prepared for administration individually or in combination.

Sec. 2. K.S.A. 65-657 is hereby amended to read as follows: 65-657. The following acts and the causing thereof within the state of Kansas are hereby prohibited:

(a) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic.

(c) The receipt in commerce of any food, drug, device, or cosmetic knowing it to be adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of K.S.A. 65-666.

(e) The dissemination of any false advertisement.

(f) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by K.S.A. 65-674.

(g) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic.

(h) The removal or disposal of a detained or embargoed article in violation of K.S.A. 65-660.

(i) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded.

(j) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized, or required by regulations promulgated under the provisions of this act.

(k) The using of any person to such person's own advantage, or revealing, other than to the administrator or officers or employees of the department of health and environment or to the courts where relevant in any jurisdictional proceeding under this act, any information acquired under authority of this act concerning any method or process which constitutes a trade secret under the uniform trade secrets act (K.S.A. 60-3320 et seq. and amendments thereto) and as a trade secret is entitled to protection.

(l) The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under K.S.A. 65-669a, as amended, or that such drug complies with the provisions of such section.

(m) In the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this act.

(n) (1) Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or (2) selling, dispensing, disposing of or causing to be sold, dispensed or disposed of or concealing or keeping in possession, control or custody, with intent to sell, dispense or dispose of, any drug, device or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by subsection (1) hereof; or (3) making, selling, disposing of or causing to be made, sold or disposed of or keeping in possession, control or custody, or concealing, with intent

to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device or container thereof.

(o) Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the person ordering or prescribing.

(p) Administering or authorizing another person to administer PCDC by injection to a human being.

Sec. 3. K.S.A. 65-656 and 65-657 are hereby repealed.

Sec. 4. This act shall take effect and be in force from and after its publication in the statute book.