FIRST REGULAR SESSION

SENATE COMMITTEE SUBSTITUTE FOR

SENATE BILL NO. 514

91ST GENERAL ASSEMBLY

Reported from the Committee on Public Health and Welfare, March 15, 2001, with recommendation that the Senate Committee Substitute do pass and be placed on the Consent Calendar.

TERRY L. SPIELER, Secretary.

1846S.03C

AN ACT

To repeal section 196.100, RSMo 2000, relating to labeling of drugs, and to enact in lieu thereof one new section relating to the same subject.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Section 196.100, RSMo 2000, is repealed and one new section enacted in lieu thereof, to be known as section 196.100, to read as follows:

196.100. 1. **[**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; and

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

(3) If any word, statement, or other information required by or under authority of sections 196.010 to 196.120 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;

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

(4) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alphaeucaine, barbituric acid, betaeucaine, 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 department after investigation, found to be, and by regulations under sections 196.010 to 196.120, 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 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, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophantin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein; provided, that to the extent that compliance with the requirements of paragraph (b) of this subdivision is impracticable, exemptions shall be established by regulations promulgated by the department of health;

(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 paragraph (a) of this subdivision, as applied to any drug or device, is not necessary for the protection of the public health, the department 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 the consent of the department. 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 department 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 department shall by regulations require as necessary for the protection of public health. No such

regulation shall be established for any drug recognized in an official compendium until the department 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) If it is a drug and its container is so made, formed, or filled as to be misleading; or if it is an imitation of another drug; or 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 it purports to be, or is represented as a drug composed wholly or in part of insulin, unless it is from a batch with respect to which a certificate or release has been issued pursuant to 21 U.S.C.A. § 356 and, such certificate or release is in effect with respect to such drug.**] Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.**

2. A drug dispensed on a written prescription signed by a licensed physician, dentist, or veterinarian, except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to a diagnosis by mail, shall be exempt from the requirements of this section if such physician, dentist, or veterinarian is licensed by law to administer such drug, and such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian.

3. The department is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of sections 196.010 to 196.120, 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, on condition that such drugs and devices are not adulterated or misbranded under the provisions of said sections upon removal from such processing, labeling, or repacking establishment.

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