

FIRST REGULAR SESSION

[PERFECTED]

HOUSE BILL NO. 796

91ST GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HOSMER.

Read 1st time February 14, 2001, and 1000 copies ordered printed.

Read 2nd time February 15, 2001, and referred to the Committee on Children, Families and Health, February 20, 2001.

Reported from the Committee on Children, Families and Health, March 13, 2001, with recommendation that the bill Do Pass by Consent.

Perfectured by Consent March 28, 2001.

TED WEDEL, Chief Clerk

1821L.01P

AN ACT

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Section A. Section 196.100, RSMo 2000, is repealed and one new section enacted in lieu thereof, to be known as section 196.100, to read as follows: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

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

13 customary conditions of purchase and use;

14 (4) If it is for use by man and contains any quantity of the narcotic or hypnotic substance
15 alphaeucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine,
16 codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any
17 chemical derivative of such substance, which derivative has been by the department after
18 investigation, found to be, and by regulations under sections 196.010 to 196.120, designated as,
19 habit forming, unless its label bears the name and quantity or proportion of such substance or
20 derivative and in juxtaposition therewith the statement "Warning--may be habit forming";

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

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

24 (b) In case it is fabricated from two or more ingredients, the common or usual name of
25 each active ingredient, including the kind and quantity or proportion of any alcohol, and also
26 including, whether active or not, the name and quantity or proportion of any bromides, ether,
27 chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine,
28 hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine,
29 thyroid, or any derivative or preparation of any such substances, contained therein; provided, that
30 to the extent that compliance with the requirements of paragraph (b) of this subdivision is
31 impracticable, exemptions shall be established by regulations promulgated by the department of
32 health;

33 (6) Unless its labeling bears:

34 (a) Adequate directions for use; and

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

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

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

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

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

60 (11) If it purports to be, or is represented as a drug composed wholly or in part of insulin,
61 unless it is from a batch with respect to which a certificate or release has been issued pursuant
62 to 21 U.S.C.A. § 356 and, such certificate or release is in effect with respect to such drug.

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

69 3. The department is hereby directed to promulgate regulations exempting from any
70 labeling or packaging requirement of sections 196.010 to 196.120, drugs and devices which are,
71 in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial
72 quantities at establishments other than those where originally processed or packed, on condition
73 that such drugs and devices are not adulterated or misbranded under the provisions of said
74 sections upon removal from such processing, labeling, or repacking establishment.] **Any**
75 **manufacturer, packer, distributor or seller of drugs or devices in this state shall comply**
76 **with the current federal labeling requirements contained in the Federal Food, Drug and**
77 **Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any**
78 **drug or device which contains labeling that is not in compliance with the provisions of this**
79 **section shall be deemed misbranded.**