126.10 Drugs and devices — misbranding — labeling.

1. A drug or device is misbranded under any of the following circumstances:

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

b. (1) If in a package form unless it bears a label containing both of the following:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

(2) However, under subparagraph (1), subparagraph division (a), reasonable variations shall be permitted, and exemptions as to small packages shall be allowed, in accordance with rules adopted by the board.

c. If any word, statement, or other information required by or under the authority of this chapter 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 humans 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, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such a substance, which derivative, after investigation, has been designated as habit forming, by rules adopted by the board under this chapter or by regulations adopted by the secretary pursuant to section 502(d) of the federal Act; 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 both of the following apply:

(a) 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 of the drug, as specified in subparagraph (3), if such exists; and

(ii) If the drug is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, 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. However, the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subparagraph subdivision, applies only to prescription drugs.

(b) For a prescription drug, the established name of the prescription drug or of an ingredient is printed, on the label and on any labeling on which a name for the prescription drug or an ingredient is used, prominently and in type at least half as large as that used thereon for any proprietary name or designation for the prescription drug or ingredient. However, to the extent that compliance with subparagraph division (a), subparagraph subdivision (ii), or this subparagraph division is impracticable, exemptions shall be allowed under rules or regulations adopted by the board or the secretary under the federal Act.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name, as defined in subparagraph (4), prominently printed in type at least half as large as that used thereon for any proprietary name or designation for the device, except that to the extent compliance with this subparagraph is impracticable, exemptions shall be allowed under rules or regulations adopted by the board or the secretary under the federal Act.

(3) As used in subparagraph (1), the term *"established name"*, with respect to a drug or ingredient thereof, means one of the following:

(a) The applicable official name designated pursuant to section 508 of the federal Act.

(b) If no such official name exists and the drug or ingredient is an article recognized in an official compendium, then its official title in the compendium.

(c) If neither subparagraph division (a) nor (b) applies, then the common or usual name, if any, of the drug or ingredient. However, if subparagraph division (b) applies to an article

recognized in the United States Pharmacopoeia National Formulary and in the Homeopathic Pharmacopoeia of the United States under different official titles, the official title used in the United States Pharmacopoeia National Formulary applies unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia of the United States applies.

(4) As used in subparagraph (2), the term *"established name"* with respect to a device means one of the following:

(a) The applicable official name of the device pursuant to section 508 of the federal Act.

(b) If no such official name exists and the device is an article recognized in an official compendium, then its official title in the compendium.

(c) If neither subparagraph division (a) nor (b) applies, then any common or usual name of the device.

f. (1) Unless its labeling bears both of the following:

(a) Adequate directions for use.

(b) 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 durations of administration or application, in the manner and form necessary for the protection of users.

(2) However, if a requirement of subparagraph (1), subparagraph division (a), as applied to a drug or device, is not necessary for the protection of the public health, the board or the secretary shall adopt rules or regulations exempting the drug or device from that requirement.

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 in the official compendium. However, the method of packing may be modified with the consent of the board or the secretary. If a drug is recognized in both the United States Pharmacopoeia National Formulary and the Homeopathic Pharmacopoeia of the United States, it is subject to the requirements of the United States Pharmacopoeia National Formulary with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it is subject to the Homeopathic Pharmacopoeia of the United States, and not to the United States Pharmacopoeia National Formulary. However, if an inconsistency exists between this paragraph and paragraph *"e"* as to the name by which the drug or its ingredients shall be designated, paragraph *"e"* prevails.

h. If it has been found by the board or the secretary to be a drug liable to deterioration, unless it is packaged in the form and manner, and its label bears a statement of the precautions that the board or the secretary by rule or regulation requires as necessary for the protection of public health. Such a rule or regulation shall not be established for a drug recognized in an official compendium until the board or the secretary has informed the appropriate body charged with the revision of the official compendium of the need for such packaging or labeling requirements and that body has 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.

(2) If it is an imitation of another drug.

(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 manner, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

k. If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless both of the following apply:

(1) It is from a batch with respect to which a certificate or release has been issued pursuant to section 506 of the federal Act.

(2) The certificate or release is in effect with respect to the drug.

l. (1) 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 both of the following apply:

(a) It is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the federal Act.

(b) The certificate or release is in effect with respect to the drug.

(2) However, this paragraph *"l"* does not apply to any drug or class of drugs exempted by regulations adopted under section 507(c) or 507(d) of the federal Act.

m. If it is a color additive, the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to that color additive, as contained in regulations adopted under section 706 of the federal Act.

n. If it is a prescription drug distributed or offered for sale in this state, unless the manufacturer, packer, or distributor includes in all advertising and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to the prescription drug a true statement of all of the following:

(1) The established name as defined in paragraph *"e"*, printed prominently and in type at least half as large as that used for any trade or brand name thereof.

(2) The formula showing quantitatively each ingredient of the prescription drug to the extent required for labels under paragraph *"e"*.

(3) Other information in brief summary relating to side effects, contraindications, and effectiveness as required in regulations adopted pursuant to section 701(e) of the federal Act.

o. If it was manufactured, prepared, propagated, compounded, or processed in an establishment in this state not duly registered under section 510 of the federal Act, if it was not included on a list required by section 510(j) of the federal Act, if a notice or other information respecting it was not provided as required by that section or section 510(k) of the federal Act, or if it does not bear the symbols from the uniform system for identification of devices prescribed under section 510(e) of the federal Act that are required by regulation.

p. If it is a drug and its packaging or labeling is in violation of an applicable regulation adopted pursuant to section 3 or 4 of the federal Poison Prevention Packaging Act of 1970, 15 U.S.C. §1471 et seq.

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

r. In the case of a restricted device distributed or offered for sale in this state, if either of the following applies:

(1) Its advertising is false or misleading in any particular.

(2) It is sold, distributed, or used in violation of regulations adopted pursuant to section 520(e) of the federal Act.

s. In the case of a restricted device distributed or offered for sale in this state, unless the manufacturer, packer, or distributor includes in all advertising and other descriptive printed matter issued by the manufacturer, packer, or distributor with respect to the device both of the following:

(1) A true statement of the device's established name as defined in paragraph *"e"*, printed prominently and in type at least half as large as that used for any trade or brand name thereof.

(2) A brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications; and in the case of a specific device made subject to regulations adopted pursuant to the federal Act, a full description of the components of the device or the formula showing quantitatively each ingredient of the device to the extent required in regulations under the federal Act.

t. If it is a device subject to a performance standard established under section 514 of the federal Act, unless it bears labeling as prescribed in that performance standard.

u. If it is a device and there was a failure or refusal to comply with any requirement prescribed under section 518 of the federal Act respecting the device, or to furnish material required by or under section 519 of the federal Act respecting the device.

2. If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations, or material with respect to consequences which may result from the use of the article to which

the labeling or advertising relates, under the conditions of use prescribed in the labeling or advertising or under customary or usual conditions of use.

3. The representation of a drug, in its labeling, 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.

89 Acts, ch 197, §10
CS89, §203B.10
C93, §126.10
2009 Acts, ch 41, §189
Referred to in **§126.11**