CHAPTER 126

DRUGS, DEVICES, AND COSMETICS

Referred to in §124B.6, 124B.11, 155A.6, 155A.6A, 155A.6B, 155A.12, 155A.13A, 155A.17, 155A.26, 155A.42, 205.11, 205.12, 205.13

[P]
See §205.11 – 205.13 for additional provisions relating to administration and enforcement
[P] This chapter not enacted as a part of this title; transferred from chapter 203B in Code 1993

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126.1 Title.

This chapter may be cited as the *"Iowa Drug, Device, and Cosmetic Act"*.

89 Acts, ch 197, §1
CS89, §203B.1
C93, §126.1

126.2 Definitions.

As used in this chapter, unless the context otherwise requires:

1. *"Advertising"* means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

2. *"Anabolic steroid"* means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, or dehydroepiandrosterone, which substance is identified as an anabolic steroid in section 124.208, subsection 6, and includes any other substance designated by the board as an anabolic steroid through the adoption of rules pursuant to chapter 17A.

3. *"Board"* means the board of pharmacy.

4. *"Contaminated with filth"* means not securely protected from dust, dirt, and as far as is necessary by all reasonable means, from all foreign or injurious contaminations.

5. *"Cosmetic"* means any of the following, but does not include soap:

a. An article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part of a human body for cleaning, beautifying, promoting attractiveness, or altering the appearance.

b. An article intended for use as a component of an article defined in paragraph *"a"*.

6. *"Counterfeit drug"* means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any such likeness, of a drug manufacturer, processor, packer, or distributor other than

the person or persons who in fact manufactured, processed, packed, or distributed the drug and which falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

7. *"Device"* means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory of any of these, which is any of the following:

a. Recognized as a device in the official United States Pharmacopoeia National Formulary or any supplement to it.

b. Intended for use in the diagnosis of diseases or other conditions, or in the cure, mitigation, treatment, or prevention of diseases or other conditions in a human.

c. Intended to affect the structure or any function of the body of a human, and which does not achieve any of its principal intended purposes through chemical action within or on the body of a human and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

8. *"Drug"* means any of the following, but does not include a device:

a. An article recognized as a drug in the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to either document.

b. An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in a human.

c. An article, other than food, intended to affect the structure or any function of the body of a human.

d. An article intended for use as a component of any articles specified in paragraphs *"a"*, *"b"*, or *"c"*.

9. *"Electronic prescription"* means a prescription which is transmitted by a computer device in a secure manner, including computer-to-computer transmission and computer-to-facsimile transmission.

10. *"Facsimile prescription"* means a prescription which is transmitted by a device which sends an exact image to the receiver.

11. *"Federal Act"* means the federal Food, Drug, and Cosmetic Act, which is codified in 21 U.S.C. § 301 et seq.

12. *"Immediate container"* does not include a package liner.

13. *"Label"* means a display of written, printed, or graphic matter upon the immediate container of an article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label is not complied with unless the word, statement, or other information also appears on the outside container or wrapper of the retail package of the article, or is easily legible through the outside container or wrapper.

14. *"Labeling"* means all labels and other written, printed, or graphic matter upon an article or any of its containers or wrappers, or accompanying an article.

15. *"New drug"* means either of the following:

a. Any drug, the composition of which is such that the 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 its labeling, except that a drug not so recognized is not a new drug if at any time prior to the enactment of this chapter it was subject to the federal Act, and if at that time its labeling contained the same representations concerning the conditions of its use.

b. Any drug, the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under the conditions prescribed, recommended, or suggested in its labeling, has become recognized as safe and effective, but which has not, other than in such investigations, been used to a material extent or for a material time under the conditions prescribed, recommended, or suggested in its labeling.

16. *"Official compendium"* means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to either document.

17. *"Person"* means an individual, partnership, corporation, or association.

18. *"Principal display panel"* means that part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

19. *"Safe"* as used in this chapter has reference to the health of a human.

20. *"Secretary"* means the secretary of the United States department of health and human services.

89 Acts, ch 197, §2
CS89, §203B.2
90 Acts, ch 1078, §1
C93, §126.2
2004 Acts, ch 1036, §4; 2007 Acts, ch 8, §20; 2007 Acts, ch 10, §17
Referred to in §280.16
[SP] Former unnumbered paragraph 2 transferred to §126.2A

126.2A Applicability.

The provisions of this chapter regarding the selling of drugs, devices, or cosmetics are applicable to the manufacture, production, processing, packaging, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such article, in the conduct of any drug, device, or cosmetic establishment.

C93, §126.2(unn. 2)
CS2007, §126.2A
[T] Section not amended; footnote deleted

126.3 Prohibited acts.

The following acts and the causing of the acts within this state are unlawful:

1. The introduction or delivery for introduction into commerce of any drug, device, or cosmetic that is adulterated or misbranded.

2. The adulteration or misbranding of any drug, device, or cosmetic in commerce.

3. The receipt in commerce of a drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

4. The introduction or delivery for introduction into commerce of a drug, device, or cosmetic in violation of section 126.12.

5. The dissemination of any false advertising.

6. The refusal to permit entry or inspection, or to permit the taking of a sample or to permit access to or copying of any record as authorized by section 126.18; or the failure to establish or maintain any record or make any report required under section 512(j), 512(l), or 512(m) of the federal Act, or the refusal to permit access to or verification or copying of any such required record.

7. The manufacture within this state of a drug, device, or cosmetic that is adulterated or misbranded.

8. The giving of a guaranty or undertaking referred to in section 126.5, subsection 2, if the guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect, signed by, and containing the name and address of, the person residing in this state from whom the person received the drug, device, or cosmetic in good faith.

9. The removal or disposal of a detained or embargoed drug, device, or cosmetic in violation of section 126.6, subsection 1.

10. 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 drug, device, or cosmetic, if the act is done while the article is held for sale, whether or not it would be the first sale, after shipment in commerce; and if the action results in the article being adulterated or misbranded.

11. Forging, counterfeiting, simulating, or falsely representing, or without proper authority using a mark, stamp, tag, label, or other identification device authorized or required by rules or regulations adopted under this chapter or the federal Act.

12. Making, selling, disposing of, or keeping in possession, control, or custody, or

concealing a punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another trademark, trade name, mark, imprint, or device or a likeness of any trademark, trade name, mark, imprint, or device upon a drug or drug container or the labeling thereof so as to render the drug a counterfeit drug.

13. The doing of an act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

14. The use by a person to the person's own advantage, or the revealing, other than to the board or to the person's authorized representative or to the courts when relevant in a judicial proceeding under this chapter, of any information acquired under authority of this chapter concerning any method or process which as a trade secret is entitled to protection.

15. The use, on the labeling of a drug or device or in advertising relating to a drug or device, of a representation or suggestion that approval of an application with respect to the drug or device is in effect under section 126.12 or section 505, 515, or 520(g) of the federal Act, or that the drug or device complies with the provisions of any of those sections.

16. The use, in labeling, advertising, or other sales promotion of a reference to a report or analysis furnished in compliance with section 126.18 or section 704 of the federal Act.

17. If a prescription drug is distributed or offered for sale in this state, the failure of the manufacturer, packer, or distributor of the prescription drug to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer the drug who makes written request for information as to the 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. This subsection does not exempt any person from a labeling requirement imposed by or under this chapter.

18. *a.* Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trademark, trade name, or other identifying mark or imprint of another trademark, trade name, mark, or imprint or any likeness of such a trademark, trade name, mark, or imprint.

b. Selling, dispensing, disposing of; 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, a drug, device, or container thereof, with knowledge that the trademark, trade name, or other identifying mark or imprint of another trademark, trade name, mark, or imprint or any likeness of any trademark, trade name, mark, or imprint has been placed thereon in a manner prohibited by paragraph *"a"*.

c. Making, selling, disposing of; causing to be made, sold, or disposed of; keeping in possession, control, or custody; or concealing with intent to defraud any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another trademark, trade name, mark, or imprint or any likeness of any trademark, trade name, mark, or imprint upon a drug or container or labeling thereof so as to render the drug a counterfeit drug.

19. The failure to register in accordance with section 510 of the federal Act, the failure to provide any information required by section 510(j) or 510(k) of the federal Act, or the failure to provide a notice required by section 510(j)(2) of the federal Act.

20. *a.* The failure or refusal to:

(1) Comply with a requirement prescribed under section 518 or 520(g) of the federal Act.

(2) Furnish any notification or other material or information required by or under section 519 or 520(g) of the federal Act.

b. With respect to any device, the submission of any report required by or under this chapter that is false or misleading in any material respect.

21. The movement of a device in violation of an order under section 304(g) of the federal Act or the removal or alteration of any mark or label required by the order to identify the device as detained.

22. The failure to provide the notice required by section 412(b) or 412(c) of the federal Act, the failure to make the reports required by section 412(d)(1)(B) of the federal Act, or the failure to meet the requirements prescribed under section 412(d)(2) of the federal Act.

23. Selling, dispensing, or distributing; causing to be sold, dispensed, or distributed; or

possessing with intent to sell, dispense, or distribute, an anabolic steroid to a person under eighteen years of age, with knowledge that the anabolic steroid is not necessary for the legitimate treatment of disease pursuant to an order of a physician.

89 Acts, ch 197, §3
CS89, §203B.3
90 Acts, ch 1078, §2
C93, §126.3
Referred to in §126.4, 126.5, 232.52, 321.215, 901.5

126.4 Injunction proceedings.

The board may apply to the district court for, and the court has jurisdiction upon hearing and for cause shown to grant, a temporary or permanent injunction restraining any person from violating any provision of section 126.3 whether or not there exists an adequate remedy at law.

89 Acts, ch 197, §4
CS89, §203B.4
C93, §126.4

126.5 Penalties — guaranty — false advertising liability.

1. A person who violates a provision of this chapter, other than a violation of section 126.3, subsection 23, is guilty of a serious misdemeanor; but if the violation is committed after a conviction of the person under this section has become final, the person is guilty of an aggravated misdemeanor.

2. A person is not subject to the penalties of subsection 1 if the person establishes a guaranty or undertaking signed by, and containing the name and address of another person residing in this state from whom the person received the article in good faith, to the effect that the article is not adulterated or misbranded.

3. A publisher, radio-broadcast licensee, or agency or medium which disseminates false advertising, except the manufacturer, packer, distributor, or seller of the article to which false advertising relates, is not liable under this section for the dissemination of the false advertising, unless the person knew or believed that the advertising was deceptive, false, or misleading or the person has refused upon the request of the board to furnish the board the name and address, if known, of the manufacturer, packer, distributor, seller, or advertising agency which caused the person to disseminate the advertisement.

4. A person who violates section 126.3, subsection 23, commits an aggravated misdemeanor.

5. A violation of this chapter is a violation of section 714.16, subsection 2, paragraph "*a*".

89 Acts, ch 197, §5
CS89, §203B.5
90 Acts, ch 1078, §3, 4; 92 Acts, ch 1062, §2
C93, §126.5
Referred to in §126.3

126.6 Embargo.

1. If a duly authorized agent of the board finds, or has probable cause to believe, that a drug, device, or cosmetic is adulterated or so misbranded as to be dangerous or fraudulent, within the meaning of this chapter, or is in violation of section 126.12, the agent shall affix to the article a tag or other appropriate marking, giving notice that the article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed, and warning all persons not to remove or dispose of the article by sale or otherwise until permission for removal or disposal is given by an authorized agent or the court. It is unlawful for a person to remove or dispose of the detained or embargoed article by sale or otherwise without such permission.

2. When an article is adulterated or misbranded or is in violation of section 126.12 and has been detained or embargoed, a petition may be filed with the district court in whose jurisdiction the article is located, detained, or embargoed for an order for condemnation of

the article. If a duly authorized agent has found that an article which is embargoed or detained is not adulterated or misbranded, the agent shall remove the tag or other marking.

3. If the court finds that a sampled, detained, or embargoed article is adulterated or misbranded, the article shall be destroyed at the expense of the claimant of the article, under the supervision of the agent, and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of the article or the claimant's agent; but if the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after costs, fees, storage, and other expenses have been paid and a good and sufficient bond, conditioned that the article shall be so labeled or processed, has been executed, may by order direct that the article be delivered to the claimant for such labeling or processing under the supervision of a duly authorized agent of the board. The expense of supervision shall be paid by the claimant. The article shall be returned to the claimant and the bond shall be discharged on the representation to the court by the board that the article is no longer in violation of this chapter, and that the expenses of supervision have been paid.

89 Acts, ch 197, §6
CS89, §203B.6
C93, §126.6
Referred to in §126.3

126.7 Prosecutions.

The attorney general, or a county attorney, or a city attorney to whom the board reports a violation of this chapter, shall cause appropriate court proceedings to be instituted without delay and to be prosecuted in the manner required by law. Before a violation of this chapter is reported to any such attorney for the institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given appropriate notice and an opportunity to present the person's views before the board or its agent, either orally or in writing, in person or by attorney, with regard to the contemplated proceeding. However, the drug, device, or cosmetic shall be embargoed by the duly authorized agent.

89 Acts, ch 197, §7
CS89, §203B.7
C93, §126.7
Referred to in §331.756(40)

126.8 Minor violations.

This chapter does not require the board to report minor violations for prosecution, or for the institution of proceedings under this chapter, if the board believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

89 Acts, ch 197, §8
CS89, §203B.8
C93, §126.8

126.9 Drugs and devices — adulteration.

A drug or device is adulterated under any of the following circumstances:

1. *a.* If it consists in whole or in part of any filthy, putrid, or decomposed substance.

b. If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

c. If it is a drug and the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that the drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

d. If its container is composed, in whole or part, of any poisonous or deleterious substance which may render the contents injurious to health.

2. If it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the

standards set forth in the official compendium. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the official compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal Act. A drug defined in an official compendium is not adulterated under this subsection because it differs from the standard of strength, quality, or purity set forth in the official compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. 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 United States Pharmacopoeia National Formulary 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.

3. If it is not subject to subsection 2 and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

4. If it is a drug and any substance has been mixed or packed with it so as to reduce its quality or strength, or any substance has been substituted for it wholly or in part.

5. If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514 of the federal Act, unless the device is in all respects in conformity with such standard.

6. If it is a device banned by the board or by the United States food and drug administration.

7. If it is a device and the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) of the federal Act or an applicable condition as prescribed by an order under section 520(f)(2) of the federal Act.

8. If it is a device for which an exemption has been granted under section 520(g) of the federal Act for investigational use and the person who was granted the exemption or any investigator who uses the device under the exemption fails to comply with a requirement prescribed by or under that section.

89 Acts, ch 197, §9
CS89, §203B.9
C93, §126.9

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

126.11 Exemptions in cases of drugs and devices — dispensing by prescription only.

1. The board shall adopt rules exempting from any labeling or packaging requirement of this chapter 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 packaged, on condition that such drugs and devices are not adulterated or misbranded upon removal from the processing, labeling, or repacking establishment.

2. Drug and device labeling or packaging exemptions adopted pursuant to the federal Act shall apply to drugs and devices in this state except insofar as modified or rejected by rules adopted by the board.

3. *a.* (1) This paragraph *"a"* applies to a drug intended for use by humans which is any of the following:

(a) Is a habit-forming drug to which section 126.10, subsection 1, paragraph *"d"* applies.

(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 the drug.

(c) Is limited by an approved application under section 505 of the federal Act to use under the professional supervision of a practitioner licensed by law to administer the drug.

(2) Such a drug shall be dispensed only upon a written, electronic, or facsimile prescription of a practitioner licensed by law to administer the drug, or upon an oral prescription of such a practitioner which is reduced promptly to writing and filed by the pharmacist, or by refilling any such written, electronic, facsimile, or oral prescription if the refilling is authorized by the prescriber either in the original written, electronic, or facsimile prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to this paragraph *"a"* while the drug is held for sale results in the drug being misbranded.

b. A drug dispensed by filling or refilling a written, electronic, facsimile, or oral prescription of a practitioner licensed by law to administer the drug is exempt from section 126.10, except section 126.10, subsection 1, paragraph *"a"*, section 126.10, subsection 1, paragraph *"i"*, subparagraphs (2) and (3), and section 126.10, subsection 1, paragraphs *"k"* and *"l"*, and the packaging requirements of section 126.10, subsection 1, paragraphs *"g"*, *"h"*, and *"p"*, if the drug bears a label containing the name and address of the dispenser, the 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 the prescription. This exemption does not apply to a drug dispensed in the course of the conduct of the business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph *"a"* of this subsection.

c. The board may, by rule, remove a drug subject to section 126.10, subsection 1, paragraph *"d"*, and section 505 of the federal Act from the requirements of paragraph *"a"* of this subsection when such requirements are not necessary for the protection of the public health.

d. A drug which is subject to paragraph *"a"* of this subsection is 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 *"a"* of this subsection does not apply is misbranded if, at any time prior to dispensing, its label bears the caution statement quoted in the preceding sentence.

e. Prescription drug samples dispensed by a practitioner licensed by law to administer such drugs are exempt from section 126.10.

f. All electronic or facsimile prescriptions transmitted under this section shall comply with section 155A.27.

89 Acts, ch 197, §11

CS89, §203B.11

C93, §126.11

2004 Acts, ch 1036, §5 – 7; 2009 Acts, ch 41, §190; 2013 Acts, ch 30, §26; 2013 Acts, ch 140, §58

[T] Subsection 3, paragraph b amended

126.12 New drugs.

1. A person shall not sell, deliver, offer for sale, hold for sale, or give away a new drug unless both of the following apply:

a. An application with respect to the new drug has been approved and the approval has not been withdrawn under section 505 of the federal Act.

b. A copy of the letter of approval or approvability issued by the United States food and drug administration is on file with the secretary of the board, if the product is manufactured in this state.

2. A person shall not use in humans a new drug limited to investigational use unless the person has filed with the United States food and drug administration a completed and signed

"Notice of Claimed Investigational Exemption for a New Drug" form in accordance with 21 C.F.R. § 312.1 and the exemption has not been terminated. The drug shall be plainly labeled in compliance with section 505(i) or 507(d) of the federal Act.

3. This section does not apply to either of the following:

a. A drug which is not a new drug as defined in the federal Act.

b. A drug which is licensed under the federal Public Health Service Act of July 1, 1944, 42 U.S.C. § 201 et seq. or under the Animal Virus-Serum-Toxin Act of March 4, 1913, 21 U.S.C. § 151 et seq.

89 Acts, ch 197, §12
CS89, §203B.12
C93, §126.12
2010 Acts, ch 1061, §24
Referred to in §126.3, 126.6

126.13 Reserved.

126.14 Cosmetics — adulteration.

A cosmetic is adulterated if any of the following apply:

1. It bears or contains a poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in its labeling or under customary or usual conditions of use. However, this does not apply to coal-tar hair dye if the label of the dye bears the following legend conspicuously displayed: "Caution — This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness"; and the label bears adequate directions for the preliminary testing. For the purposes of this subsection and subsection 5, *"hair dye"* does not include eyelash dyes or eyebrow dyes.

2. It consists in whole or in part of any filthy, putrid, or decomposed substance.

3. It has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

4. Its container is composed, in whole or in part, of a poisonous or deleterious substance which may render the contents injurious to health.

5. It is not a hair dye and it is, or it bears or contains a color additive which is "unsafe" within the meaning of section 706(a) of the federal Act.

89 Acts, ch 197, §13
CS89, §203B.14
C93, §126.14
Referred to in §126.15
[T] Section not amended; editorial change applied

126.15 Cosmetics — misbranding.

1. A cosmetic is misbranded if any of the following apply:

a. Its labeling is false or misleading in any particular.

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

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

(2) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label.

c. A 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 there 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. Its container is so made, formed, or filled as to be misleading.

e. It is a color additive, unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to that color additive prescribed under

section 706 of the federal Act. This paragraph does not apply to packages of color additives which, with respect to their use of cosmetics, are marketed and intended for use only in or on hair dyes, as specified in section 126.14, subsection 1.

f. 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.

2. The board shall adopt rules exempting from any labeling requirement of this chapter, cosmetics which are in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where they are originally processed or packed, on condition that such cosmetics are not adulterated or misbranded upon removal from the processing, labeling, or repacking establishment. Cosmetic labeling exemptions adopted under the federal Act apply to cosmetics in this state except as modified or rejected by rules adopted by the board.

89 Acts, ch 197, §14
CS89, §203B.15
C93, §126.15
2009 Acts, ch 41, §263

126.16 False advertising.

1. The advertising of a drug, device, or cosmetic is false if it is false or misleading in any particular.

2. For the purpose of this chapter, advertising is false if it represents a drug, device, or cosmetic to have any effect in the diagnosis, prevention, or treatment of arthritis, blood disorders, bone or joint diseases, kidney diseases or disorders, cancer, diabetes, gall bladder disease or disorders, heart and vascular disease, high blood pressure, diseases or disorders of the ear, mental disease or an intellectual disability, degenerative neurological diseases, paralysis, prostate gland disorders, conditions of the scalp affecting hair loss, baldness, endocrine disorders, sexual impotence, tumors, venereal diseases, varicose ulcers, breast enlargement, purifying blood, metabolic disorders, immune system disorders or conditions affecting the immune system, extension of life expectancy, stress and tension, brain stimulation or performance, the body's natural defense mechanisms, blood flow, and depression. However, advertising not in violation of subsection 1 is not false under this subsection if it is disseminated only to members of the medical, dental, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices. However, if the board determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named in this subsection, the board shall by rule authorize the advertising of drugs having curative or therapeutic effect for such disease, subject to the conditions and restrictions the board deems necessary in the interests of the public health. However, this subsection does not indicate that self-medication for diseases other than those named in this subsection is safe and efficacious.

89 Acts, ch 197, §15
CS89, §203B.16
C93, §126.16
2012 Acts, ch 1019, §6

126.17 Rules — hearings.

1. The board may adopt rules pursuant to chapter 17A for the efficient enforcement of this chapter. The board may make the rules adopted under this chapter conform, insofar as practicable, with those regulations adopted pursuant to the federal Act.

2. Hearings authorized or required by this chapter shall be conducted by the board or by an officer, agent, or employee designated by the board.

89 Acts, ch 197, §16
CS89, §203B.17
C93, §126.17

126.18 Inspections.

1. *a.* For purposes of enforcement of this chapter, the board or any of its authorized agents, upon presenting appropriate credentials to the owner, operator, or agent in charge, may do both of the following:

(1) Enter at reasonable times any factory, warehouse, or other establishment in which drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into commerce or after such introduction; or enter a vehicle being used to transport or hold drugs, devices, or cosmetics in commerce.

(2) Inspect at reasonable times and within reasonable limits and in a reasonable manner such a factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, and obtain samples necessary to the enforcement of this chapter. In the case of a factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein, including records, files, papers, processes, controls, and facilities, bearing on whether prescription drugs or restricted devices which are adulterated or misbranded or which may not be manufactured, introduced into commerce, or sold or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in violation of or bearing on a violation of this chapter. An inspection authorized for prescription drugs by the preceding sentence shall not extend to financial data, sales data other than shipment data, pricing data, personnel data other than data as to qualifications of technical and professional personnel performing functions subject to this chapter, and research data other than data relating to new drugs, and antibiotic drugs, and devices, and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or 505(j), or section 507(d) or 507(g), section 519, or section 520(g) of the federal Act, and data, relating to other drugs, or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the federal Act. The inspection shall be commenced and completed with reasonable promptness.

b. Paragraph *"a"* does not apply to any of the following:

(1) Pharmacies which maintain establishments in conformance with laws of this state regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, or devices, upon prescription of practitioners licensed to administer the drugs or devices to patients under the care of the practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

(2) Practitioners licensed by law to prescribe or administer drugs or prescribe or use devices, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice.

(3) Persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale.

(4) Duly employed sales representatives of pharmaceutical companies acting in the normal and customary performance of their duties.

(5) Other classes of persons the board exempts from the application of this section by rule upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

2. *a.* Upon completion of an inspection of a factory, warehouse, consulting laboratory, or other establishment and prior to leaving the premises, the authorized agent making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by the authorized agent which, in the judgment of the authorized agent, indicate that any drug, device, or cosmetic in the establishment meets either of the following:

(1) Consists in whole or in part of a filthy, putrid, or decomposed substance.

(2) Has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

b. A copy of the report shall be sent promptly to the board.

3. If the authorized agent making an inspection of a factory, warehouse, or other establishment has obtained a sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises the authorized agent shall give to the owner, operator, or agent in charge a receipt describing the sample obtained.

4. A person required under this chapter or section 519 or 520(g) of the federal Act to maintain records and a person who is in charge or custody of such records shall, upon request of an authorized agent designated by the board, permit the authorized agent at all reasonable times to have access and to copy and verify such records.

5. For the purposes of enforcing this chapter, carriers engaged in commerce, and persons receiving drugs, devices, or cosmetics in commerce or holding such articles so received, shall, upon the request of a duly authorized agent of the board, permit the agent, at reasonable times, to have access to and to copy all records showing the movement in commerce of a drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof. It is unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when the request is accompanied by a statement in writing specifying the nature or kind of drug, device, or cosmetic to which the request relates.

6. Evidence obtained under this section or evidence which is directly or indirectly derived from such evidence obtained under this section, shall not be used in a criminal prosecution of the person from whom the evidence was obtained; and carriers are not subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of drugs, devices, or cosmetics in the usual course of business as carriers.

89 Acts, ch 197, §17
CS89, §203B.18
C93, §126.18
2009 Acts, ch 41, §263
Referred to in §126.3

126.19 Publicity.

1. The board may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charges and their disposition.

2. The board may also cause to be disseminated information regarding drugs, devices, or cosmetics, in situations involving, in the opinion of the board, imminent danger to health, or gross deception of the consumer. This section does not prohibit the board from collecting, reporting, and illustrating the results of investigations by the board.

89 Acts, ch 197, §18
CS89, §203B.19
C93, §126.19

126.20 Chapter not applicable to commercial feed.

This chapter does not apply to the Iowa Commercial Feed Law of 1974 under chapter 198 or to administrative rules adopted pursuant to chapter 198.

89 Acts, ch 197, §19
CS89, §203B.20
C93, §126.20

126.21 Chapter not applicable to animal drugs.

This chapter does not apply to drugs intended for use for animals and not for humans.

89 Acts, ch 197, §20
CS89, §203B.21
C93, §126.21

126.22 Nitrous oxide.

1. *Unlawful possession.* Any person who possesses nitrous oxide or any substance

containing nitrous oxide, with the intent to breathe, inhale, or ingest for the purpose of causing a condition of intoxication, elation, euphoria, dizziness, stupefaction, or dulling of the senses, or who knowingly and with the intent to do so is under the influence of nitrous oxide or any material containing nitrous oxide, is guilty of a serious misdemeanor. This subsection shall not apply to a person who is under the influence of nitrous oxide or any material containing nitrous oxide for the purpose of medical, surgical, or dental care by a person duly licensed to administer such an agent.

2. *Unlawful distribution.* Any person who distributes nitrous oxide, or possesses nitrous oxide with intent to distribute to any other person, if such distribution is with the intent to induce unlawful inhaling of the substance or is with the knowledge that the other person will unlawfully inhale the substance, is guilty of a serious misdemeanor.

97 Acts, ch 39, §6

126.23 Gamma-hydroxybutyrate.

1. *Unlawful possession.* Any person who possesses gamma-hydroxybutyrate (also known as gamma-hydroxybutyric acid, or GHB), or any substance containing gamma-hydroxybutyrate, commits an aggravated misdemeanor. This subsection shall not apply to any person who obtains or possesses gamma-hydroxybutyrate or any material containing gamma-hydroxybutyrate pursuant to a lawful order of a physician or other authorized prescriber for the legitimate treatment of disease.

2. *Unlawful distribution.* Any person who distributes gamma-hydroxybutyrate, or possesses gamma-hydroxybutyrate with the intent to distribute to any other person, commits an aggravated misdemeanor if the person intends to promote or allow the unlawful use of the substance or if the person knows that the other person will use the substance for unlawful purposes.

97 Acts, ch 95, §1

126.23A Pseudoephedrine retail restrictions.

1. *a.* A retailer or an employee of a retailer shall not do any of the following:

(1) Sell more than seven thousand five hundred milligrams of pseudoephedrine to the same person within a thirty-day period.

(2) Knowingly sell more than one package of a product containing pseudoephedrine to a person in a twenty-four-hour period.

(3) Sell a package of a pseudoephedrine product that can be further broken down or subdivided into two or more separate and distinct packages or offer promotions where a pseudoephedrine product is given away for free as part of any purchase transaction.

b. A retailer or an employee of a retailer shall do the following:

(1) Provide for the sale of a pseudoephedrine product from a locked cabinet or behind a sales counter where the public is unable to reach the product and where the public is not permitted.

(2) Require a purchaser to present a government-issued photo identification card identifying the purchaser prior to purchasing a pseudoephedrine product.

(3) Require the purchaser to sign a logbook and to also require the purchaser to legibly print the purchaser's name and address in the logbook.

(4) Print the name of the pseudoephedrine product purchased and quantity sold next to the name of each purchaser in the logbook.

(5) Determine the signature in the logbook corresponds with the name on the government-issued photo identification card.

(6) Keep the logbook twenty-four months from the date of the last entry.

(7) Provide notification in a clear and conspicuous manner in a location where a pseudoephedrine product is offered for sale stating the following:

Iowa law prohibits the over-the-counter purchase of more than one package of a product containing pseudoephedrine in a twenty-four-hour period or of more than seven thousand five hundred milligrams of pseudoephedrine within a thirty-day period. If you purchase a product

containing pseudoephedrine, you are required to sign a logbook which may be accessible to law enforcement officers.

(8) Provide notification affixed to the logbook stating that a purchaser entering a false statement or misrepresentation in the logbook may subject the purchaser to criminal penalties under 18 U.S.C. § 1001.

(9) Disclose logbook information as provided by state and federal law.

(10) Comply with training requirements pursuant to federal law.

2. A purchaser shall not do any of the following:

a. Purchase more than one package of a pseudoephedrine product within a twenty-four-hour period from a retailer.

b. Purchase more than seven thousand five hundred milligrams of pseudoephedrine from a retailer, either separately or collectively, within a thirty-day period.

3. A purchaser shall sign the logbook and also legibly print the purchaser's name and address in the logbook.

4. Enforcement of this section shall be implemented uniformly throughout the state. A political subdivision of the state shall not adopt an ordinance regulating the display or sale of products containing pseudoephedrine. An ordinance adopted in violation of this section is void and unenforceable and any enforcement activity of an ordinance in violation of this section is void.

5. The logbook may be kept in an electronic format upon approval by the department of public safety.

6. A pharmacy that sells a product that contains three hundred sixty milligrams or less of pseudoephedrine on a retail basis shall comply with the provisions of this section with respect to the sale of such product. However, a pharmacy is exempted from the provisions of this section when selling a pseudoephedrine product pursuant to section 124.212.

7. A retailer or an employee of a retailer that reports to any law enforcement agency any alleged criminal activity related to the purchase or sale of pseudoephedrine or who refuses to sell a pseudoephedrine product to a person is immune from civil liability for that conduct, except in cases of willful misconduct.

8. If a retailer or an employee of a retailer violates any provision of this section, a city or county may assess a civil penalty against the retailer upon hearing and notice as provided in section 126.23B.

9. An employee of a retailer who commits a violation of subsection 1 or a purchaser who commits a violation of subsection 2 commits a simple misdemeanor punishable by a scheduled fine under section 805.8C, subsection 6.

10. As used in this section, *"retailer"* means a person or business entity engaged in this state in the business of selling products on a retail basis. An *"employee of a retailer"* means any employee, contract employee, or agent of the retailer.

2004 Acts, ch 1127, §1; 2005 Acts, ch 15, §3, 14; 2005 Acts, ch 179, §115 – 117; 2009 Acts, ch 25, §7, 8; 2010 Acts, ch 1061, §25

Referred to in §124.212, 124.213, 126.23B, 602.8105, 714.7C, 805.8C(6)

[P] Theft of pseudoephedrine, see §714.7C

126.23B Civil penalty.

1. A city or a county may enforce section 126.23A, after giving the retailer an opportunity to be heard upon ten days' written notice by restricted certified mail stating the alleged violation and the time and place at which the retailer may appear and be heard.

2. For a violation of section 126.23A by the retailer or an employee of the retailer a civil penalty shall be assessed against the retailer as follows:

a. For a first violation, the retailer shall be assessed a civil penalty in the amount of three hundred dollars.

b. For a second violation within a period of two years, the retailer shall be assessed a civil penalty in the amount of one thousand five hundred dollars.

c. For a third violation within a period of three years, the retailer shall be assessed a civil

penalty in the amount of two thousand dollars. The retailer may also be prohibited from selling pseudoephedrine for up to three years from the date of assessment of the civil penalty.

d. For a fourth or subsequent violation within a period of three years, the retailer shall be assessed a civil penalty in the amount of three thousand dollars. On a fourth or subsequent violation, the retailer shall be prohibited from selling pseudoephedrine products for three years from the date of the assessment of the civil penalty.

3. The city or county that takes legal action against a retailer under this section shall report the assessment of a civil penalty to the department of public safety within thirty days of the penalty being assessed.

4. The civil penalty shall be collected by the clerk of the district court and shall be distributed as provided in section 602.8105, subsection 4.

2005 Acts, ch 15, §4, 14
Referred to in §126.23A, 602.8105

126.24 Anthrax. Transferred to § 708B.1; 2003 Acts, ch 44, § 115.

126.25 Human immunodeficiency virus home testing kits — prohibition — penalties. Repealed by 2013 Acts, ch 81, § 4.

126.26 Notice of conviction under chapter.

If a person enters a plea of guilty, or forfeits bail or collateral deposited to secure the person's appearance in court, and the forfeiture is not vacated, or if a person is found guilty upon an indictment or information alleging a violation of this chapter, a copy of the minutes attached to the indictment returned by the grand jury, or to the county attorney's information, a copy of the judgment and sentence, and a copy of the opinion of the judge if one is filed, shall be sent by the clerk of the district court or the judge to the state department of transportation.

93 Acts, ch 16, §2
Referred to in §901.5