

FILED MAR 1 1988

SENATE FILE 2249
BY COMMITTEE ON HUMAN RESOURCES
Approved (S 528)

(Formerly SSB 2175)

Passed Senate, Date 3/1/88 (p. 154) Passed House, Date _____
Vote: Ayes 32 Nays 8 Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

- 1 An Act relating to the labeling, advertising, adulteration,
- 2 misbranding, and dispensing of drugs, devices, and cosmetics,
- 3 providing penalties, and providing properly related matters.
- 4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

SENATE FILE 2249

S-5280

- 1 Amend Senate File 2249 as follows:
- 2 1. Page 8, by striking lines 26 through 35 and
- 3 inserting the following:
- 4 "3. Section 203B.3, subsection 5, does not apply
- 5 to the newspaper, magazine, publication, or other
- 6 print media in which the advertising appears, or to
- 7 the radio station, television station, or other
- 8 electronic media which disseminates the advertising."

S-5280

Filed March 9, 1988
2-11 (p. 154)

BY LARRY MURPHY

18
19
20
21
22
23
24
25

1 Section 1. NEW SECTION. 203B.1 TITLE.

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

4 Sec. 2. NEW SECTION. 203B.2 DEFINITIONS --
5 APPLICABILITY.

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

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

12 2. "Board" means the board of pharmacy examiners.

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

16 4. "Cosmetic" means any of the following, but does not
17 include soap:

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

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

24 5. "Counterfeit drug" means a drug which, or the container
25 or labeling of which, without authorization, bears the
26 trademark, trade name, or other identifying mark, imprint, or
27 device, or any such likeness, of a drug manufacturer,
28 processor, packer, or distributor other than the person or
29 persons who in fact manufactured, processed, packed, or
30 distributed the drug and which falsely purports or is
31 represented to be the product of, or to have been packed or
32 distributed by, such other drug manufacturer, processor,
33 packer, or distributor.

34 6. "Device" means an instrument, apparatus, implement,
35 machine, contrivance, implant, in vitro reagent, or other

1 similar or related article, including any component, part, or
2 accessory of any of these, which is any of the following:

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

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

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

15 7. "Drug" means any of the following, but does not include
16 a device:

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

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

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

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

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

31 9. "Immediate container" does not include a package liner.

32 10. "Label" means a display of written, printed, or
33 graphic matter upon the immediate container of an article; and
34 a requirement made by or under authority of this chapter that
35 any word, statement, or other information appear on the label

1 is not complied with unless the word, statement, or other
2 information also appears on the outside container or wrapper
3 of the retail package of the article, or is easily legible
4 through the outside container or wrapper.

5 11. "Labeling" means all labels and other written,
6 printed, or graphic matter upon an article or any of its
7 containers or wrappers, or accompanying an article.

8 12. "New animal drug" means any drug intended for use for
9 animals and not for humans, including any drug intended for
10 use in animal feed.

11 13. "New drug" means either of the following:

12 a. Any drug, except a new animal drug, the composition of
13 which is such that the drug is not generally recognized among
14 experts qualified by scientific training and experience to
15 evaluate the safety and effectiveness of drugs, as safe and
16 effective for use under the conditions prescribed,
17 recommended, or suggested in its labeling, except that a drug
18 not so recognized is not a new drug if at any time prior to
19 the enactment of this chapter it was subject to the federal
20 Act, and if at that time its labeling contained the same
21 representations concerning the conditions of its use.

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

30 14. "Official compendium" means the official United States
31 Pharmacopoeia National Formulary, official Homeopathic
32 Pharmacopoeia of the United States, or any supplement to
33 either document.

34 15. "Person" means an individual, partnership,
35 corporation, or association.

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

5 17. "Safe" as used in this chapter has reference to the
6 health of a human or animal.

7 18. "Secretary" means the secretary of the United States
8 department of health and human services.

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

16 Sec. 3. NEW SECTION. 203B.3 PROHIBITED ACTS.

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

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

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

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

27 4. The introduction or delivery for introduction into
28 commerce of a drug, device, or cosmetic in violation of
29 section 203B.12 or 203B.13.

30 5. The dissemination of any false advertising.

31 6. The refusal to permit entry or inspection, or to permit
32 the taking of a sample or to permit access to or copying of
33 any record as authorized by section 203B.18; or the failure to
34 establish or maintain any record or make any report required
35 under section 512(j), 512(l), or 512(m) of the federal Act, or

1 the refusal to permit access to or verification or copying of
2 any such required record.

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

5 8. The giving of a guaranty or undertaking referred to in
6 section 203B.5, subsection 2, if the guaranty or undertaking
7 is false, except by a person who relied upon a guaranty or
8 undertaking to the same effect, signed by, and containing the
9 name and address of, the person residing in this state from
10 whom the person received the drug, device, or cosmetic in good
11 faith.

12 9. The removal or disposal of a detained or embargoed
13 drug, device, or cosmetic in violation of section 203B.6,
14 subsection 1.

15 10. The alteration, mutilation, destruction,
16 obliteration, or removal of the whole or any part of the
17 labeling of, or the doing of any other act with respect to a
18 drug, device, or cosmetic, if the act is done while the
19 article is held for sale, whether or not it would be the first
20 sale, after shipment in commerce; and if the action results in
21 the article being adulterated or misbranded.

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

27 12. Making, selling, disposing of, or keeping in
28 possession, control, or custody, or concealing a punch, die,
29 plate, stone, or other thing designed to print, imprint, or
30 reproduce the trademark, trade name, or other identifying
31 mark, imprint, or device of another trademark, trade name,
32 mark, imprint, or device or a likeness of any trademark, trade
33 name, mark, imprint, or device upon a drug or drug container
34 or the labeling thereof so as to render the drug a counterfeit
35 drug.

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

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

10 15. The use, on the labeling of a drug or device or in
11 advertising relating to a drug or device, of a representation
12 or suggestion that approval of an application with respect to
13 the drug or device is in effect under section 203B.12 or
14 sections 505, 515, or 520(g) of the federal Act, or that the
15 drug or device complies with the provisions of any of those
16 sections.

17 16. The use, in labeling, advertising, or other sales
18 promotion of a reference to a report or analysis furnished in
19 compliance with section 203B.18 or section 704 of the federal
20 Act.

21 17. If a prescription drug is distributed or offered for
22 sale in this state, the failure of the manufacturer, packer,
23 or distributor of the prescription drug to maintain for
24 transmittal, or to transmit, to any practitioner licensed by
25 applicable law to administer the drug who makes written
26 request for information as to the drug, true and correct
27 copies of all printed matter which is required to be included
28 in any package in which that drug is distributed or sold, or
29 such other printed matter as is approved under the federal
30 Act. This subsection does not exempt any person from a
31 labeling requirement imposed by or under this chapter.

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

1 likeness of such a trademark, trade name, mark, or imprint.

2 b. Selling, dispensing, disposing of; causing to be sold,
3 dispensed, or disposed of; or concealing or keeping in
4 possession, control, or custody, with intent to sell,
5 dispense, or dispose of, a drug, device, or container thereof,
6 with knowledge that the trademark, trade name, or other
7 identifying mark or imprint of another trademark, trade name,
8 mark, or imprint or any likeness of any trademark, trade name,
9 mark, or imprint has been placed thereon in a manner
10 prohibited by paragraph "a".

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

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

25 20. a. The failure or refusal to:

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

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

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

34 21. The movement of a device in violation of an order
35 under section 304(g) of the federal Act or the removal or

1 alteration of any mark or label required by the order to
2 identify the device as detained.

3 22. The failure to provide the notice required by section
4 412(b) or 412(c) of the federal Act, the failure to make the
5 reports required by section 412(d)(1)(B) of the federal Act,
6 or the failure to meet the requirements prescribed under
7 section 412(d)(2) of the federal Act.

8 Sec. 4. NEW SECTION. 203B.4 INJUNCTION PROCEEDINGS.

9 The board may apply to the district court for, and the
10 court has jurisdiction upon hearing and for cause shown to
11 grant, a temporary or permanent injunction restraining any
12 person from violating any provision of section 203B.3 whether
13 or not there exists an adequate remedy at law.

14 Sec. 5. NEW SECTION. 203B.5 PENALTIES AND GUARANTY.

15 1. A person who violates a provision of this chapter is
16 guilty of a serious misdemeanor; but if the violation is
17 committed after a conviction of the person under this section
18 has become final, the person is guilty of an aggravated
19 misdemeanor.

20 2. A person is not subject to the penalties of subsection
21 1 if the person establishes a guaranty or undertaking signed
22 by, and containing the name and address of another person
23 residing in this state from whom the person received the
24 article in good faith, to the effect that the article is not
25 adulterated or misbranded.

26 3. A publisher, radio-broadcast licensee, or agency or
27 medium which disseminates false advertising, except the
28 manufacturer, packer, distributor, or seller of the article to
29 which false advertising relates, is not liable under this
30 section for the dissemination of the false advertising, unless
31 the person has refused, on the request of the board, to
32 furnish the board the name and post office address of the
33 manufacturer, packer, distributor, seller, or advertising
34 agency, residing in this state which caused the person to
35 disseminate the advertisement.

1 Sec. 6. NEW SECTION. 203B.6 EMBARGO.

2 1. If a duly authorized agent of the board finds, or has
3 probable cause to believe, that a drug, device, or cosmetic is
4 adulterated or so misbranded as to be dangerous or fraudulent,
5 within the meaning of this chapter, or is in violation of
6 section 203B.12 or 203B.13, the agent shall affix to the
7 article a tag or other appropriate marking, giving notice that
8 the article is, or is suspected of being, adulterated or
9 misbranded and has been detained or embargoed, and warning all
10 persons not to remove or dispose of the article by sale or
11 otherwise until permission for removal or disposal is given by
12 an authorized agent or the court. It is unlawful for a person
13 to remove or dispose of the detained or embargoed article by
14 sale or otherwise without such permission.

15 2. When an article is adulterated or misbranded or is in
16 violation of section 203B.12 or 203B.13 and has been detained
17 or embargoed, a petition may be filed with the district court
18 in whose jurisdiction the article is located, detained, or
19 embargoed for an order for condemnation of the article. If a
20 duly authorized agent has found that an article which is
21 embargoed or detained is not adulterated or misbranded, the
22 agent shall remove the tag or other marking.

23 3. If the court finds that a sampled, detained, or
24 embargoed article is adulterated or misbranded, the article
25 shall be destroyed at the expense of the claimant of the
26 article, under the supervision of the agent, and all court
27 costs and fees, and storage and other proper expenses, shall
28 be taxed against the claimant of the article or the claimant's
29 agent; but if the adulteration or misbranding can be corrected
30 by proper labeling or processing of the article, the court,
31 after entry of the decree and after costs, fees, storage, and
32 other expenses have been paid and a good and sufficient bond,
33 conditioned that the article shall be so labeled or processed,
34 has been executed, may by order direct that the article be
35 delivered to the claimant for such labeling or processing

1 under the supervision of a duly authorized agent of the board.
2 The expense of supervision shall be paid by the claimant. The
3 article shall be returned to the claimant and the bond shall
4 be discharged on the representation to the court by the board
5 that the article is no longer in violation of this chapter,
6 and that the expenses of supervision have been paid.

7 Sec. 7. NEW SECTION. 203B.7 PROSECUTIONS.

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

21 Sec. 8. NEW SECTION. 203B.8 MINOR VIOLATIONS.

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

27 Sec. 9. NEW SECTION. 203B.9 DRUGS AND DEVICES --
28 ADULTERATION.

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

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

33 b. If it has been produced, prepared, packed, or held
34 under insanitary conditions whereby it may have been
35 contaminated with filth, or whereby it may have been rendered

1 injurious to health.

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

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

13 2. If it purports to be or is represented as a drug, the
14 name of which is recognized in an official compendium, and its
15 strength differs from, or its quality or purity falls below,
16 the standards set forth in the official compendium. A
17 determination as to strength, quality, or purity shall be made
18 in accordance with the tests or methods of assay set forth in
19 the official compendium, or in the absence of or inadequacy of
20 such tests or methods of assay, those prescribed under
21 authority of the federal Act. A drug defined in an official
22 compendium is not adulterated under this subsection because it
23 differs from the standard of strength, quality, or purity set
24 forth in the official compendium, if its difference in
25 strength, quality, or purity from such standards is plainly
26 stated on its label. If a drug is recognized in both the
27 United States Pharmacopoeia National Formulary and the
28 Homeopathic Pharmacopoeia of the United States it is subject
29 to the United States Pharmacopoeia National Formulary unless
30 it is labeled and offered for sale as a homeopathic drug, in
31 which case it is subject to the Homeopathic Pharmacopoeia of
32 the United States and not to the United States Pharmacopoeia
33 National Formulary.

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

1 it purports or is represented to possess.

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

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

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

11 7. If it is a device and the methods used in, or the
12 facilities or controls used for its manufacture, packing,
13 storage, or installation are not in conformity with applicable
14 requirements under section 520(f)(1) of the federal Act or an
15 applicable condition as prescribed by an order under section
16 520(f)(2) of the federal Act.

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

23 Sec. 10. NEW SECTION. 203B.10 DRUGS AND DEVICES --
24 MISBRANDING -- LABELING.

25 A drug or device is misbranded under any of the following
26 circumstances:

27 1. If its labeling is false or misleading in any
28 particular.

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

31 a. The name and place of business of the manufacturer,
32 packer, or distributor.

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

35 However, under paragraph "a" reasonable variations shall be

1 permitted, and exemptions as to small packages shall be
2 allowed, in accordance with rules adopted by the board.

3 3. If any word, statement, or other information required
4 by or under the authority of this chapter to appear on the
5 label or labeling is not prominently placed thereon with such
6 conspicuousness, as compared with other words, statements,
7 designs, or devices, in the labeling, and in such terms as to
8 render it likely to be read and understood by the ordinary
9 individual under customary conditions of purchase and use.

10 4. If it is for use by humans and contains any quantity of
11 the narcotic or hypnotic substance alpha-eucaine, barbituric
12 acid, beta-eucaine, bromal, cannabis, carbromal, chloral,
13 coca, cocaine, codeine, heroin, marijuana, morphine, opium,
14 paraldehyde, peyote, or sulphonmethane; or any chemical
15 derivative of such a substance, which derivative, after
16 investigation, has been designated as habit forming, by rules
17 adopted by the board under this chapter or by regulations
18 adopted by the secretary pursuant to section 502(d) of the
19 federal Act; unless its label bears the name and quantity or
20 proportion of such substance or derivative and in
21 juxtaposition therewith the statement "Warning -- May Be Habit
22 Forming."

23 5. a. If it is a drug, unless both of the following
24 apply:

25 (1) Its label bears, to the exclusion of any other
26 nonproprietary name except the applicable systematic chemical
27 name or the chemical formula:

28 (a) The established name of the drug, as specified in
29 paragraph "c", if such exists; and

30 (b) If the drug is fabricated from two or more
31 ingredients, the established name and quantity of each active
32 ingredient, including the quantity, kind, and proportion of
33 any alcohol, and also including, whether active or not, the
34 established name and quantity or proportion of any bromides,
35 ether, chloroform, acetanilide, acetophenetidin, amidopyrine,

1 antipyrine, atropine, hyoscine, hyoscyamine, arsenic,
2 digitalis, digitalis glucosides, mercury, ouabain,
3 strophanthin, strychnine, thyroid, or any derivative or
4 preparation of any such substances, contained therein.
5 However, the requirement for stating the quantity of the
6 active ingredients, other than the quantity of those
7 specifically named in this subparagraph subdivision, applies
8 only to prescription drugs.

9 (2) For a prescription drug, the established name of the
10 prescription drug or of an ingredient is printed, on the label
11 and on any labeling on which a name for the prescription drug
12 or an ingredient is used, prominently and in type at least
13 half as large as that used thereon for any proprietary name or
14 designation for the prescription drug or ingredient. However,
15 to the extent that compliance with subparagraph (1),
16 subparagraph subdivision (b) or this subparagraph is
17 impracticable, exemptions shall be allowed under rules or
18 regulations adopted by the board or the secretary under the
19 federal Act.

20 b. If it is a device and it has an established name,
21 unless its label bears, to the exclusion of any other
22 nonproprietary name, its established name, as defined in
23 paragraph "d", prominently printed in type at least half as
24 large as that used thereon for any proprietary name or
25 designation for the device, except that to the extent
26 compliance with this paragraph is impracticable, exemptions
27 shall be allowed under rules or regulations adopted by the
28 board or the secretary under the federal Act.

29 c. As used in paragraph "a", the term "established name",
30 with respect to a drug or ingredient thereof, means one of the
31 following:

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

34 (2) If no such official name exists and the drug or
35 ingredient is an article recognized in an official compendium,

1 then its official title in the compendium.

2 (3) If neither subparagraph (1) nor (2) applies, then the
3 common or usual name, if any, of the drug or ingredient.
4 However, if subparagraph (2) applies to an article recognized
5 in the United States Pharmacopoeia National Formulary and in
6 the Homeopathic Pharmacopoeia of the United States under
7 different official titles, the official title used in the
8 United States Pharmacopoeia National Formulary applies unless
9 it is labeled and offered for sale as a homeopathic drug, in
10 which case the official title used in the Homeopathic
11 Pharmacopoeia of the United States applies.

12 d. As used in paragraph "b", the term "established name"
13 with respect to a device means one of the following:

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

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

19 (3) If neither subparagraph (1) nor (2) applies, then any
20 common or usual name of the device.

21 6. Unless its labeling bears both of the following:

22 a. Adequate directions for use.

23 b. Adequate warnings against use in those pathological
24 conditions, or by children, where its use may be dangerous to
25 health, or against unsafe dosage or methods or durations of
26 administration or application, in the manner and form
27 necessary for the protection of users.

28 However, if a requirement of paragraph "a", as applied to a
29 drug or device, is not necessary for the protection of the
30 public health, the board or the secretary shall adopt rules or
31 regulations exempting the drug or device from that
32 requirement.

33 7. If it purports to be a drug the name of which is
34 recognized in an official compendium, unless it is packaged
35 and labeled as prescribed in the official compendium.

1 However, the method of packing may be modified with the
2 consent of the board or the secretary. If a drug is
3 recognized in both the United States Pharmacopoeia National
4 Formulary and the Homeopathic Pharmacopoeia of the United
5 States, it is subject to the requirements of the United States
6 Pharmacopoeia National Formulary with respect to packaging and
7 labeling unless it is labeled and offered for sale as a
8 homeopathic drug, in which case it is subject to the
9 Homeopathic Pharmacopoeia of the United States, and not to the
10 United States Pharmacopoeia National Formulary. However, if
11 an inconsistency exists between this subsection and subsection
12 5 as to the name by which the drug or its ingredients shall be
13 designated, subsection 5 prevails.

14 8. If it has been found by the board or the secretary to
15 be a drug liable to deterioration, unless it is packaged in
16 the form and manner, and its label bears a statement of the
17 precautions that the board or the secretary by rule or
18 regulation requires as necessary for the protection of public
19 health. Such a rule or regulation shall not be established
20 for a drug recognized in an official compendium until the
21 board or the secretary has informed the appropriate body
22 charged with the revision of the official compendium of the
23 need for such packaging or labeling requirements and that body
24 has failed within a reasonable time to prescribe such
25 requirements.

26 9. a. If it is a drug and its container is so made,
27 formed, or filled as to be misleading.

28 b. If it is an imitation of another drug.

29 c. If it is offered for sale under the name of another
30 drug.

31 10. If it is dangerous to health when used in the dosage
32 or manner, or with the frequency or duration prescribed,
33 recommended, or suggested in its labeling.

34 11. If it is, or purports to be, or is represented as a
35 drug composed wholly or partly of insulin, unless both of the

1 following apply:

2 a. It is from a batch with respect to which a certificate
3 or release has been issued pursuant to section 506 of the
4 federal Act.

5 b. The certificate or release is in effect with respect to
6 the drug.

7 12. If it is, or purports to be, or is represented as a
8 drug, except a drug for use in animals and not in humans,
9 composed wholly or partly of any kind of penicillin,
10 streptomycin, chlortetracycline, chloramphenicol, bacitracin,
11 or any other antibiotic drug, or any derivative thereof,
12 unless both of the following apply:

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

16 b. The certificate or release is in effect with respect to
17 the drug.

18 However, this subsection does not apply to any drug or
19 class of drugs exempted by regulations adopted under section
20 507(c) or 507(d) of the federal Act.

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

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

32 a. The established name as defined in subsection 5,
33 printed prominently and in type at least half as large as that
34 used for any trade or brand name thereof.

35 b. The formula showing quantitatively each ingredient of

1 the prescription drug to the extent required for labels under
2 subsection 5.

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

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

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

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

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

28 a. Its advertising is false or misleading in any
29 particular.

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

33 19. In the case of a restricted device distributed or
34 offered for sale in this state, unless the manufacturer,
35 packer, or distributor includes in all advertising and other

1 descriptive printed matter issued by the manufacturer, packer,
2 or distributor with respect to the device both of the
3 following:

4 a. A true statement of the device's established name as
5 defined in subsection 5, printed prominently and in type at
6 least half as large as that used for any trade or brand name
7 thereof.

8 b. A brief statement of the intended uses of the device
9 and relevant warnings, precautions, side effects, and
10 contraindications; and in the case of a specific device made
11 subject to regulations adopted pursuant to the federal Act, a
12 full description of the components of the device or the
13 formula showing quantitatively each ingredient of the device
14 to the extent required in regulations under the federal Act.

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

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

23 If an article is alleged to be misbranded because the
24 labeling or advertising is misleading, then in determining
25 whether the labeling or advertising is misleading, there shall
26 be taken into account, among other things, not only
27 representations made or suggested by statement, word, design,
28 device, or any combination thereof, but also the extent to
29 which the labeling or advertising fails to reveal facts
30 material in the light of such representations, or material
31 with respect to consequences which may result from the use of
32 the article to which the labeling or advertising relates,
33 under the conditions of use prescribed in the labeling or
34 advertising or under customary or usual conditions of use.

35 The representation of a drug, in its labeling, as an

1 which is reduced promptly to writing and filed by the
2 pharmacist, or by refilling any such written or oral
3 prescription if the refilling is authorized by the prescriber
4 either in the original prescription or by oral order which is
5 reduced promptly to writing and filed by the pharmacist. The
6 act of dispensing a drug contrary to this paragraph while the
7 drug is held for sale results in the drug being misbranded.

8 b. A drug dispensed by filling or refilling a written or
9 oral prescription of a practitioner licensed by law to
10 administer the drug is exempt from section 203B.10, except
11 subsection 1, subsection 9, paragraphs "b" and "c", and
12 subsections 11 and 12, and the packaging requirements of
13 subsections 7, 8, and 16, if the drug bears a label containing
14 the name and address of the dispenser, the serial number and
15 date of the prescription or of its filling, the name of the
16 prescriber, and, if stated in the prescription, the name of
17 the patient, and the directions for use and cautionary
18 statements, if any, contained in the prescription. This
19 exemption does not apply to a drug dispensed in the course of
20 the conduct of the business of dispensing drugs pursuant to
21 diagnosis by mail, or to a drug dispensed in violation of
22 paragraph "a" of this subsection.

23 c. The board may, by rule, remove a drug subject to
24 section 203B.10, subsection 4, and section 505 of the federal
25 Act from the requirements of paragraph "a" of this subsection
26 when such requirements are not necessary for the protection of
27 the public health.

28 d. A drug which is subject to paragraph "a" of this
29 subsection is misbranded if, at any time prior to dispensing,
30 its label fails to bear the statement: "Caution: Federal Law
31 Prohibits Dispensing Without Prescription", or "Caution:
32 State Law Prohibits Dispensing Without Prescription". A drug
33 to which paragraph "a" of this subsection does not apply is
34 misbranded if, at any time prior to dispensing, its label
35 bears the caution statement quoted in the preceding sentence.

1 Sec. 12. NEW SECTION. 203B.12 NEW DRUGS.

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

5 a. An application with respect to the new drug has been
6 approved and the approval has not been withdrawn under section
7 505 of the federal Act.

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

12 2. A person shall not use in human beings or animals a new
13 drug or new animal drug limited to investigational use unless
14 the person has filed with the United States food and drug
15 administration a completed and signed "Notice of Claimed
16 Investigational Exemption for a New Drug" form in accordance
17 with 21 C.F.R. § 312.1 and the exemption has not been
18 terminated. The drug shall be plainly labeled in compliance
19 with section 505(i) or 507(d) of the federal Act.

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

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

23 b. A drug which is licensed under the federal Public
24 Health Service Act of July 1, 1944, 42 U.S.C. § 201 et seq. or
25 under the Animal Virus, Serum, Toxin, Antitoxin Act of March
26 4, 1913, 21 U.S.C. § 151 et seq.

27 Sec. 13. NEW SECTION. 203B.13 NEW ANIMAL DRUGS.

28 A new animal drug, with respect to any particular use or
29 intended use of the drug, is unsafe for the purposes of this
30 chapter unless both of the following apply:

31 1. There is in effect an approval of an application filed
32 pursuant to section 512(b) of the federal Act with respect to
33 the use or intended use of the drug.

34 2. The drug, its labeling, and its use or intended use
35 conform to the approved application.

1 Sec. 14. NEW SECTION. 203B.14 COSMETICS -- ADULTERATION.

2 A cosmetic is adulterated if any of the following apply:

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

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

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

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

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

29 Sec. 15. NEW SECTION. 203B.15 COSMETICS -- MISBRANDING.

30 A cosmetic is misbranded if any of the following apply:

31 1. Its labeling is false or misleading in any particular.

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

34 a. The name and place of business of the manufacturer,
35 packer, or distributor.

1 Sec. 14. NEW SECTION. 203B.14 COSMETICS -- ADULTERATION.

2 A cosmetic is adulterated if any of the following apply:

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

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

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

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

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

29 Sec. ~~14~~ 5. NEW SECTION. 203B.15 COSMETICS -- MISBRANDING.

30 A cosmetic is misbranded if any of the following apply:
 labeling is false or misleading in any particular.
 in package form unless it bears a label containing
 the following:
 name and place of business of the manufacturer,
 distributor.

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

6 3. A word, statement, or other information required by or
7 under the authority of this chapter to appear on the label or
8 labeling is not prominently placed there with such
9 conspicuousness, as compared with other words, statements,
10 designs, or devices in the labeling, and in such terms as to
11 render it likely to be read and understood by the ordinary
12 individual under customary conditions of purchase and use.

13 4. Its container is so made, formed, or filled as to be
14 misleading.

15 5. It is a color additive, unless its packaging and
16 labeling are in conformity with the packaging and labeling
17 requirements applicable to that color additive prescribed
18 under section 706 of the federal Act. This subsection does
19 not apply to packages of color additives which, with respect
20 to their use of cosmetics, are marketed and intended for use
21 only in or on hair dyes, as specified in section 203B.14,
22 subsection 1.

23 6. Its packaging or labeling is in violation of an
24 applicable regulation adopted pursuant to section 3 or 4 of
25 the federal Poison Prevention Packaging Act of 1970, 15 U.S.C.
26 § 1471 et seq.

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

1 as modified or rejected by rules adopted by the board.

2 Sec. 16. NEW SECTION. 203B.16 FALSE ADVERTISING.

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

5 2. For the purpose of this chapter, advertising is false
6 if it represents a drug or device to have any effect on any of
7 the following conditions, disorders, diseases, or processes:
8 blood disorders, bone or joint diseases, kidney diseases or
9 disorders, cancer, diabetes, gall bladder disease or
10 disorders, heart and vascular disease, high blood pressure,
11 diseases or disorders of the ear, mental disease or mental
12 retardation, paralysis, prostate gland disorders, conditions
13 of the scalp affecting hair loss, baldness, endocrine
14 disorders, sexual impotence, tumors, venereal diseases,
15 varicose ulcers, breast enlargement, purifying blood,
16 metabolic disorders, immune system disorders or conditions
17 affecting the immune system, extension of life expectancy,
18 stress and tension, brain stimulation or performance, the
19 body's natural defense mechanisms, blood flow, and depression.
20 However, advertising not in violation of subsection 1 is not
21 false under this subsection if it is disseminated only to
22 members of the medical, dental, or veterinary professions, or
23 appears only in the scientific periodicals of these
24 professions, or is disseminated only for the purpose of public
25 health education by persons not commercially interested,
26 directly or indirectly, in the sale of such drugs or devices.
27 However, if the board determines that an advance in medical
28 science has made any type of self-medication safe as to any of
29 the diseases named in this subsection, the board shall by rule
30 authorize the advertising of drugs having curative or
31 therapeutic effect for such disease, subject to the conditions
32 and restrictions the board deems necessary in the interests of
33 the public health. However, this subsection does not indicate
34 that self-medication for diseases other than those named in
35 this subsection is safe and efficacious.

1 Sec. 17. NEW SECTION. 203B.17 RULES -- HEARINGS.

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

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

10 Sec. 18. NEW SECTION. 203B.18 INSPECTIONS.

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

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

21 (2) Inspect at reasonable times and within reasonable
22 limits and in a reasonable manner such a factory, warehouse,
23 establishment, or vehicle and all pertinent equipment,
24 finished and unfinished materials, containers, and labeling
25 therein, and obtain samples necessary to the enforcement of
26 this chapter. In the case of a factory, warehouse,
27 establishment, or consulting laboratory in which prescription
28 drugs are manufactured, processed, packed, or held, the
29 inspection shall extend to all things therein, including
30 records, files, papers, processes, controls, and facilities,
31 bearing on whether prescription drugs or restricted devices
32 which are adulterated or misbranded or which may not be
33 manufactured, introduced into commerce, or sold or offered for
34 sale by reason of any provision of this chapter, have been or
35 are being manufactured, processed, packed, transported, or

1 held in violation of or bearing on a violation of this
2 chapter. An inspection authorized for prescription drugs by
3 the preceding sentence shall not extend to financial data,
4 sales data other than shipment data, pricing data, personnel
5 data other than data as to qualifications of technical and
6 professional personnel performing functions subject to this
7 chapter, and research data other than data relating to new
8 drugs, and antibiotic drugs, and devices, and subject to
9 reporting and inspection under regulations lawfully issued
10 pursuant to section 505(i) or 505(j), or section 507(d) or
11 507(g), section 519, or section 520(g) of the federal Act, and
12 data, relating to other drugs, or devices which in the case of
13 a new drug would be subject to reporting or inspection under
14 lawful regulations issued pursuant to section 505(j) of the
15 federal Act. The inspection shall be commenced and completed
16 with reasonable promptness.

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

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

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

34 (3) Persons who manufacture, prepare, propagate, compound,
35 or process drugs, or manufacture or process devices solely for

1 use in research, teaching, or chemical analysis and not for
2 sale.

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

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

17 a. Consists in whole or in part of a filthy, putrid, or
18 decomposed substance.

19 b. Has been prepared, packed, or held under insanitary
20 conditions whereby it may have become contaminated with filth,
21 or whereby it may have been rendered injurious to health.

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

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

29 4. A person required under this chapter or section 519 or
30 520(g) of the federal Act to maintain records and a person who
31 is in charge or custody of such records shall, upon request of
32 an authorized agent designated by the board, permit the
33 authorized agent at all reasonable times to have access and to
34 copy and verify such records.

35 5. For the purposes of enforcing this chapter, carriers

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

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

21 Sec. 19. NEW SECTION. 203B.19 PUBLICITY.

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

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

32 Sec. 20. Section 125.2, subsection 3, Code 1987, is
33 amended to read as follows:

34 3. "Chemical substance" means alcohol, wine, spirits, and
35 beer as defined in chapter 123 and drugs as defined in section

1 ~~203A-2~~ 203B.2, subsection 3 7, which when used improperly
2 could result in chemical dependency.

3 Sec. 21. Section 147.99, Code 1987, is amended to read as
4 follows:

5 147.99 DUTIES OF SECRETARY.

6 The secretary of the board of pharmacy examiners shall,
7 upon the direction of ~~said-examiners~~ the board, make
8 inspections of alleged violations of the provisions of this
9 title relative to the practice of pharmacy and of chapters ~~203~~
10 203B, 204, and 205. ~~Said~~ The secretary shall be allowed
11 necessary traveling and hotel expenses in making such
12 inspections.

13 Sec. 22. Section 155A.12, subsection 9, Code Supplement
14 1987, is amended to read as follows:

15 9. Been convicted of an offense or subjected to a penalty
16 or fine for violation of chapter 147, ~~203-~~~~203A~~ 203B, 204, or
17 the Federal Food, Drug and Cosmetic Act. A plea or verdict of
18 guilty, or a conviction following a plea of nolo contendere,
19 is deemed to be a conviction within the meaning of this
20 section.

21 Sec. 23. Section 159.6, subsection 9, Code 1987, is
22 amended to read as follows:

23 9. Regulation and inspection of foods, drugs, and other
24 articles, Title X, but chapters ~~203~~ 203B, 204 and 205 of said
25 title shall be enforced as therein provided.

26 Sec. 24. Section 189.2, subsection 1, Code 1987, is
27 amended to read as follows:

28 1. Execute and enforce this title, except chapters ~~203-~~
29 ~~203A~~ 203B, 204, 204A and 205.

30 Sec. 25. Section 205.11, Code 1987, is amended to read as
31 follows:

32 205.11 ENFORCEMENT.

33 The provisions of this chapter and chapters ~~203~~ 203B and
34 204 shall be administered and enforced by the board of
35 pharmacy examiners. In discharging any duty or exercising any

1 power under said those chapters, the board of pharmacy
2 examiners shall be governed by all the provisions of chapter
3 189, which govern the department of agriculture and land
4 stewardship when discharging a similar duty or exercising a
5 similar power with reference to any of the articles dealt with
6 in this title, to the extent that chapter 189 is not
7 inconsistent with this chapter and chapters 203B and 204.

8 Sec. 26. Section 205.12, Code 1987, is amended to read as
9 follows:

10 205.12 CHEMICAL ANALYSIS OF DRUGS.

11 Any chemical analysis deemed necessary by the board of
12 pharmacy examiners in the enforcement of this chapter and
13 chapters ~~203~~ 203B and 204 shall be made by the department of
14 agriculture and land stewardship when requested by said the
15 board of pharmacy examiners.

16 Sec. 27. Section 205.13, Code 1987, is amended to read as
17 follows:

18 205.13 APPLICABILITY OF OTHER STATUTES.

19 Insofar as applicable the provisions of chapter 189, shall
20 apply to the articles dealt with in this chapter and chapters
21 ~~203~~ 203B and 204. The powers vested in the department of
22 agriculture and land stewardship by said chapter 189 shall be
23 deemed for the purpose of this chapter and chapters ~~203~~ 203B
24 and 204 to be vested in the board of pharmacy examiners.

25 Sec. 28. Section 331.756, subsection 40, Code Supplement
26 1987, is amended to read as follows:

27 40. Prosecute violations of the Iowa drug, device, and
28 cosmetic Act as requested by the board of pharmacy examiners
29 as provided in section ~~203A.7~~ 203B.7.

30 Sec. 29.

31 1. Chapter 203, Code 1987, is repealed.

32 2. Chapter 203A, Code 1987 and Code Supplement 1987, is
33 repealed.

34

EXPLANATION

35 This bill relates to the regulation of labeling,

1 advertising, adulteration, misbranding, and dispensing of
2 drugs, devices, and cosmetics by the board of pharmacy
3 examiners.

4 The bill repeals chapters 203, adulteration and labeling of
5 drugs, and 203A, the Iowa drug and cosmetic Act. It creates a
6 new chapter 203B, the Iowa drug, device, and cosmetic Act.

7 The definitions in the new chapter are similar to those in
8 section 203A.2 with a few changes, additions, and deletions.

9 The list of prohibited acts is based on section 203A.3 with
10 a few revisions and several additions.

11 Provisions for injunctions and penalties are based on
12 sections 203A.4 and 203A.5. Sections relating to embargoes,
13 prosecutions, and minor violations are based on sections
14 203A.6, 203A.7, and 203A.8 respectively.

15 The section on adulteration of drugs is based on sections
16 203A.9 and 203.2 with several additions. The section on
17 misbranding of drugs is based on sections 203A.10, 203A.19(1),
18 203A.2(10) and (12), and 203.3 with a number of changes and
19 additions.

20 With respect to the provision on exemptions and dispensing
21 by prescription only, much of the material is new, but current
22 provisions in sections 203.5 and 203A.20 are relevant.

23 Provisions relating to new drugs are based in part on
24 section 203A.11 with several changes. Requirements for
25 approval at the state level are deleted. The section on new
26 animal drugs is new.

27 Sections on adulteration and misbranding of cosmetics are
28 based on sections 203A.12 and 203A.13 with changes and
29 additions.

30 The section on false advertising is similar to section
31 203A.14; section 203.4 is also relevant.

32 The section relating to rules and hearings of the board of
33 pharmacy examiners is based on section 203A.15. The Iowa
34 Administrative Procedure Act (chapter 17A) applies to
35 rulemaking and other procedures of the board of pharmacy

1 examiners.

2 Inspection provisions are revised and expanded from those
3 in section 203A.16.

4 The section on publicity is based on section 203A.17 with
5 revisions.

6 Several amendatory sections are included to make necessary
7 conforming amendments.

8 Among the provisions appearing in the current law but not
9 included in new chapter 203B are requirements for licensing
10 itinerant vendors of drugs (sections 203.6 and 203.7), a
11 specific exception for commercial feeds (section 203.8), a
12 requirement to keep a copy of the United States Pharmacopoeia
13 and National Formulary (section 203.9), a statement of
14 legislative intent (part of section 203A.1), requirements for
15 state level approval of certain new drugs (part of section
16 203A.11), a reference to analyses by the state chemist when
17 requested by the board of pharmacy (section 203A.18), and a
18 requirement for manufacturers, packers, and distributors to
19 file certain information with the board of pharmacy with
20 respect to prescription drugs (part of section 203A.19).

21 SUCCESSOR TO SSB 2175 (LSB 7213DS)

22
23
24
25
26
27
28
29
30
31
32
33
34
35

SSB 2175

SSB 2175
Human Resources
New

HUMAN RESOURCES: Surgeon, Chair: Bruner and Lind

SENATE FILE 2249
BY (PROPOSED BOARD OF PHARMACY
EXAMINERS BILL)

Passed Senate, Date _____ Passed House, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act relating to the labeling, advertising, adulteration,
2 misbranding, and dispensing of drugs, devices, and cosmetics,
3 providing penalties, and providing properly related matters.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24

1 Section 1. NEW SECTION. 203B.1 TITLE.

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

4 Sec. 2. NEW SECTION. 203B.2 DEFINITIONS --
5 APPLICABILITY.

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

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

12 2. "Board" means the board of pharmacy examiners.

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

16 4. "Cosmetic" means any of the following, but does not
17 include soap:

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

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

24 5. "Counterfeit drug" means a drug which, or the container
25 or labeling of which, without authorization, bears the
26 trademark, trade name, or other identifying mark, imprint, or
27 device, or any such likeness, of a drug manufacturer,
28 processor, packer, or distributor other than the person or
29 persons who in fact manufactured, processed, packed, or
30 distributed the drug and which falsely purports or is
31 represented to be the product of, or to have been packed or
32 distributed by, such other drug manufacturer, processor,
33 packer, or distributor.

34 6. "Device" means an instrument, apparatus, implement,
35 machine, contrivance, implant, in vitro reagent, or other

1 similar or related article, including any component, part, or
2 accessory of any of these, which is any of the following:

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

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

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

15 7. "Drug" means any of the following, but does not include
16 a device:

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

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

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

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

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

31 9. "Immediate container" does not include a package liner.

32 10. "Label" means a display of written, printed, or
33 graphic matter upon the immediate container of an article; and
34 a requirement made by or under authority of this chapter that
35 any word, statement, or other information appear on the label.

1 is not complied with unless the word, statement, or other
2 information also appears on the outside container or wrapper
3 of the retail package of the article, or is easily legible
4 through the outside container or wrapper.

5 11. "Labeling" means all labels and other written,
6 printed, or graphic matter upon an article or any of its
7 containers or wrappers, or accompanying an article.

8 12. "New animal drug" means any drug intended for use for
9 animals and not for humans, including any drug intended for
10 use in animal feed.

11 13. "New drug" means either of the following:

12 a. Any drug, except a new animal drug, the composition of
13 which is such that the drug is not generally recognized among
14 experts qualified by scientific training and experience to
15 evaluate the safety and effectiveness of drugs, as safe and
16 effective for use under the conditions prescribed,
17 recommended, or suggested in its labeling, except that a drug
18 not so recognized is not a new drug if at any time prior to
19 the enactment of this chapter it was subject to the federal
20 Act, and if at that time its labeling contained the same
21 representations concerning the conditions of its use.

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

30 14. "Official compendium" means the official United States
31 Pharmacopoeia National Formulary, official Homeopathic
32 Pharmacopoeia of the United States, or any supplement to
33 either document.

34 15. "Person" means an individual, partnership,
35 corporation, or association.

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

5 17. "Safe" as used in this chapter has reference to the
6 health of a human or animal.

7 18. "Secretary" means the secretary of the United States
8 department of health and human services.

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

16 Sec. 3. NEW SECTION. 203B.3 PROHIBITED ACTS.

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

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

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

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

27 4. The introduction or delivery for introduction into
28 commerce of a drug, device, or cosmetic in violation of
29 section 203B.12 or 203B.13.

30 5. The dissemination of any false advertising.

31 6. The refusal to permit entry or inspection, or to permit
32 the taking of a sample or to permit access to or copying of
33 any record as authorized by section 203B.18; or the failure to
34 establish or maintain any record or make any report required
35 under section 512(j), 512(l), or 512(m) of the federal Act, or

1 the refusal to permit access to or verification or copying of
2 any such required record.

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

5 8. The giving of a guaranty or undertaking referred to in
6 section 203B.5, subsection 2, if the guaranty or undertaking
7 is false, except by a person who relied upon a guaranty or
8 undertaking to the same effect, signed by, and containing the
9 name and address of, the person residing in this state from
10 whom the person received the drug, device, or cosmetic in good
11 faith.

12 9. The removal or disposal of a detained or embargoed
13 drug, device, or cosmetic in violation of section 203B.6,
14 subsection 1.

15 10. The alteration, mutilation, destruction,
16 obliteration, or removal of the whole or any part of the
17 labeling of, or the doing of any other act with respect to a
18 drug, device, or cosmetic, if the act is done while the
19 article is held for sale, whether or not it would be the first
20 sale, after shipment in commerce; and if the action results in
21 the article being adulterated or misbranded.

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

27 12. Making, selling, disposing of, or keeping in
28 possession, control, or custody, or concealing a punch, die,
29 plate, stone, or other thing designed to print, imprint, or
30 reproduce the trademark, trade name, or other identifying
31 mark, imprint, or device of another trademark, trade name,
32 mark, imprint, or device or a likeness of any trademark, trade
33 name, mark, imprint, or device upon a drug or drug container
34 or the labeling thereof so as to render the drug a counterfeit
35 drug.

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

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

10 15. The use, on the labeling of a drug or device or in
11 advertising relating to a drug or device, of a representation
12 or suggestion that approval of an application with respect to
13 the drug or device is in effect under section 203B.12 or
14 sections 505, 515, or 520(g) of the federal Act, or that the
15 drug or device complies with the provisions of any of those
16 sections.

17 16. The use, in labeling, advertising, or other sales
18 promotion of a reference to a report or analysis furnished in
19 compliance with section 203B.18 or section 704 of the federal
20 Act.

21 17. If a prescription drug is distributed or offered for
22 sale in this state, the failure of the manufacturer, packer,
23 or distributor of the prescription drug to maintain for
24 transmittal, or to transmit, to any practitioner licensed by
25 applicable law to administer the drug who makes written
26 request for information as to the drug, true and correct
27 copies of all printed matter which is required to be included
28 in any package in which that drug is distributed or sold, or
29 such other printed matter as is approved under the federal
30 Act. This subsection does not exempt any person from a
31 labeling requirement imposed by or under this chapter.

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

1 likeness of such a trademark, trade name, mark, or imprint.

2 b. Selling, dispensing, disposing of; causing to be sold,
3 dispensed, or disposed of; or concealing or keeping in
4 possession, control, or custody, with intent to sell,
5 dispense, or dispose of, a drug, device, or container thereof,
6 with knowledge that the trademark, trade name, or other
7 identifying mark or imprint of another trademark, trade name,
8 mark, or imprint or any likeness of any trademark, trade name,
9 mark, or imprint has been placed thereon in a manner
10 prohibited by paragraph "a".

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

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

25 20. a. The failure or refusal to:

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

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

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

34 21. The movement of a device in violation of an order
35 under section 304(g) of the federal Act or the removal or

1 alteration of any mark or label required by the order to
2 identify the device as detained.

3 22. The failure to provide the notice required by section
4 412(b) or 412(c) of the federal Act, the failure to make the
5 reports required by section 412(d)(1)(B) of the federal Act,
6 or the failure to meet the requirements prescribed under
7 section 412(d)(2) of the federal Act.

8 Sec. 4. NEW SECTION. 203B.4 INJUNCTION PROCEEDINGS.

9 The board may apply to the district court for, and the
10 court has jurisdiction upon hearing and for cause shown to
11 grant, a temporary or permanent injunction restraining any
12 person from violating any provision of section 203B.3 whether
13 or not there exists an adequate remedy at law.

14 Sec. 5. NEW SECTION. 203B.5 PENALTIES AND GUARANTY.

15 1. A person who violates a provision of this chapter is
16 guilty of a serious misdemeanor; but if the violation is
17 committed after a conviction of the person under this section
18 has become final, the person is guilty of an aggravated
19 misdemeanor.

20 2. A person is not subject to the penalties of subsection
21 1 if the person establishes a guaranty or undertaking signed
22 by, and containing the name and address of another person
23 residing in this state from whom the person received the
24 article in good faith, to the effect that the article is not
25 adulterated or misbranded.

26 3. A publisher, radio-broadcast licensee, or agency or
27 medium which disseminates false advertising, except the
28 manufacturer, packer, distributor, or seller of the article to
29 which false advertising relates, is not liable under this
30 section for the dissemination of the false advertising, unless
31 the person has refused, on the request of the board, to
32 furnish the board the name and post office address of the
33 manufacturer, packer, distributor, seller, or advertising
34 agency, residing in this state which caused the person to
35 disseminate the advertisement.

1 Sec. 6. NEW SECTION. 203B.6 EMBARGO.

2 1. If a duly authorized agent of the board finds, or has
3 probable cause to believe, that a drug, device, or cosmetic is
4 adulterated or so misbranded as to be dangerous or fraudulent,
5 within the meaning of this chapter, or is in violation of
6 section 203B.12 or 203B.13, the agent shall affix to the
7 article a tag or other appropriate marking, giving notice that
8 the article is, or is suspected of being, adulterated or
9 misbranded and has been detained or embargoed, and warning all
10 persons not to remove or dispose of the article by sale or
11 otherwise until permission for removal or disposal is given by
12 an authorized agent or the court. It is unlawful for a person
13 to remove or dispose of the detained or embargoed article by
14 sale or otherwise without such permission.

15 2. When an article is adulterated or misbranded or is in
16 violation of section 203B.12 or 203B.13 and has been detained
17 or embargoed, a petition may be filed with the district court
18 in whose jurisdiction the article is located, detained, or
19 embargoed for an order for condemnation of the article. If a
20 duly authorized agent has found that an article which is
21 embargoed or detained is not adulterated or misbranded, the
22 agent shall remove the tag or other marking.

23 3. If the court finds that a sampled, detained, or
24 embargoed article is adulterated or misbranded, the article
25 shall be destroyed at the expense of the claimant of the
26 article, under the supervision of the agent, and all court
27 costs and fees, and storage and other proper expenses, shall
28 be taxed against the claimant of the article or the claimant's
29 agent; but if the adulteration or misbranding can be corrected
30 by proper labeling or processing of the article, the court,
31 after entry of the decree and after costs, fees, storage, and
32 other expenses have been paid and a good and sufficient bond,
33 conditioned that the article shall be so labeled or processed,
34 has been executed, may by order direct that the article be
35 delivered to the claimant for such labeling or processing

1 under the supervision of a duly authorized agent of the board.
2 The expense of supervision shall be paid by the claimant. The
3 article shall be returned to the claimant and the bond shall
4 be discharged on the representation to the court by the board
5 that the article is no longer in violation of this chapter,
6 and that the expenses of supervision have been paid.

7 Sec. 7. NEW SECTION. 203B.7 PROSECUTIONS.

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

21 Sec. 8. NEW SECTION. 203B.8 MINOR VIOLATIONS.

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

27 Sec. 9. NEW SECTION. 203B.9 DRUGS AND DEVICES --
28 ADULTERATION.

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

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

33 b. If it has been produced, prepared, packed, or held
34 under insanitary conditions whereby it may have been
35 contaminated with filth, or whereby it may have been rendered

1 injurious to health.

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

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

13 2. If it purports to be or is represented as a drug, the
14 name of which is recognized in an official compendium, and its
15 strength differs from, or its quality or purity falls below,
16 the standards set forth in the official compendium. A
17 determination as to strength, quality, or purity shall be made
18 in accordance with the tests or methods of assay set forth in
19 the official compendium, or in the absence of or inadequacy of
20 such tests or methods of assay, those prescribed under
21 authority of the federal Act. A drug defined in an official
22 compendium is not adulterated under this subsection because it
23 differs from the standard of strength, quality, or purity set
24 forth in the official compendium, if its difference in
25 strength, quality, or purity from such standards is plainly
26 stated on its label. If a drug is recognized in both the
27 United States Pharmacopoeia National Formulary and the
28 Homeopathic Pharmacopoeia of the United States it is subject
29 to the United States Pharmacopoeia National Formulary unless
30 it is labeled and offered for sale as a homeopathic drug, in
31 which case it is subject to the Homeopathic Pharmacopoeia of
32 the United States and not to the United States Pharmacopoeia
33 National Formulary.

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

1 it purports or is represented to possess.

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

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

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

11 7. If it is a device and the methods used in, or the
12 facilities or controls used for its manufacture, packing,
13 storage, or installation are not in conformity with applicable
14 requirements under section 520(f)(1) of the federal Act or an
15 applicable condition as prescribed by an order under section
16 520(f)(2) of the federal Act.

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

23 Sec. 10. NEW SECTION. 203B.10 DRUGS AND DEVICES --
24 MISBRANDING -- LABELING.

25 A drug or device is misbranded under any of the following
26 circumstances:

27 1. If its labeling is false or misleading in any
28 particular.

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

31 a. The name and place of business of the manufacturer,
32 packer, or distributor.

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

35 However, under paragraph "a" reasonable variations shall be

1 permitted, and exemptions as to small packages shall be
2 allowed, in accordance with rules adopted by the board.

3 3. If any word, statement, or other information required
4 by or under the authority of this chapter to appear on the
5 label or labeling is not prominently placed thereon with such
6 conspicuousness, as compared with other words, statements,
7 designs, or devices, in the labeling, and in such terms as to
8 render it likely to be read and understood by the ordinary
9 individual under customary conditions of purchase and use.

10 4. If it is for use by humans and contains any quantity of
11 the narcotic or hypnotic substance alpha-eucaine, barbituric
12 acid, beta-eucaine, bromal, cannabis, carbromal, chloral,
13 coca, cocaine, codeine, heroin, marijuana, morphine, opium,
14 paraldehyde, peyote, or sulphonmethane; or any chemical
15 derivative of such a substance, which derivative, after
16 investigation, has been designated as habit forming, by rules
17 adopted by the board under this chapter or by regulations
18 adopted by the secretary pursuant to section 502(d) of the
19 federal Act; unless its label bears the name and quantity or
20 proportion of such substance or derivative and in
21 juxtaposition therewith the statement "Warning -- May Be Habit
22 Forming."

23 5. a. If it is a drug, unless both of the following
24 apply:

25 (1) Its label bears, to the exclusion of any other
26 nonproprietary name except the applicable systematic chemical
27 name or the chemical formula:

28 (a) The established name of the drug, as specified in
29 paragraph "c", if such exists; and

30 (b) If the drug is fabricated from two or more
31 ingredients, the established name and quantity of each active
32 ingredient, including the quantity, kind, and proportion of
33 any alcohol, and also including, whether active or not, the
34 established name and quantity or proportion of any bromides,
35 ether, chloroform, acetanilide, acetophenetidin, amidopyrine,

1 antipyrine, atropine, hyoscine, hyoscyamine, arsenic,
2 digitalis, digitalis glucosides, mercury, ouabain,
3 strophanthin, strychnine, thyroid, or any derivative or
4 preparation of any such substances, contained therein.
5 However, the requirement for stating the quantity of the
6 active ingredients, other than the quantity of those
7 specifically named in this subparagraph subdivision, applies
8 only to prescription drugs.

9 (2) For a prescription drug, the established name of the
10 prescription drug or of an ingredient is printed, on the label
11 and on any labeling on which a name for the prescription drug
12 or an ingredient is used, prominently and in type at least
13 half as large as that used thereon for any proprietary name or
14 designation for the prescription drug or ingredient. However,
15 to the extent that compliance with subparagraph (1),
16 subparagraph subdivision (b) or this subparagraph is
17 impracticable, exemptions shall be allowed under rules or
18 regulations adopted by the board or the secretary under the
19 federal Act.

20 b. If it is a device and it has an established name,
21 unless its label bears, to the exclusion of any other
22 nonproprietary name, its established name, as defined in
23 paragraph "d", prominently printed in type at least half as
24 large as that used thereon for any proprietary name or
25 designation for the device, except that to the extent
26 compliance with this paragraph is impracticable, exemptions
27 shall be allowed under rules or regulations adopted by the
28 board or the secretary under the federal Act.

29 c. As used in paragraph "a", the term "established name",
30 with respect to a drug or ingredient thereof, means one of the
31 following:

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

34 (2) If no such official name exists and the drug or
35 ingredient is an article recognized in an official compendium,

1 then its official title in the compendium.

2 (3) If neither subparagraph (1) nor (2) applies, then the
3 common or usual name, if any, of the drug or ingredient.

4 However, if subparagraph (2) applies to an article recognized
5 in the United States Pharmacopoeia National Formulary and in
6 the Homeopathic Pharmacopoeia of the United States under
7 different official titles, the official title used in the
8 United States Pharmacopoeia National Formulary applies unless
9 it is labeled and offered for sale as a homeopathic drug, in
10 which case the official title used in the Homeopathic
11 Pharmacopoeia of the United States applies.

12 d. As used in paragraph "b", the term "established name"
13 with respect to a device means one of the following:

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

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

19 (3) If neither subparagraph (1) nor (2) applies, then any
20 common or usual name of the device.

21 6. Unless its labeling bears both of the following:

22 a. Adequate directions for use.

23 b. Adequate warnings against use in those pathological
24 conditions, or by children, where its use may be dangerous to
25 health, or against unsafe dosage or methods or durations of
26 administration or application, in the manner and form
27 necessary for the protection of users.

28 However, if a requirement of paragraph "a", as applied to a
29 drug or device, is not necessary for the protection of the
30 public health, the board or the secretary shall adopt rules or
31 regulations exempting the drug or device from that
32 requirement.

33 7. If it purports to be a drug the name of which is
34 recognized in an official compendium, unless it is packaged
35 and labeled as prescribed in the official compendium.

1 However, the method of packing may be modified with the
2 consent of the board or the secretary. If a drug is
3 recognized in both the United States Pharmacopoeia National
4 Formulary and the Homeopathic Pharmacopoeia of the United
5 States, it is subject to the requirements of the United States
6 Pharmacopoeia National Formulary with respect to packaging and
7 labeling unless it is labeled and offered for sale as a
8 homeopathic drug, in which case it is subject to the
9 Homeopathic Pharmacopoeia of the United States, and not to the
10 United States Pharmacopoeia National Formulary. However, if
11 an inconsistency exists between this subsection and subsection
12 5 as to the name by which the drug or its ingredients shall be
13 designated, subsection 5 prevails.

14 8. If it has been found by the board or the secretary to
15 be a drug liable to deterioration, unless it is packaged in
16 the form and manner, and its label bears a statement of the
17 precautions that the board or the secretary by rule or
18 regulation requires as necessary for the protection of public
19 health. Such a rule or regulation shall not be established
20 for a drug recognized in an official compendium until the
21 board or the secretary has informed the appropriate body
22 charged with the revision of the official compendium of the
23 need for such packaging or labeling requirements and that body
24 has failed within a reasonable time to prescribe such
25 requirements.

26 9. a. If it is a drug and its container is so made,
27 formed, or filled as to be misleading.

28 b. If it is an imitation of another drug.

29 c. If it is offered for sale under the name of another
30 drug.

31 10. If it is dangerous to health when used in the dosage
32 or manner, or with the frequency or duration prescribed,
33 recommended, or suggested in its labeling.

34 11. If it is, or purports to be, or is represented as a
35 drug composed wholly or partly of insulin, unless both of the

1 following apply:

2 a. It is from a batch with respect to which a certificate
3 or release has been issued pursuant to section 506 of the
4 federal Act.

5 b. The certificate or release is in effect with respect to
6 the drug.

7 12. If it is, or purports to be, or is represented as a
8 drug, except a drug for use in animals and not in humans,
9 composed wholly or partly of any kind of penicillin,
10 streptomycin, chlortetracycline, chloramphenicol, bacitracin,
11 or any other antibiotic drug, or any derivative thereof,
12 unless both of the following apply:

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

16 b. The certificate or release is in effect with respect to
17 the drug.

18 However, this subsection does not apply to any drug or
19 class of drugs exempted by regulations adopted under section
20 507(c) or 507(d) of the federal Act.

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

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

32 a. The established name as defined in subsection 5,
33 printed prominently and in type at least half as large as that
34 used for any trade or brand name thereof.

35 b. The formula showing quantitatively each ingredient of

1 the prescription drug to the extent required for labels under
2 subsection 5.

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

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

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

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

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

28 a. Its advertising is false or misleading in any
29 particular.

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

33 19. In the case of a restricted device distributed or
34 offered for sale in this state, unless the manufacturer,
35 packer, or distributor includes in all advertising and other

1 descriptive printed matter issued by the manufacturer, packer,
2 or distributor with respect to the device both of the
3 following:

4 a. A true statement of the device's established name as
5 defined in subsection 5, printed prominently and in type at
6 least half as large as that used for any trade or brand name
7 thereof.

8 b. A brief statement of the intended uses of the device
9 and relevant warnings, precautions, side effects, and
10 contraindications; and in the case of a specific device made
11 subject to regulations adopted pursuant to the federal Act, a
12 full description of the components of the device or the
13 formula showing quantitatively each ingredient of the device
14 to the extent required in regulations under the federal Act.

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

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

23 If an article is alleged to be misbranded because the
24 labeling or advertising is misleading, then in determining
25 whether the labeling or advertising is misleading, there shall
26 be taken into account, among other things, not only
27 representations made or suggested by statement, word, design,
28 device, or any combination thereof, but also the extent to
29 which the labeling or advertising fails to reveal facts
30 material in the light of such representations, or material
31 with respect to consequences which may result from the use of
32 the article to which the labeling or advertising relates,
33 under the conditions of use prescribed in the labeling or
34 advertising or under customary or usual conditions of use.

35 The representation of a drug, in its labeling, as an

1 antiseptic shall be considered to be a representation that it
2 is a germicide, except in the case of a drug purporting to be,
3 or represented as, an antiseptic for inhibitory use as a wet
4 dressing, ointment, dusting powder, or such other use as
5 involves prolonged contact with the body.

6 Sec. 11. NEW SECTION. 203B.11 EXEMPTIONS IN CASES OF
7 DRUGS AND DEVICES -- DISPENSING BY PRESCRIPTION ONLY.

8 1. The board shall adopt rules exempting from any labeling
9 or packaging requirement of this chapter drugs and devices
10 which are, in accordance with the practice of the trade, to be
11 processed, labeled, or repacked in substantial quantities at
12 establishments other than those where originally processed or
13 packaged, on condition that such drugs and devices are not
14 adulterated or misbranded upon removal from the processing,
15 labeling, or repacking establishment.

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

20 3. a. This lettered paragraph applies to a drug intended
21 for use by humans which is any of the following:

22 (1) Is a habit-forming drug to which section 203B.10, sub-
23 section 4 applies.

24 (2) Because of its toxicity or other potentiality for
25 harmful effect, or the method of its use, or the collateral
26 measures necessary to its use, is not safe for use except
27 under the supervision of a practitioner licensed by law to
28 administer the drug.

29 (3) Is limited by an approved application under section
30 505 of the federal Act to use under the professional
31 supervision of a practitioner licensed by law to administer
32 the drug.

33 Such a drug shall be dispensed only upon a written
34 prescription of a practitioner licensed by law to administer
35 the drug, or upon an oral prescription of such a practitioner

1 which is reduced promptly to writing and filed by the
2 pharmacist, or by refilling any such written or oral
3 prescription if the refilling is authorized by the prescriber
4 either in the original prescription or by oral order which is
5 reduced promptly to writing and filed by the pharmacist. The
6 act of dispensing a drug contrary to this paragraph while the
7 drug is held for sale results in the drug being misbranded.

8 b. A drug dispensed by filling or refilling a written or
9 oral prescription of a practitioner licensed by law to
10 administer the drug is exempt from section 203B.10, except
11 subsection 1, subsection 9, paragraphs "b" and "c", and
12 subsections 11 and 12, and the packaging requirements of
13 subsections 7, 8, and 16, if the drug bears a label containing
14 the name and address of the dispenser, the serial number and
15 date of the prescription or of its filling, the name of the
16 prescriber, and, if stated in the prescription, the name of
17 the patient, and the directions for use and cautionary
18 statements, if any, contained in the prescription. This
19 exemption does not apply to a drug dispensed in the course of
20 the conduct of the business of dispensing drugs pursuant to
21 diagnosis by mail, or to a drug dispensed in violation of
22 paragraph "a" of this subsection.

23 c. The board may, by rule, remove a drug subject to
24 section 203B.10, subsection 4, and section 505 of the federal
25 Act from the requirements of paragraph "a" of this subsection
26 when such requirements are not necessary for the protection of
27 the public health.

28 d. A drug which is subject to paragraph "a" of this
29 subsection is misbranded if, at any time prior to dispensing,
30 its label fails to bear the statement: "Caution: Federal Law
31 Prohibits Dispensing Without Prescription", or "Caution:
32 State Law Prohibits Dispensing Without Prescription". A drug
33 to which paragraph "a" of this subsection does not apply is
34 misbranded if, at any time prior to dispensing, its label
35 bears the caution statement quoted in the preceding sentence.

1 Sec. 12. NEW SECTION. 203B.12 NEW DRUGS.

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

5 a. An application with respect to the new drug has been
6 approved and the approval has not been withdrawn under section
7 505 of the federal Act.

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

12 2. A person shall not use in human beings or animals a new
13 drug or new animal drug limited to investigational use unless
14 the person has filed with the United States food and drug
15 administration a completed and signed "Notice of Claimed
16 Investigational Exemption for a New Drug" form in accordance
17 with 21 C.F.R. § 312.1 and the exemption has not been
18 terminated. The drug shall be plainly labeled in compliance
19 with section 505(i) or 507(d) of the federal Act.

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

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

23 b. A drug which is licensed under the federal Public
24 Health Service Act of July 1, 1944, 42 U.S.C. § 201 et seq. or
25 under the Animal Virus, Serum, Toxin, Antitoxin Act of March
26 4, 1913, 21 U.S.C. § 151 et seq.

27 Sec. 13. NEW SECTION. 203B.13 NEW ANIMAL DRUGS.

28 A new animal drug, with respect to any particular use or
29 intended use of the drug, is unsafe for the purposes of this
30 chapter unless both of the following apply:

31 1. There is in effect an approval of an application filed
32 pursuant to section 512(b) of the federal Act with respect to
33 the use or intended use of the drug.

34 2. The drug, its labeling, and its use or intended use
35 conform to the approved application.

1 Sec. 14. NEW SECTION. 203B.14 COSMETICS -- ADULTERATION.

2 A cosmetic is adulterated if any of the following apply:

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

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

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

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

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

29 Sec. 15. NEW SECTION. 203B.15 COSMETICS -- MISBRANDING.

30 A cosmetic is misbranded if any of the following apply:

31 1. Its labeling is false or misleading in any particular.

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

34 a. The name and place of business of the manufacturer,
35 packer, or distributor.

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

6 3. A word, statement, or other information required by or
7 under the authority of this chapter to appear on the label or
8 labeling is not prominently placed there with such
9 conspicuousness, as compared with other words, statements,
10 designs, or devices in the labeling, and in such terms as to
11 render it likely to be read and understood by the ordinary
12 individual under customary conditions of purchase and use.

13 4. Its container is so made, formed, or filled as to be
14 misleading.

15 5. It is a color additive, unless its packaging and
16 labeling are in conformity with the packaging and labeling
17 requirements applicable to that color additive prescribed
18 under section 706 of the federal Act. This subsection does
19 not apply to packages of color additives which, with respect
20 to their use of cosmetics, are marketed and intended for use
21 only in or on hair dyes, as specified in section 203B.14,
22 subsection 1.

23 6. Its packaging or labeling is in violation of an
24 applicable regulation adopted pursuant to section 3 or 4 of
25 the federal Poison Prevention Packaging Act of 1970, 15 U.S.C.
26 § 1471 et seq.

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

1 as modified or rejected by rules adopted by the board.

2 Sec. 16. NEW SECTION. 203B.16 FALSE ADVERTISING.

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

5 2. For the purpose of this chapter, advertising is false
6 if it represents a drug or device to have any effect on any of
7 the following conditions, disorders, diseases, or processes:
8 blood disorders, bone or joint diseases, kidney diseases or
9 disorders, cancer, diabetes, gall bladder disease or
10 disorders, heart and vascular disease, high blood pressure,
11 diseases or disorders of the ear, mental disease or mental
12 retardation, paralysis, prostate gland disorders, conditions
13 of the scalp affecting hair loss, baldness, endocrine
14 disorders, sexual impotence, tumors, venereal diseases,
15 varicose ulcers, breast enlargement, purifying blood,
16 metabolic disorders, immune system disorders or conditions
17 affecting the immune system, extension of life expectancy,
18 stress and tension, brain stimulation or performance, the
19 body's natural defense mechanisms, blood flow, and depression.
20 However, advertising not in violation of subsection 1 is not
21 false under this subsection if it is disseminated only to
22 members of the medical, dental, or veterinary professions, or
23 appears only in the scientific periodicals of these
24 professions, or is disseminated only for the purpose of public
25 health education by persons not commercially interested,
26 directly or indirectly, in the sale of such drugs or devices.
27 However, if the board determines that an advance in medical
28 science has made any type of self-medication safe as to any of
29 the diseases named in this subsection, the board shall by rule
30 authorize the advertising of drugs having curative or
31 therapeutic effect for such disease, subject to the conditions
32 and restrictions the board deems necessary in the interests of
33 the public health. However, this subsection does not indicate
34 that self-medication for diseases other than those named in
35 this subsection is safe and efficacious.

1 Sec. 17. NEW SECTION. 203B.17 RULES -- HEARINGS.

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

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

10 Sec. 18. NEW SECTION. 203B.18 INSPECTIONS.

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

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

21 (2) Inspect at reasonable times and within reasonable
22 limits and in a reasonable manner such a factory, warehouse,
23 establishment, or vehicle and all pertinent equipment,
24 finished and unfinished materials, containers, and labeling
25 therein, and obtain samples necessary to the enforcement of
26 this chapter. In the case of a factory, warehouse,
27 establishment, or consulting laboratory in which prescription
28 drugs are manufactured, processed, packed, or held, the
29 inspection shall extend to all things therein, including
30 records, files, papers, processes, controls, and facilities,
31 bearing on whether prescription drugs or restricted devices
32 which are adulterated or misbranded or which may not be
33 manufactured, introduced into commerce, or sold or offered for
34 sale by reason of any provision of this chapter, have been or
35 are being manufactured, processed, packed, transported, or

1 held in violation of or bearing on a violation of this
2 chapter. An inspection authorized for prescription drugs by
3 the preceding sentence shall not extend to financial data,
4 sales data other than shipment data, pricing data, personnel
5 data other than data as to qualifications of technical and
6 professional personnel performing functions subject to this
7 chapter, and research data other than data relating to new
8 drugs, and antibiotic drugs, and devices, and subject to
9 reporting and inspection under regulations lawfully issued
10 pursuant to section 505(i) or 505(j), or section 507(d) or
11 507(g), section 519, or section 520(g) of the federal Act, and
12 data, relating to other drugs, or devices which in the case of
13 a new drug would be subject to reporting or inspection under
14 lawful regulations issued pursuant to section 505(j) of the
15 federal Act. The inspection shall be commenced and completed
16 with reasonable promptness.

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

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

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

34 (3) Persons who manufacture, prepare, propagate, compound,
35 or process drugs, or manufacture or process devices solely for

1 use in research, teaching, or chemical analysis and not for
2 sale.

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

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

17 a. Consists in whole or in part of a filthy, putrid, or
18 decomposed substance.

19 b. Has been prepared, packed, or held under insanitary
20 conditions whereby it may have become contaminated with filth,
21 or whereby it may have been rendered injurious to health.

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

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

29 4. A person required under this chapter or section 519 or
30 520(g) of the federal Act to maintain records and a person who
31 is in charge or custody of such records shall, upon request of
32 an authorized agent designated by the board, permit the
33 authorized agent at all reasonable times to have access and to
34 copy and verify such records.

35 5. For the purposes of enforcing this chapter, carriers

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

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

21 Sec. 19. NEW SECTION. 203B.19 PUBLICITY.

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

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

32 Sec. 20. Section 125.2, subsection 3, Code 1987, is
33 amended to read as follows:

34 3. "Chemical substance" means alcohol, wine, spirits, and
35 beer as defined in chapter 123 and drugs as defined in section

1 ~~203A-2~~ 203B.2, subsection 3 7, which when used improperly
2 could result in chemical dependency.

3 Sec. 21. Section 147.99, Code 1987, is amended to read as
4 follows:

5 147.99 DUTIES OF SECRETARY.

6 The secretary of the board of pharmacy examiners shall,
7 upon the direction of ~~said-examiners~~ the board, make
8 inspections of alleged violations of the provisions of this
9 title relative to the practice of pharmacy and of chapters ~~203~~
10 203B, 204, and 205. ~~Said~~ The secretary shall be allowed
11 necessary traveling and hotel expenses in making such
12 inspections.

13 Sec. 22. Section 155A.12, subsection 9, Code Supplement
14 1987, is amended to read as follows:

15 9. Been convicted of an offense or subjected to a penalty
16 or fine for violation of chapter 147, ~~2037-203A~~ 203B, 204, or
17 the Federal Food, Drug and Cosmetic Act. A plea or verdict of
18 guilty, or a conviction following a plea of nolo contendere,
19 is deemed to be a conviction within the meaning of this
20 section.

21 Sec. 23. Section 159.6, subsection 9, Code 1987, is
22 amended to read as follows:

23 9. Regulation and inspection of foods, drugs, and other
24 articles, Title X, but chapters ~~203~~ 203B, 204 and 205 of said
25 title shall be enforced as therein provided.

26 Sec. 24. Section 189.2, subsection 1, Code 1987, is
27 amended to read as follows:

28 1. Execute and enforce this title, except chapters ~~2037~~
29 ~~203A~~ 203B, 204, 204A and 205.

30 Sec. 25. Section 205.11, Code 1987, is amended to read as
31 follows:

32 205.11 ENFORCEMENT.

33 The provisions of this chapter and chapters ~~203~~ 203B and
34 204 shall be administered and enforced by the board of
35 pharmacy examiners. In discharging any duty or exercising any

1 power under said those chapters, the board of pharmacy
2 examiners shall be governed by all the provisions of chapter
3 189, which govern the department of agriculture and land
4 stewardship when discharging a similar duty or exercising a
5 similar power with reference to any of the articles dealt with
6 in this title, to the extent that chapter 189 is not
7 inconsistent with this chapter and chapters 203B and 204.

8 Sec. 26. Section 205.12, Code 1987, is amended to read as
9 follows:

10 205.12 CHEMICAL ANALYSIS OF DRUGS.

11 Any chemical analysis deemed necessary by the board of
12 pharmacy examiners in the enforcement of this chapter and
13 chapters ~~203~~ 203B and 204 shall be made by the department of
14 agriculture and land stewardship when requested by said the
15 board of pharmacy examiners.

16 Sec. 27. Section 205.13, Code 1987, is amended to read as
17 follows:

18 205.13 APPLICABILITY OF OTHER STATUTES.

19 Insofar as applicable the provisions of chapter 189, shall
20 apply to the articles dealt with in this chapter and chapters
21 ~~203~~ 203B and 204. The powers vested in the department of
22 agriculture and land stewardship by said chapter 189 shall be
23 deemed for the purpose of this chapter and chapters ~~203~~ 203B
24 and 204 to be vested in the board of pharmacy examiners.

25 Sec. 28. Section 331.756, subsection 40, Code Supplement
26 1987, is amended to read as follows:

27 40. Prosecute violations of the Iowa drug, device, and
28 cosmetic Act as requested by the board of pharmacy examiners
29 as provided in section ~~203A-7~~ 203B.7.

30 Sec. 29.

31 1. Chapter 203, Code 1987, is repealed.

32 2. Chapter 203A, Code 1987 and Code Supplement 1987, is
33 repealed.

34

EXPLANATION

35 This bill relates to the regulation of labeling,

1 advertising, adulteration, misbranding, and dispensing of
2 drugs, devices, and cosmetics by the board of pharmacy
3 examiners.

4 The bill repeals chapters 203, adulteration and labeling of
5 drugs, and 203A, the Iowa drug and cosmetic Act. It creates a
6 new chapter 203B, the Iowa drug, device, and cosmetic Act.

7 The definitions in the new chapter are similar to those in
8 section 203A.2 with a few changes, additions, and deletions.

9 The list of prohibited acts is based on section 203A.3 with
10 a few revisions and several additions.

11 Provisions for injunctions and penalties are based on
12 sections 203A.4 and 203A.5. Sections relating to embargoes,
13 prosecutions, and minor violations are based on sections
14 203A.6, 203A.7, and 203A.8 respectively.

15 The section on adulteration of drugs is based on sections
16 203A.9 and 203.2 with several additions. The section on
17 misbranding of drugs is based on sections 203A.10, 203A.19(1),
18 203A.2(10) and (12), and 203.3 with a number of changes and
19 additions.

20 With respect to the provision on exemptions and dispensing
21 by prescription only, much of the material is new, but current
22 provisions in sections 203.5 and 203A.20 are relevant.

23 Provisions relating to new drugs are based in part on
24 section 203A.11 with several changes. Requirements for
25 approval at the state level are deleted. The section on new
26 animal drugs is new.

27 Sections on adulteration and misbranding of cosmetics are
28 based on sections 203A.12 and 203A.13 with changes and
29 additions.

30 The section on false advertising is similar to section
31 203A.14; section 203.4 is also relevant.

32 The section relating to rules and hearings of the board of
33 pharmacy examiners is based on section 203A.15. The Iowa
34 Administrative Procedure Act (chapter 17A) applies to
35 rulemaking and other procedures of the board of pharmacy

1 examiners.

2 Inspection provisions are revised and expanded from those
3 in section 203A.16.

4 The section on publicity is based on section 203A.17 with
5 revisions.

6 Several amendatory sections are included to make necessary
7 conforming amendments.

8 Among the provisions appearing in the current law but not
9 included in new chapter 203B are requirements for licensing
10 itinerant vendors of drugs (sections 203.6 and 203.7), a
11 specific exception for commercial feeds (section 203.8), a
12 requirement to keep a copy of the United States Pharmacopoeia
13 and National Formulary (section 203.9), a statement of
14 legislative intent (part of section 203A.1), requirements for
15 state level approval of certain new drugs (part of section
16 203A.11), a reference to analyses by the state chemist when
17 requested by the board of pharmacy (section 203A.18), and a
18 requirement for manufacturers, packers, and distributors to
19 file certain information with the board of pharmacy with
20 respect to prescription drugs (part of section 203A.19).

21 BACKGROUND STATEMENT

22 SUBMITTED BY THE AGENCY

23 Current chapters 203, adulteration and labeling of drugs,
24 and 203A, Iowa drug and cosmetic Act, need to be updated and
25 changed for the following reasons:

26 1. The language in chapter 203 should be incorporated into
27 that of chapter 203A because that language is sometimes
28 duplicative and sometimes conflicting.

29 2. The licensing of itinerant vendors of drugs called for
30 in section 203.6 is outmoded and unnecessary. Drugs and
31 medicines are no longer distributed by "persons who go from
32 place-to-place or house-to-house."

33 3. The requirement in section 203.9 for a "Pharmacopoeia"
34 and "National Formulary" primarily relates to pharmacies and
35 is in possible conflict with the requirements enacted in 1987

1 and found in Iowa Code chapter 155A. Additionally, the need
2 for these particular compendia has changed since the time the
3 requirement was first adopted.

4 4. In addition to incorporating some of the provisions
5 from chapter 203 into chapter 203A, there is a need to make
6 the language now found in chapter 203A "uniform" with the
7 federal laws regulating drugs, devices, and cosmetics. The
8 essentials of this bill have as their genesis a model uniform
9 act whose adoption is supported and encouraged by officials of
10 the federal food and drug administration.

11 5. A major purpose for this bill is to enact a law which,
12 in its essential provisions, is uniform with federal drug,
13 device, and cosmetic laws, and through the adoption of rules
14 conforming to those adopted under the federal act, will
15 maintain uniformity with the federal act and ensure
16 coordination of enforcement with the federal act.

17 6. Section 16 expands the current list of conditions for
18 which drugs may not be advertised to the public. Those
19 expanded conditions include conditions of the scalp affecting
20 hair loss and immune system disorders or conditions affecting
21 the immune system. These are included to prevent fraudulent
22 representations from being made relative to drugs to restore
23 hair and drugs to cure AIDS.

24 7. The current language in section 203A.19 is
25 unenforceable because of the language in section 203A.20. All
26 firms who market prescription drugs in Iowa are subject to the
27 federal act. It is also unnecessary because federal
28 requirements already relate to the items required by section
29 203A.19.

30 8. The distribution of drugs, devices, and cosmetics
31 within the state is constantly changing. There is a need to
32 deal with the misbranding and adulteration of those drugs,
33 devices, and cosmetics in a more effective, efficient manner.
34 Having a statute which is essentially uniform with federal law
35 will assist in that effort. This statute will also enable the

1 state to protect its citizens against the health fraud and
2 quackery claims being made for drugs, devices, and cosmetics
3 where those claims cannot be substantiated by scientific
4 evidence.

5 COMPANION TO LSB 7517DH

6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35