AN ACT

relating to the labeling of certain drugs.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subdivision (8), Section 431.002, Health and Safety Code, is amended to read as follows:

(8) "Consumer commodity," except as otherwise provided by this subdivision, means any food, drug, device, or cosmetic, as those terms are defined by this chapter or by the federal Act, and any other article, product, or commodity of any kind or class that is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or for use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and that usually is consumed or expended in the course of the consumption or use. The term does not include:

(A) a meat or meat product, poultry or poultry product, or tobacco or tobacco product;

(B) a commodity subject to packaging or labeling requirements imposed under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136), or <u>The</u> [~~Section 8,~~] Virus-Serum-Toxin Act (21 U.S.C. <u>151 et seq.</u> [~~158~~]);

(C) a drug subject to the provisions of Section 431.113(c)(1) or <u>431.112(j)</u> [~~431.112(k)~~], or Section 503(b)(1) [~~or 506~~] of the federal Act;

(D) a beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C. 205(e)); or

(E) a commodity subject to the provisions of Chapter 61, Agriculture Code, relating to the inspection, labeling, and sale of agricultural and vegetable seed.

SECTION 2. Subsection (c), Section 431.042, Health and Safety Code, is amended to read as follows:

(c) An inspection under Subsection (b) may not extend to:

(1) financial data;

(2) sales data other than shipment data;

(3) pricing data;

(4) personnel data other than data relating to the qualifications of technical and professional personnel performing functions under this chapter;

(5) research data other than data:

(A) relating to new drugs, antibiotic drugs, and devices; and

(B) subject to reporting and inspection under regulations issued under Section 505(i) or (j), [~~507(d) or (g),~~] 519, or 520(g) of the federal Act; or

(6) data relating to other drugs or devices that, in the case of a new drug, would be subject to reporting or inspection under regulations issued under Section 505(j) of the federal Act.

SECTION 3. Subsection (b), Section 431.059, Health and Safety Code, is amended to read as follows:

(b) A person is not subject to the penalties of Subsection

(a):

(1) for having received an article in commerce and having delivered or offered delivery of the article, if the delivery or offer was made in good faith, unless the person refuses to furnish on request of the commissioner, an authorized agent, or a health authority, the name and address of the person from whom the article was received and copies of any documents relating to the receipt of the article;

(2) for having violated Section 431.021(a) or (e) if the person establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in this state from whom the person received in good faith the article, to the effect that:

(A) in the case of an alleged violation of Section 431.021(a), the article is not adulterated or misbranded within the meaning of this chapter; and

(B) in the case of an alleged violation of Section 431.021(e), the article is not an article that may not, under the provisions of Section 404 or 405 of the federal Act or Section 431.084 or 431.114, be introduced into commerce;

(3) for having violated Section 431.021, if the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated under the federal Act, if the person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that the color additive was from a batch

certified in accordance with the applicable regulations promulgated under the federal Act;

(4) for having violated Section 431.021(b), (c), or (k) by failure to comply with Section 431.112(i) [~~431.112(j)~~] with respect to an article received in commerce to which neither Section 503(a) nor Section 503(b)(1) of the federal Act applies if the delivery or offered delivery was made in good faith and the labeling at the time of the delivery or offer contained the same directions for use and warning statements as were contained in the labeling at the same time of the receipt of the article; or

(5) for having violated Section 431.021(l)(2) if the person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing would result in a drug being a counterfeit drug, or for having violated Section 431.021(l)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

SECTION 4. Section 431.112, Health and Safety Code, is amended to read as follows:

Sec. 431.112. MISBRANDED DRUG OR DEVICE. A drug or device shall be deemed to be misbranded:

(a)(1) if its labeling is false or misleading in any particular; or

(2) if its labeling or packaging fails to conform with the requirements of Section 431.181.

(b) if in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or

distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; provided, that under Subdivision (2) reasonable variations shall be permitted, and exemptions as to small packages shall be allowed in accordance with regulations prescribed by the secretary under the federal Act;

(c) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(d) [~~if it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substance, which derivative, after investigation, has been found to be designated as habit forming, by regulations issued by the secretary under Section 502(d) of the federal Act, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement, "Warning: May be habit forming";~~

[~~(e)~~] (1) if it is a drug, unless:

(A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic

chemical name or the chemical formula):

(i) the established name (as defined in Subdivision (3)) of the drug, if any; and

(ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein; provided, that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subparagraph shall apply only to prescription drugs; and

(B) for any prescription drug the established name of the drug or ingredient, as the case may be, on the label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient; and provided, that to the extent that compliance with the requirements of Paragraph (A)(ii) or this paragraph is impracticable, exemptions shall be allowed under regulations promulgated by the secretary under the federal Act;

(2) if it is a device and it has an established name, unless its label bears, to the exclusion of any other

nonproprietary name, its established name (as defined in Subdivision (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with this subdivision is impracticable, exemptions shall be allowed under regulations promulgated by the secretary under the federal Act;

(3) as used in Subdivision (1), the term "established name," with respect to a drug or ingredient thereof, means:

(A) the applicable official name designated pursuant to Section 508 of the federal Act; or

(B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium; or

(C) if neither Paragraph (A) nor Paragraph (B) applies, then the common or usual name, if any, of such drug or of such ingredient; provided further, that where Paragraph (B) applies to an article recognized in the United States Pharmacopoeia National Formulary, the official title used in the United States Pharmacopoeia National Formulary shall apply;

(4) as used in Subdivision (2), the term "established name" with respect to a device means:

(A) the applicable official name of the device designated pursuant to Section 508 of the federal Act;

(B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium; or

(C) if neither Paragraph (A) nor Paragraph (B)

applies, then any common or usual name of such device;

(e) [~~(f)~~] unless its labeling bears:

(1) adequate directions for use; and

(2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or durations of administration or application, in such manner and form, as are necessary for the protection of users unless the drug or device has been exempted from those requirements by the regulations adopted by the secretary;

(f) [~~(g)~~] if it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein unless the method of packing has been modified with the consent of the secretary. Whenever a drug is recognized in the United States Pharmacopoeia National Formulary, it shall be subject to the requirements of the United States Pharmacopoeia National Formulary with respect to packaging and labeling. If there is an inconsistency between the requirements of this subsection and those of Subsection (d) [~~(e)~~] as to the name by which the drug or its ingredients shall be designated, the requirements of Subsection (d) [~~(e)~~] prevail;

(g) [~~(h)~~] if it has been found by the secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the secretary shall by regulations require as necessary for the protection of public health;

(h) [~~(i)~~] if:

(1) it is a drug and its container is so made, formed, or filled as to be misleading; or

(2) it is an imitation of another drug; or

(3) it is offered for sale under the name of another drug;

(i) [~~(j)~~] if it is dangerous to health when used in the dosage, or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

(j) [~~(k)~~] if it is, or purports to be, or is represented as a drug composed wholly or partly of insulin[~~, unless:~~

[~~(1) it is from a batch with respect to which a certificate or release has been issued pursuant to Section 506 of the federal Act; and~~

[~~(2) such certificate or release is in effect with respect to such drug~~];

(k) [~~(l)~~] if it is, or purports to be, or is represented as a drug (except a drug for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof[~~, unless:~~

[~~(1) it is from a batch with respect to which a certificate or release has been issued pursuant to Section 507 of the federal Act; and~~

[~~(2) the certificate or release is in effect with respect to the drug; provided, that this subdivision shall not apply to any drug or class of drugs exempted by regulations promulgated under Section 507(c) or (d) of the federal Act~~];

(l) [~~(m)~~] if it is a color additive, the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in rules issued under Section 431.161(b);

(m) [~~(n)~~] in the case of any prescription drug distributed or offered for sale in this state, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of:

(1) the established name as defined in Subsection (d) [~~(e)~~], printed prominently and in type at least half as large as that used for any trade or brand name;

(2) the formula showing quantitatively each ingredient of the drug to the extent required for labels under Subsection (d) [~~(e)~~]; and

(3) other information in brief summary relating to side effects, contraindications, and effectiveness as required in regulations issued under Section 701(e) of the federal Act;

(n) [~~(o)~~] if it was manufactured, prepared, propagated, compounded, or processed in an establishment in this state not registered under Section 510 of the federal Act, if it was not included in a list required by Section 510(j) of the federal Act, if a notice or other information respecting it was not provided as required by that section or Section 510(k) of the federal Act, or if it does not bear symbols from the uniform system for identification

of devices prescribed under Section 510(e) of the federal Act as required by regulation;

(o) [~~(p)~~] if it is a drug and its packaging or labeling is in violation of an applicable regulation issued under Section 3 or 4 of the federal [~~Federal~~] Poison Prevention Packaging Act of 1970 (15 [~~21~~] U.S.C. 1472 or 1473);

(p) [~~(q)~~] if a trademark, trade name, or other identifying mark, imprint or device of another, or any likeness of the foregoing has been placed thereon or on its container with intent to defraud;

(q) [~~(r)~~] in the case of any restricted device distributed or offered for sale in this state, if:

(1) its advertising is false or misleading in any particular; or

(2) it is sold, distributed, or used in violation of regulations prescribed under Section 520(e) of the federal Act;

(r) [~~(s)~~] in the case of any restricted device distributed or offered for sale in this state, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued by the manufacturer, packer, or distributor with respect to that device:

(1) a true statement of the device's established name as defined in Section 502(e) of the federal Act, printed prominently and in type at least half as large as that used for any trade or brand name thereof; and

(2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and in the case of specific devices made subject

to regulations issued under the federal Act, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations under the federal Act;

(s) [~~(t)~~] if it is a device subject to a performance standard established under Section 514 of the federal Act, unless it bears such labeling as may be prescribed in such performance standard; or

(t) [~~(u)~~] if it is a device and there was a failure or refusal:

(1) to comply with any requirement prescribed under Section 518 of the federal Act respecting the device; or

(2) to furnish material required by or under Section 519 of the federal Act respecting the device.

SECTION 5. Subsection (c), Section 431.113, Health and Safety Code, is amended to read as follows:

(c)(1) A drug intended for use by man that:

(A) [~~is a habit-forming drug to which Section 431.112(d) applies; or~~

[~~(B)~~] because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) [~~(C)~~] is limited by an approved application under Section 505 of the federal Act to use under the professional supervision of a practitioner licensed by law to administer such

drug shall be dispensed only:

(i) on a written prescription of a practitioner licensed by law to administer such drug; or

(ii) on an oral prescription of such practitioner that is reduced promptly to writing and filed by the pharmacist; or

(iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order that is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act that results in a drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of Section 431.112, except Sections 431.112(a)(1), (h)(2), (h)(3), (j), and [~~(i)(2), (i)(3),~~] (k), [~~and (l),~~] and the packaging requirements of Sections 431.112(f), (g), and (o) [~~431.112(g), (h), and (p)~~], if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drugs dispensed in the course of the conduct of business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of

Subdivision (1).

(3) [~~The board may, by rule, remove drugs subject to Section 431.112(d) and Section 505 of the federal Act from the requirements of Subdivision (1) when such requirements are not necessary for the protection of the public health.~~

[~~(4)~~] A drug that is subject to Subdivision (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear at a minimum, the symbol "RX Only [~~the statement "Caution: Federal Law Prohibits Dispensing Without Prescription," or "Caution: State Law Prohibits Dispensing Without Prescription~~]." A drug to which Subdivision (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

SECTION 6. Subsection (b), Section 431.114, Health and Safety Code, is amended to read as follows:

(b) A person shall not use in or on human beings or animals a new drug or new animal drug limited to investigational use unless the person has filed with the Federal Food and Drug Administration a completed and signed "Notice of claimed investigational exemption for a new drug" form in accordance with 21 C.F.R. 312.1 (1980) and the exemption has not been terminated. The drug shall be plainly labeled in compliance with Section 505(i) [~~or 507(d)~~] of the federal Act.

SECTION 7. This Act applies only to the dispensing of a drug as provided by Sections 431.112 and 431.113, Health and Safety Code, as amended by this Act, on or after the effective date of this

Act.

SECTION 8. (a) The change in law made by this Act applies only to an offense committed on or after the effective date of this Act. For purposes of this section, an offense is committed before the effective date of this Act if any element of the offense occurs before that date.

(b) An offense committed before the effective date of this Act is covered by the law in effect when the offense was committed, and the former law is continued in effect for that purpose.

SECTION 9. This Act takes effect September 1, 2003.

President of the Senate

Speaker of the House

I hereby certify that S.B. No. 1400 passed the Senate on April 25, 2003, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

I hereby certify that S.B. No. 1400 passed the House on May 6, 2003, by a non-record vote.

Chief Clerk of the House

Approved:

Date

Governor