

HEALTH AND SAFETY CODE CHAPTER 431. TEXAS FOOD, DRUG, AND COSMETIC ACT

HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES

SUBTITLE A. FOOD AND DRUG HEALTH REGULATIONS

CHAPTER 431. TEXAS FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 431.001. SHORT TITLE. This chapter may be cited as the Texas Food, Drug, and Cosmetic Act.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.002. DEFINITIONS. In this chapter:

(1) "Advertising" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(2) "Animal feed," as used in Subdivision (23), in Section 512 of the federal Act, and in provisions of this chapter referring to those paragraphs or sections, means an article intended for use as food for animals other than man as a substantial source of nutrients in the diet of the animals. The term is not limited to a mixture intended to be the sole ration of the animals.

(3) "Authorized agent" means an employee of the department who is designated by the commissioner to enforce the provisions of this chapter.

(4) "Board" means the Texas Board of Health.

(5) "Butter" means the food product usually known as butter that is made exclusively from milk or cream, or both, with or without common salt or additional coloring matter, and containing not less than 80 percent by weight of milk fat, after allowing for all tolerances.

(6)(A) "Color additive" means a material that:

(i) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or

other source; and

(ii) when added or applied to a food, drug, or cosmetic, or to the human body or any part of the human body, is capable, alone or through reaction with other substance, of imparting color. The term does not include any material exempted under the federal Act.

(B) "Color" includes black, white, and intermediate grays.

(C) Paragraph (A) does not apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(7) "Commissioner" means the commissioner of health.

(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 The Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.);

(C) a drug subject to the provisions of Section 431.113(c)(1) or 431.112(j), or Section 503(b)(1) 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.

(9) "Contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

(10) "Cosmetic" means articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part of the human body for cleaning, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of those articles. The term does not include soap.

(11) "Counterfeit drug" means a drug, or the container or labeling of a drug, that, without authorization, bears the trademark, trade name or other identifying mark, imprint, or device of a drug manufacturer, processor, packer, or distributor other than the person who in fact manufactured, processed, packed, or distributed the drug, and that falsely purports or is represented to be the product of, or to have been packed or distributed by, the other drug manufacturer, processor, packer, or distributor.

(12) "Department" means the Texas Department of Health.

(13) "Device," except when used in Sections 431.003, 431.021(1), 431.082(g), 431.112(c) and 431.142(c), means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is:

(A) recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(C) intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not

dependent on metabolization for the achievement of any of its principal intended purposes.

(14) "Drug" means articles recognized in the official United States Pharmacopoeia National Formulary, or any supplement to it, articles designed or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, articles, other than food, intended to affect the structure or any function of the body of man or other animals, and articles intended for use as a component of any article specified in this subdivision. The term does not include devices or their components, parts, or accessories. A food for which a claim is made in accordance with Section 403(r) of the federal Act, and for which the claim is approved by the secretary, is not a drug solely because the label or labeling contains such a claim.

(15) "Federal Act" means the Federal Food, Drug and Cosmetic Act (Title 21 U.S.C. 301 et seq.).

(16) "Food" means:

- (A) articles used for food or drink for man;
- (B) chewing gum; and
- (C) articles used for components of any such article.

(17) "Food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include:

- (A) a pesticide chemical in or on a raw agricultural commodity;

(B) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity;

(C) a color additive;

(D) any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, Pub. L. No. 85-929, 52 Stat. 1041 (codified as amended in various sections of 21 U.S.C.), pursuant to the federal Act, the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) or the Meat Inspection Act of 1907 (21 U.S.C. 603); or

(E) a new animal drug.

(18) "Health authority" means a physician designated to administer state and local laws relating to public health.

(19) "Immediate container" does not include package liners.

(20) "Infant formula" means a food that is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

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

(22) "Labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(23) "Manufacture" means:

(A) the process of combining or purifying food or packaging food for sale to a person at wholesale or retail, and includes repackaging, labeling, or relabeling of any food;

(B) the process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing, or quality control of a drug or drug product, but does not

include compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Section 562.154, Occupations Code;

(C) the process of preparing, fabricating, assembling, processing, packing, repacking, labeling, or relabeling a device; or

(D) the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.

(24) "New animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed:

(A) the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of the drug (except that such an unrecognized drug is not deemed to be a "new animal drug" if at any time before June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, and if at that time its labeling contained the same representations concerning the conditions of its use);

(B) the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under those conditions, has become recognized but that has not, otherwise than in the investigations, been used to a material extent or for a material time under those conditions; or

(C) is composed wholly or partly of penicillin, streptomycin, chlorotetracycline, chloramphenicol, or bacitracin, or any derivative of those substances, unless:

(i) a published order of the secretary is in effect that declares the drug not to be a new animal drug on the grounds that the requirement of certification of batches of the drug, as provided by Section 512(n) of the federal Act, is not necessary to ensure that the objectives specified in Section

512(n)(3) of that Act are achieved; and

(ii) Paragraph (A) or (B) of this subdivision does not apply to the drug.

(25) "New drug" means:

(A) any drug, except a new animal drug, the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof (except that such an unrecognized drug is not a "new drug" if at any time before May 26, 1985, it was subject to the Food and Drug Act of June 30, 1906, and if at that time its labeling contained the same representations concerning the conditions of its use); or

(B) any drug, except a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(26) "Official compendium" means the official United States Pharmacopoeia National Formulary, or any supplement to it.

(27) "Package" means any container or wrapping in which a consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers. The term includes wrapped meats enclosed in papers or other materials as prepared by the manufacturers thereof for sale. The term does not include:

(A) shipping containers or wrappings used solely for the transportation of a consumer commodity in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors;

(B) shipping containers or outer wrappings used by retailers to ship or deliver a commodity to retail customers if the containers and wrappings do not bear printed matter relating to any particular commodity; or

(C) containers subject to the provisions of the

Standard Barrel Act (Apple Barrels) (15 U.S.C. 231, 21 U.S.C. 20) or the Standard Barrel Act (Fruits and Vegetables) (15 U.S.C. 234-236).

(28) "Person" includes individual, partnership, corporation, and association.

(29) "Pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is a "pesticide" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u)), as now in force or as amended, and that is used in the production, storage, or transportation of raw agricultural commodities.

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

(31) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(32) "Saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(33) "Safe" refers to the health of humans or animals.

(34) "Secretary" means the secretary of the United States Department of Health and Human Services.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 149, eff. Sept. 1, 1991; Acts 1991, 72nd Leg., ch. 539, Sec. 1, eff. Sept. 1, 1991; Acts 1993, 73rd Leg., ch. 459, Sec. 1, eff. Sept. 1, 1993; Acts 1997, 75th Leg., ch. 629, Sec. 1, eff. Sept. 1, 1997; Acts 2003, 78th Leg., ch. 111, Sec. 1, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 383, Sec. 1, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 982, Sec. 1, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 1099, Sec. 1, eff. Sept. 1, 2003.

Amended by:

Acts 2005, 79th Leg., Ch. 28, Sec. 5, eff. September 1, 2005.

Sec. 431.003. ARTICLE MISBRANDED BECAUSE OF MISLEADING LABELING OR ADVERTISING. If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or any combination of these, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof, or under such conditions of use as are customary or usual.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 150, eff. Sept. 1, 1991.

Sec. 431.004. REPRESENTATION OF DRUG AS ANTISEPTIC. The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that the drug is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.005. PROVISIONS REGARDING SALE OF FOOD, DRUGS, DEVICES, OR COSMETICS. The provisions of this chapter regarding the selling of food, drugs, devices, or cosmetics, shall be considered to include the manufacture, production, processing, packaging, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.006. CERTAIN COMBINATION PRODUCTS. If the United States Food and Drug Administration determines, with respect to a

product that is a combination of a drug and a device, that:

(1) the primary mode of action of the product is as a drug, a person who engages in wholesale distribution of the product is subject to licensure under Subchapter I; and

(2) the primary mode of action of the product is as a device, a distributor or manufacturer of the product is subject to licensure under Subchapter L.

Added by Acts 1999, 76th Leg., ch. 132, Sec. 1, eff. May 20, 1999.

Sec. 431.007. COMPLIANCE WITH OTHER LAW; MOLLUSCAN SHELLFISH. A person who is subject to this chapter and who handles molluscan shellfish, as that term is defined by Section 436.002, shall comply with Section 436.105.

Added by Acts 1999, 76th Leg., ch. 1298, Sec. 1, eff. June 18, 1999.

Renumbered from Sec. 431.006 by Acts 2001, 77th Leg., ch. 1420, Sec. 21.001(78), eff. Sept. 1, 2001.

Sec. 431.008. APPLICABILITY OF CHAPTER TO DISTRESSED OR RECONDITIONED MERCHANDISE AND CERTAIN LICENSED ENTITIES.

(a) This chapter applies to a food, drug, device, or cosmetic that is distressed merchandise for purposes of Chapter 432 or that has been subject to reconditioning in accordance with Chapter 432.

(b) Except as provided by Subsection (c), this chapter applies to the conduct of a person licensed under Chapter 432.

(c) A person who holds a license under Chapter 432 and is engaging in conduct within the scope of that license is not required to hold a license as a wholesale drug distributor under Subchapter I, a food wholesaler under Subchapter J, or a device distributor under Subchapter L.

Added by Acts 2001, 77th Leg., ch. 265, Sec. 1, eff. May 22, 2001.

Sec. 431.009. APPLICABILITY OF CHAPTER TO FROZEN DESSERTS.

(a) This chapter applies to a frozen dessert, an imitation frozen dessert, a product sold in semblance of a frozen dessert, or a mix for one of those products subject to Chapter 440. A frozen dessert, an imitation frozen dessert, a product sold in semblance of a frozen dessert, or a mix for one of those products is food for purposes of

this chapter.

(b) Except as provided by Subsection (c), this chapter applies to the conduct of a person licensed under Chapter 440.

(c) A person who holds a license under Chapter 440 related to the manufacturing of a product regulated under that chapter and is engaging in conduct within the scope of that license is not required to hold a license as a food manufacturer or food wholesaler under Subchapter J.

Added by Acts 2003, 78th Leg., ch. 112, Sec. 1, eff. Sept. 1, 2003.

Sec. 431.010. APPLICABILITY OF CHAPTER TO MILK AND MILK PRODUCTS. (a) This chapter applies to milk or a milk product subject to Chapter 435. Milk or a milk product is a food for purposes of this chapter.

(b) Except as provided by Subsection (c), this chapter applies to the conduct of a person who holds a permit under Chapter 435.

(c) A person who holds a permit under Chapter 435 related to the processing, producing, bottling, receiving, transferring, or transporting of Grade A milk or milk products and who is engaging in conduct within the scope of that permit is not required to hold a license as a food manufacturer or food wholesaler under Subchapter J.

Added by Acts 2003, 78th Leg., ch. 757, Sec. 1, eff. Sept. 1, 2003.

SUBCHAPTER B. PROHIBITED ACTS

Sec. 431.021. PROHIBITED ACTS. The following acts and the causing of the following acts within this state are unlawful and prohibited:

(a) the introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded;

(b) the adulteration or misbranding of any food, drug, device, or cosmetic in commerce;

(c) the receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(d) the distribution in commerce of a consumer commodity, if such commodity is contained in a package, or if there is affixed to that commodity a label that does not conform to the provisions of this chapter and of rules adopted under the authority of this chapter; provided, however, that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons:

(1) are engaged in the packaging or labeling of such commodities; or

(2) prescribe or specify by any means the manner in which such commodities are packaged or labeled;

(e) the introduction or delivery for introduction into commerce of any article in violation of Section 431.084, 431.114, or 431.115;

(f) the dissemination of any false advertisement;

(g) the refusal to permit entry or inspection, or to permit the taking of a sample or to permit access to or copying of any record as authorized by Sections 431.042-431.044; or the failure to establish or maintain any record or make any report required under Section 512(j), (l), or (m) of the federal Act, or the refusal to permit access to or verification or copying of any such required record;

(h) the manufacture within this state of any food, drug, device, or cosmetic that is adulterated or misbranded;

(i) the giving of a guaranty or undertaking referred to in Section 431.059, which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in this state from whom the person received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in Section 431.059, which guaranty or undertaking is false;

(j) the use, removal, or disposal of a detained or embargoed article in violation of Section 431.048;

(k) the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic,

if such act is done while such article is held for sale after shipment in commerce and results in such article being adulterated or misbranded;

(1)(1) forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this chapter or the regulations promulgated under the provisions of the federal Act;

(2) making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing on any drug or container or labeling thereof so as to render such drug a counterfeit drug;

(3) the doing of any act that causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug;

(m) the using by any person to the person's own advantage, or revealing, other than to the commissioner, an authorized agent, a health authority or to the courts when relevant in any judicial proceeding under this chapter, of any information acquired under the authority of this chapter concerning any method or process that as a trade secret is entitled to protection;

(n) the using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under Section 431.114 or Section 505, 515, or 520(g) of the federal Act, as the case may be, or that such drug or device complies with the provisions of such sections;

(o) the using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with Sections 431.042-431.044 or Section 704 of the federal Act;

(p) in the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer,

packer, or distributor of the drug to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter that is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal Act. Nothing in this subsection shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter;

(q)(1) placing or causing to be placed on any drug or device or container of any drug or device, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing;

(2) selling, dispensing, disposing of or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container of any drug or device, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by Subdivision (1) of this subsection; or

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

(r) dispensing or causing to be dispensed a different drug in place of the drug ordered or prescribed without the express permission in each case of the person ordering or prescribing;

(s) the failure to register in accordance with Section 510 of the federal Act, the failure to provide any information required by Section 510(j) or (k) of the federal Act, or the failure to provide a notice required by Section 510(j)(2) of the federal Act;

(t)(1) the failure or refusal to:

(A) comply with any requirement prescribed under Section 518 or 520(g) of the federal Act; or

(B) furnish any notification or other material or information required by or under Section 519 or 520(g) of the federal Act;

(2) with respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect;

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

(v) the failure to provide the notice required by Section 412(b) or 412(c), the failure to make the reports required by Section 412(d)(1)(B), or the failure to meet the requirements prescribed under Section 412(d)(2) of the federal Act;

(w) except as provided under Subchapter M of this chapter and Section 562.1085, Occupations Code, the acceptance by a person of an unused prescription or drug, in whole or in part, for the purpose of resale, after the prescription or drug has been originally dispensed, or sold;

(x) engaging in the wholesale distribution of drugs or operating as a distributor or manufacturer of devices in this state without obtaining a license issued by the department under Subchapter I, L, or N, as applicable;

(y) engaging in the manufacture of food in this state or operating as a warehouse operator in this state without having a license as required by Section 431.222 or operating as a food wholesaler in this state without having a license under Section 431.222 or being registered under Section 431.2211, as appropriate;

(z) unless approved by the United States Food and Drug Administration pursuant to the federal Act, the sale, delivery, holding, or offering for sale of a self-testing kit designed to indicate whether a person has a human immunodeficiency virus infection, acquired immune deficiency syndrome, or a related disorder or condition;

(aa) making a false statement or false representation in an

application for a license or in a statement, report, or other instrument to be filed with or requested by the department under this chapter;

(bb) failing to comply with a requirement or request to provide information or failing to submit an application, statement, report, or other instrument required by the department;

(cc) performing, causing the performance of, or aiding and abetting the performance of an act described by Subdivision (x);

(dd) purchasing or otherwise receiving a prescription drug from a pharmacy in violation of Section 431.411(a);

(ee) selling, distributing, or transferring a prescription drug to a person who is not authorized under state or federal law to receive the prescription drug in violation of Section 431.411(b);

(ff) failing to deliver prescription drugs to specified premises as required by Section 431.411(c);

(gg) failing to maintain or provide pedigrees as required by Section 431.412 or 431.413;

(hh) failing to obtain, pass, or authenticate a pedigree as required by Section 431.412 or 431.413;

(ii) the introduction or delivery for introduction into commerce of a drug or prescription device at a flea market;

(jj) the receipt of a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such a drug for payment or otherwise; or

(kk) the alteration, mutilation, destruction, obliteration, or removal of all or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 151, eff. Sept. 1, 1991; Acts 1991, 72nd Leg., ch. 539, Sec. 2, eff. Sept. 1, 1991; Acts 1993, 73rd Leg., ch. 440, Sec. 1, eff. Sept. 1, 1993; Acts 1995, 74th Leg., ch. 1047, Sec. 6, eff. Sept. 1, 1995; Acts 1997, 75th Leg., ch. 282, Sec. 1, eff. Sept. 1, 1997; Acts 2001, 77th Leg., ch. 262, Sec. 1, eff. Sept. 1, 2001; Acts 2001, 77th Leg., ch. 1138, Sec. 2,

eff. Jan. 1, 2002; Acts 2003, 78th Leg., ch. 198, Sec. 2.71, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 321, Sec. 2, eff. June 18, 2003; Acts 2003, 78th Leg., ch. 383, Sec. 2, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 982, Sec. 2, eff. Sept. 1, 2003.

Amended by:

Acts 2005, 79th Leg., Ch. 282, Sec. 3(i), eff. March 1, 2006.

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 1, eff. September 1, 2007.

Sec. 431.0211. EXCEPTION. Any provision of Section 431.021 that relates to a prescription drug does not apply to a prescription drug manufacturer, or an agent of a prescription drug manufacturer, who is obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

Added by Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 2, eff. September 1, 2007.

Sec. 431.022. OFFENSE: TRANSFER OF PRODUCT CONTAINING EPHEDRINE. (a) A person commits an offense if the person knowingly sells, transfers, or otherwise furnishes a product containing ephedrine to a person 17 years of age or younger, unless:

(1) the actor is:

(A) a practitioner or other health care provider licensed by this state who has obtained, as required by law, consent to the treatment of the person to whom the product is furnished; or

(B) the parent, guardian, or managing conservator of the person to whom the product is furnished;

(2) the person to whom the product is furnished has had the disabilities of minority removed for general purposes under Chapter 31, Family Code; or

(3) the product is a drug.

(b) An offense under this section is a Class C misdemeanor unless it is shown on the trial of the offense that the defendant has been previously convicted of an offense under this section, in which event the offense is a Class B misdemeanor.

(c) A product containing ephedrine that is not described in Subsection (a)(3) must be labeled in accordance with rules adopted

by the Texas Department of Health to indicate that sale to persons 17 years of age or younger is prohibited.

Added by Acts 1999, 76th Leg., ch. 151, Sec. 1, eff. Sept. 1, 1999.

Sec. 431.023. LIMITED EXEMPTION FOR DISTRESSED FOOD, DRUGS, DEVICES, OR COSMETICS. In relation to a food, drug, device, or cosmetic that is distressed merchandise for purposes of Chapter 432, Sections 431.021(a), (c), and (d) do not prohibit:

(1) the introduction or delivery for introduction into commerce of the merchandise for the purpose of reconditioning in accordance with Chapter 432 and not for sale to the ultimate consumer;

(2) the receipt in commerce of the merchandise for the purpose of reconditioning in accordance with Chapter 432 and not for sale to the ultimate consumer;

(3) the holding of merchandise for the purpose of reconditioning in accordance with Chapter 432 and not for resale to the ultimate consumer; or

(4) the reconditioning of the merchandise in accordance with Chapter 432.

Added by Acts 2001, 77th Leg., ch. 265, Sec. 2, eff. May 22, 2001.

SUBCHAPTER C. ENFORCEMENT

Sec. 431.041. DEFINITION. In this subchapter, "detained or embargoed article" means a food, drug, device, cosmetic, or consumer commodity that has been detained or embargoed under Section 431.048.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.042. INSPECTION. (a) To enforce this chapter, the commissioner, an authorized agent, or a health authority may, on presenting appropriate credentials to the owner, operator, or agent in charge:

(1) enter at reasonable times an establishment, including a factory or warehouse, in which a food, drug, device, or cosmetic is manufactured, processed, packed, or held for introduction into commerce or held after the introduction;

(2) enter a vehicle being used to transport or hold the food, drug, device, or cosmetic in commerce; or

(3) inspect at reasonable times, within reasonable limits, and in a reasonable manner, the establishment or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of this chapter.

(b) The inspection of an establishment, including a factory, warehouse, or consulting laboratory, in which a prescription drug or restricted device is manufactured, processed, packed, or held for introduction into commerce extends to any place or thing, including a record, file, paper, process, control, or facility, in order to determine whether the drug or device:

(1) is adulterated or misbranded;

(2) may not be manufactured, introduced into commerce, sold, or offered for sale under this chapter; or

(3) is otherwise in violation of this chapter.

(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), 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.

(d) An inspection under Subsection (b) shall be started and completed with reasonable promptness.

(e) This section does not apply to:

(1) a pharmacy that:

(A) complies with Subtitle J, Title 3, Occupations Code;

(B) regularly engages in dispensing prescription drugs or devices on prescriptions of practitioners licensed to administer the drugs or devices to their patients in the course of their professional practice; and

(C) does not, through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process a drug or device for sale other than in the regular course of its business of dispensing or selling drugs or devices at retail;

(2) a practitioner licensed to prescribe or administer a drug who manufactures, prepares, propagates, compounds, or processes the drug solely for use in the course of the practitioner's professional practice;

(3) a practitioner licensed to prescribe or use a device who manufactures or processes the device solely for use in the course of the practitioner's professional practice; or

(4) a person who manufactures, prepares, propagates, compounds, or processes a drug or manufactures or processes a device solely for use in research, teaching, or chemical analysis and not for sale.

(f) The board may exempt a class of persons from inspection under this section if the board finds that inspection as applied to the class is not necessary for the protection of the public health.

(g) An authorized agent or health authority who makes an inspection under this section to enforce the provisions of this chapter applicable to infant formula shall be permitted, at all reasonable times, to have access to and to copy and verify records:

(1) in order to determine whether the infant formula manufactured or held in the inspected facility meets the requirements of this chapter; or

(2) that are required by this chapter.

(h) An authorized agent or health authority who makes an inspection of an establishment, including a factory or warehouse, and obtains a sample during or on completion of the inspection and before leaving the establishment, shall give to the owner, operator, or the owner's or operator's agent a receipt describing

the sample.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 2001, 77th Leg., ch. 1420, Sec. 14.793, eff. Sept. 1, 2001; Acts 2003, 78th Leg., ch. 111, Sec. 2, eff. Sept. 1, 2003.

Sec. 431.043. ACCESS TO RECORDS. A person who is required to maintain records under this chapter or Section 519 or 520(g) of the federal Act or a person who is in charge or custody of those records shall, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times access to and to copy and verify the records.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.044. ACCESS TO RECORDS SHOWING MOVEMENT IN COMMERCE. (a) To enforce this chapter, a carrier engaged in commerce or other person receiving a food, drug, device, or cosmetic in commerce or holding a food, drug, device, or cosmetic received in commerce shall, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times to have access to and to copy all records showing:

(1) the movement in commerce of the food, drug, device, or cosmetic;

(2) the holding of the food, drug, device, or cosmetic after movement in commerce; and

(3) the quantity, shipper, and consignee of the food, drug, device, or cosmetic.

(b) The carrier or other person may not refuse access to and copying of the requested record if the request is accompanied by a written statement that specifies the nature or kind of food, drug, device, or cosmetic to which the request relates.

(c) Evidence obtained under this section or evidence that is directly or indirectly derived from the evidence obtained under this section may not be used in a criminal prosecution of the person from whom the evidence is obtained.

(d) A carrier is not subject to other provisions of this chapter because of the carrier's receipt, carriage, holding, or

delivery of a food, drug, device, or cosmetic in the usual course of business as a carrier.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.045. EMERGENCY ORDER. (a) The commissioner or a person designated by the commissioner may issue an emergency order, either mandatory or prohibitory in nature, in relation to the manufacture or distribution of a food, drug, device, or cosmetic in the department's jurisdiction if the commissioner or the person designated by the commissioner determines that:

(1) the manufacture or distribution of the food, drug, device, or cosmetic creates or poses an immediate and serious threat to human life or health; and

(2) other procedures available to the department to remedy or prevent the occurrence of the situation will result in unreasonable delay.

(b) The commissioner or a person designated by the commissioner may issue the emergency order without notice and hearing if the commissioner or a person designated by the commissioner determines this is practicable under the circumstances.

(c) If an emergency order is issued without a hearing, the department shall determine a time and place for a hearing at which the emergency order is affirmed, modified, or set aside. The hearing shall be held under the contested case provisions of Chapter 2001, Government Code, and the board's formal hearing rules.

(d) This section prevails over Sections 11.013 and 12.001. Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1997, 75th Leg., ch. 629, Sec. 4, eff. Sept. 1, 1997; Acts 2001, 77th Leg., ch. 262, Sec. 2, eff. Sept. 1, 2001.

Sec. 431.046. VIOLATION OF RULES. A violation of a rule adopted under this chapter is a violation of this chapter.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.047. VIOLATION; INJUNCTION. (a) The

commissioner, an authorized agent, or a health authority may petition the district court for a temporary restraining order to restrain a continuing violation of Subchapter B or a threat of a continuing violation of Subchapter B if the commissioner, authorized agent, or health authority finds that:

(1) a person has violated, is violating, or is threatening to violate Subchapter B; and

(2) the violation or threatened violation creates an immediate threat to the health and safety of the public.

(b) A district court, on petition of the commissioner, an authorized agent, or a health authority, and on a finding by the court that a person is violating or threatening to violate Subchapter B shall grant any injunctive relief warranted by the facts.

(c) Venue for a suit brought under this section is in the county in which the violation or threat of violation is alleged to have occurred or in Travis County.

(d) The commissioner and the attorney general may each recover reasonable expenses incurred in obtaining injunctive relief under this section, including investigative costs, court costs, reasonable attorney fees, witness fees, and deposition expenses. The expenses recovered by the commissioner are hereby appropriated to the department for the administration and enforcement of this chapter. The expenses recovered by the attorney general are hereby appropriated to the attorney general. Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 539, Sec. 3, eff. Sept. 1, 1991.

Sec. 431.048. DETAINED OR EMBARGOED ARTICLE. (a) The commissioner or an authorized agent shall affix to an article that is a food, drug, device, cosmetic, or consumer commodity a tag or other appropriate marking that gives notice that the article is, or is suspected of being, adulterated or misbranded and that the article has been detained or embargoed if the commissioner or the authorized agent finds or has probable cause to believe that the article:

(1) is adulterated;

(2) is misbranded so that the article is dangerous or fraudulent under this chapter; or

(3) violates Section 431.084, 431.114, or 431.115.

(b) The tag or marking on a detained or embargoed article must warn all persons not to use the article, remove the article from the premises, or dispose of the article by sale or otherwise until permission for use, removal, or disposal is given by the commissioner, the authorized agent, or a court.

(c) A person may not use a detained or embargoed article, remove a detained or embargoed article from the premises, or dispose of a detained or embargoed article by sale or otherwise without permission of the commissioner, the authorized agent, or a court. The commissioner or the authorized agent may permit perishable goods to be moved to a place suitable for proper storage.

(d) The commissioner or an authorized agent shall remove the tag or other marking from an embargoed or detained article if the commissioner or an authorized agent finds that the article is not adulterated or misbranded.

(e) The commissioner or an authorized agent may not detain or embargo an article, including an article that is distressed merchandise, that is in the possession of a person licensed under Chapter 432 and that is being held for the purpose of reconditioning in accordance with Chapter 432, unless the commissioner or an authorized agent finds or has probable cause to believe that the article cannot be adequately reconditioned in accordance with that chapter and applicable rules.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1997, 75th Leg., ch. 282, Sec. 2, eff. Sept. 1, 1997; Acts 2001, 77th Leg., ch. 265, Sec. 3, eff. May 22, 2001.

Sec. 431.049. REMOVAL ORDER FOR DETAINED OR EMBARGOED ARTICLE. (a) If the claimant of the detained or embargoed articles or the claimant's agent fails or refuses to transfer the articles to a secure place after the tag or other appropriate marking has been affixed as provided by Section 431.048, the commissioner or an authorized agent may order the transfer of the articles to one or more secure storage areas to prevent their

unauthorized use, removal, or disposal.

(b) The commissioner or an authorized agent may provide for the transfer of the article if the claimant of the article or the claimant's agent does not carry out the transfer order in a timely manner. The costs of the transfer shall be assessed against the claimant of the article or the claimant's agent.

(c) The claimant of the article or the claimant's agent shall pay the costs of the transfer.

(d) The commissioner may request the attorney general to bring an action in the district court in Travis County to recover the costs of the transfer. In a judgment in favor of the state, the court may award costs, attorney fees, court costs, and interest from the time the expense was incurred through the date the department is reimbursed.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 152, eff. Sept. 1, 1991; Acts 1997, 75th Leg., ch. 282, Sec. 3, eff. Sept. 1, 1997.

Sec. 431.0495. RECALL ORDERS. (a) In conjunction with the issuance of an emergency order under Section 431.045 or the detention or embargo of an article under Section 431.048, the commissioner may order a food, drug, device, cosmetic, or consumer commodity to be recalled from commerce.

(b) The commissioner's recall order may require the articles to be removed to one or more secure areas approved by the commissioner or an authorized agent.

(c) The recall order must be in writing and signed by the commissioner.

(d) The recall order may be issued before or in conjunction with the affixing of the tag or other appropriate marking as provided by Section 431.048(a) or in conjunction with the commissioner's issuance of an emergency order under Section 431.045.

(e) The recall order is effective until the order:

- (1) expires on its own terms;
- (2) is withdrawn by the commissioner;
- (3) is reversed by a court in an order denying

condemnation under Section 431.050; or

(4) is set aside at the hearing provided to affirm, modify, or set aside an emergency order under Section 431.045.

(f) The claimant of the articles or the claimant's agent shall pay the costs of the removal and storage of the articles removed.

(g) If the claimant or the claimant's agent fails or refuses to carry out the recall order in a timely manner, the commissioner may provide for the recall of the articles. The costs of the recall shall be assessed against the claimant of the articles or the claimant's agent.

(h) The commissioner may request the attorney general to bring an action in the district court of Travis County to recover the costs of the recall. In a judgment in favor of the state, the court may award costs, attorney fees, court costs, and interest from the time the expense was incurred through the date the department is reimbursed.

Added by Acts 1991, 72nd Leg., ch. 14, Sec. 153, eff. Sept. 1, 1991.

Sec. 431.050. CONDEMNATION. An action for the condemnation of an article may be brought before a court in whose jurisdiction the article is located, detained, or embargoed if the article is adulterated, misbranded, or in violation of Section 431.084, 431.114, or 431.115.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.051. DESTRUCTION OF ARTICLE. (a) A court shall order the destruction of a sampled article or a detained or embargoed article if the court finds that the article is adulterated or misbranded.

(b) After entry of the court's order, an authorized agent shall supervise the destruction of the article.

(c) The claimant of the article shall pay the cost of the destruction of the article.

(d) The court shall tax against the claimant of the article or the claimant's agent all court costs and fees, and storage and other proper expenses.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.052. CORRECTION BY PROPER LABELING OR PROCESSING.

(a) A court may order the delivery of a sampled article or a detained or embargoed article that is adulterated or misbranded to the claimant of the article for labeling or processing under the supervision of an agent of the commissioner or an authorized agent if:

(1) the decree has been entered in the suit;

(2) the costs, fees, and expenses of the suit have been paid;

(3) the adulteration or misbranding can be corrected by proper labeling or processing; and

(4) a good and sufficient bond, conditioned on the correction of the adulteration or misbranding by proper labeling or processing, has been executed.

(b) The claimant shall pay the costs of the supervision.

(c) The court shall order that the article be returned to the claimant and the bond discharged on the representation to the court by the commissioner or an authorized agent that the article no longer violates this chapter and that the expenses of the supervision are paid.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.053. CONDEMNATION OF PERISHABLE ARTICLES.

(a) The commissioner or an authorized agent shall immediately condemn or render by any means unsalable as human food an article that is a nuisance under Subsection (b) and that the commissioner or authorized agent finds in any room, building, or other structure or in a vehicle.

(b) Any meat, seafood, poultry, vegetable, fruit, or other perishable article is a nuisance if it:

(1) is unsound;

(2) contains a filthy, decomposed, or putrid substance; or

(3) may be poisonous or deleterious to health or otherwise unsafe.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.054. ADMINISTRATIVE PENALTY. (a) The commissioner may assess an administrative penalty against a person who violates Subchapter B or an order adopted or registration issued under this chapter.

(b) In determining the amount of the penalty, the commissioner shall consider:

- (1) the person's previous violations;
- (2) the seriousness of the violation;
- (3) any hazard to the health and safety of the public;
- (4) the person's demonstrated good faith; and
- (5) such other matters as justice may require.

(c) The penalty may not exceed \$25,000 a day for each violation.

(d) Each day a violation continues may be considered a separate violation.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 539, Sec. 4, eff. Sept. 1, 1991.

Sec. 431.055. ADMINISTRATIVE PENALTY ASSESSMENT PROCEDURE. (a) An administrative penalty may be assessed only after a person charged with a violation is given an opportunity for a hearing.

(b) If a hearing is held, the commissioner shall make findings of fact and shall issue a written decision regarding the occurrence of the violation and the amount of the penalty that may be warranted.

(c) If the person charged with the violation does not request a hearing, the commissioner may assess a penalty after determining that a violation has occurred and the amount of the penalty that may be warranted.

(d) After making a determination under this section that a penalty is to be assessed against a person, the commissioner shall issue an order requiring that the person pay the penalty.

(e) The commissioner may consolidate a hearing held under this section with another proceeding.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.056. PAYMENT OF ADMINISTRATIVE PENALTY. (a) Not later than the 30th day after the date an order finding that a violation has occurred is issued, the commissioner shall inform the person against whom the order is issued of the amount of the penalty for the violation.

(b) Not later than the 30th day after the date on which a decision or order charging a person with a penalty is final, the person shall:

(1) pay the penalty in full; or

(2) if the person seeks judicial review of the amount of the penalty, the fact of the violation, or both:

(A) send the amount of the penalty to the commissioner for placement in an escrow account; or

(B) post with the commissioner a bond for the amount of the penalty.

(c) A bond posted under this section must be in a form approved by the commissioner and be effective until all judicial review of the order or decision is final.

(d) A person who does not send money to the commissioner or post the bond within the period prescribed by Subsection (b) waives all rights to contest the violation or the amount of the penalty.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.057. REFUND OF ADMINISTRATIVE PENALTY. Not later than the 30th day after the date of a judicial determination that an administrative penalty against a person should be reduced or not assessed, the commissioner shall:

(1) remit to the person the appropriate amount of any penalty payment plus accrued interest; or

(2) execute a release of the bond if the person has posted a bond.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.058. RECOVERY OF ADMINISTRATIVE PENALTY BY ATTORNEY GENERAL. The attorney general at the request of the

commissioner may bring a civil action to recover an administrative penalty under this subchapter.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.0585. CIVIL PENALTY. (a) At the request of the commissioner, the attorney general or a district, county, or city attorney shall institute an action in district court to collect a civil penalty from a person who has violated Section 431.021.

(b) The civil penalty may not exceed \$25,000 a day for each violation. Each day of violation constitutes a separate violation for purposes of the penalty assessment.

(c) The court shall consider the following in determining the amount of the penalty:

(1) the person's history of any previous violations of Section 431.021;

(2) the seriousness of the violation;

(3) any hazard posed to the public health and safety by the violation; and

(4) demonstrations of good faith by the person charged.

(d) Venue for a suit brought under this section is in the city or county in which the violation occurred or in Travis County.

(e) A civil penalty recovered in a suit instituted by a local government under this section shall be paid to that local government.

Added by Acts 1991, 72nd Leg., ch. 14, Sec. 154, eff. Sept. 1, 1991.

Sec. 431.059. CRIMINAL PENALTY; DEFENSES. (a) A person commits an offense if the person violates any of the provisions of Section 431.021 relating to unlawful or prohibited acts. A first offense under this subsection is a Class A misdemeanor unless it is shown on the trial of an offense under this subsection that the defendant was previously convicted of an offense under this subsection, in which event the offense is a state jail felony. In a criminal proceeding under this section, it is not necessary to prove intent, knowledge, recklessness, or criminal negligence of the defendant beyond the degree of culpability, if any, stated in

Subsection (a-2) or Section 431.021, as applicable, to establish criminal responsibility for the violation.

(a-1) A person commits an offense if the person engages in the wholesale distribution of prescription drugs in violation of Subchapter N. An offense under this subsection is punishable by a fine not to exceed \$50,000.

(a-1) Repealed by Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 14.

(a-2) A person commits an offense if the person knowingly engages in the wholesale distribution of prescription drugs in violation of Subchapter N. An offense under this subsection is punishable by imprisonment for not more than 15 years, a fine not to exceed \$500,000, or both imprisonment and a fine.

(a-2) Repealed by Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 14.

(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) 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(1)(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(1)(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.

(c) A publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, is not liable under this section for the dissemination of the false advertisement, unless the person has refused, on the request of the commissioner to furnish the commissioner the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in this state who caused the person to disseminate the advertisement.

(d) A person is not subject to the penalties of Subsection (a) for a violation of Section 431.021 involving misbranded food if the violation exists solely because the food is misbranded under Section 431.082 because of its advertising, and a person is not

subject to the penalties of Subsection (a) for such a violation unless the violation is committed with the intent to defraud or mislead.

(e) It is an affirmative defense to prosecution under Subsection (a) that the conduct charged is exempt, in accordance with Section 431.023, from the application of Section 431.021.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 155, eff. Sept. 1, 1991; Acts 2001, 77th Leg., ch. 265, Sec. 4, eff. May 22, 2001; Acts 2003, 78th Leg., ch. 111, Sec. 3, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 383, Sec. 3, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 982, Sec. 3, eff. Sept. 1, 2003.

Amended by:

Acts 2005, 79th Leg., Ch. 282, Sec. 3(h), eff. March 1, 2006.

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 14.

Sec. 431.060. INITIATION OF PROCEEDINGS. (a) The attorney general, or a district, county, or municipal attorney to whom the commissioner, an authorized agent, or a health authority reports a violation of this chapter, shall initiate and prosecute appropriate proceedings without delay.

(b) The commissioner, the commissioner's authorized agent, or the attorney general may, as authorized by Section 307 of the federal Act, bring in the name of this state a suit for civil penalties or to restrain a violation of Section 401 or Section 403(b) through (i), (k), (q), or (r) of the federal Act if the food that is the subject of the proceedings is located in this state.

(c) The commissioner, the commissioner's authorized agent, or the attorney general may not bring a proceeding under Subsection (b):

(1) before the 31st day after the date on which the state has given notice to the secretary of its intent to bring a suit;

(2) before the 91st day after the date on which the state has given notice to the secretary of its intent to bring a suit if the secretary has, not later than the 30th day after receiving notice from the state, commenced an informal or formal

enforcement action pertaining to the food that would be the subject of the suit brought by the state; or

(3) if the secretary is diligently prosecuting a suit in court pertaining to that food, has settled a suit pertaining to that food, or has settled the informal or formal enforcement action pertaining to that food.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1993, 73rd Leg., ch. 459, Sec. 2, eff. Sept. 1, 1993.

Sec. 431.061. MINOR VIOLATION. This chapter does not require the commissioner, an authorized agent, or a health authority to report for prosecution or the institution of proceedings under this chapter a minor violation of this chapter if the commissioner, authorized agent, or health authority believes that the public interest is adequately served by a suitable written notice or warning.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

SUBCHAPTER D. FOOD

Sec. 431.081. ADULTERATED FOOD. A food shall be deemed to be adulterated:

(a) if:

(1) it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance the food shall not be considered adulterated under this subdivision if the quantity of the substance in the food does not ordinarily render it injurious to health; or

(2) it:

(A) bears or contains any added poisonous or added deleterious substance, other than one that is a pesticide chemical in or on a raw agricultural commodity, a food additive, a color additive, or a new animal drug which is unsafe within the meaning of Section 431.161; or

(B) is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 431.161(a); or

(C) is, or it bears or contains, any food

additive which is unsafe within the meaning of Section 431.161(a); provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under Section 431.161(a), and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of Section 431.161 and Section 409 of the federal Act, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of such residue in the processed food, when ready to eat, is not greater than the tolerance prescribed for the raw agricultural commodity; or

(D) is, or it bears or contains, a new animal drug, or a conversion product of a new animal drug, that is unsafe under Section 512 of the federal Act; or

(3) it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for foods; or

(4) it has been produced, prepared, packed or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome, or injurious to health; or

(5) it is, in whole or in part, the product of a diseased animal, an animal which has died otherwise than by slaughter, or an animal that has been fed upon the uncooked offal from a slaughterhouse; or

(6) its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect in accordance with Section 409 of the federal Act;

(b) if:

(1) any valuable constituent has been in whole or in

part omitted or abstracted therefrom; or

(2) any substance has been substituted wholly or in part therefor; or

(3) damage or inferiority has been concealed in any manner; or

(4) any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength or make it appear better or of greater value than it is; or

(5) it contains saccharin, dulcin, glucin, or other sugar substitutes except in dietary foods, and when so used shall be declared; or

(6) it be fresh meat and it contains any chemical substance containing sulphites, sulphur dioxide, or any other chemical preservative which is not approved by the United States Department of Agriculture, the Animal Plant Health Inspection Service (A.P.H.I.S.) or by rules of the board;

(c) if it is, or it bears or contains, a color additive that is unsafe under Section 431.161(a); or

(d) if it is confectionery and:

(1) has any nonnutritive object partially or completely imbedded in it; provided, that this subdivision does not apply if, in accordance with rules of the board, the object is of practical, functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol, other than alcohol not in excess of five percent by volume. Any confectionery that bears or contains any alcohol in excess of one-half of one percent by volume derived solely from the use of flavoring extracts and less than five percent by volume:

(A) may not be sold to persons under the legal age necessary to consume an alcoholic beverage in this state;

(B) must be labeled with a conspicuous, readily legible statement that reads, "Sale of this product to a person under the legal age necessary to consume an alcoholic beverage is prohibited";

(C) may not be sold in a form containing liquid

alcohol such that it is capable of use for beverage purposes as that term is used in the Alcoholic Beverage Code;

(D) may not be sold through a vending machine;

(E) must be labeled with a conspicuous, readily legible statement that the product contains not more than five percent alcohol by volume; and

(F) may not be sold in a business establishment which derives less than 50 percent of its gross sales from the sale of confectioneries; or

(3) bears or contains any nonnutritive substance; provided, that this subdivision does not apply to a nonnutritive substance that is in or on the confectionery by reason of its use for a practical, functional purpose in the manufacture, packaging, or storage of the confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of this chapter; and provided further, that the board may for the purpose of avoiding or resolving uncertainty as to the application of this subdivision, adopt rules allowing or prohibiting the use of particular nonnutritive substances.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1993, 73rd Leg., ch. 439, Sec. 1, eff. Sept. 1, 1993.

Sec. 431.082. MISBRANDED FOOD. A food shall be deemed to be misbranded:

(a) if its labeling is false or misleading in any particular or fails to conform with the requirements of Section 431.181;

(b) if, in the case of a food to which Section 411 of the federal Act applies, its advertising is false or misleading in a material respect or its labeling is in violation of Section 411(b)(2) of the federal Act;

(c) if it is offered for sale under the name of another food;

(d) if it is an imitation of another food, unless its label bears, in prominent type of uniform size, the word "imitation" and immediately thereafter the name of the food

imitated;

(e) if its container is so made, formed, or filled as to be misleading;

(f) if in 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, in a uniform location on the principal display panel of the label, of the quantity of the contents in terms of weight, measure, or numerical count; provided, that under this subsection reasonable variations shall be permitted, and exemptions as to small packages shall be established, by rules adopted by the board;

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

(h) if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by federal regulations or rules of the board as provided by Section 431.245, unless:

(1) it conforms to such definition and standard; and

(2) its label bears the name of the food specified in the definition and standard, and, in so far as may be required by those regulations or rules, the common names of ingredients, other than spices, flavoring, and coloring, present in such food;

(i) if it purports to be or is represented as:

(1) a food for which a standard of quality has been prescribed by federal regulations or rules of the board as provided by Section 431.245, and its quality falls below such standard unless its label bears, in such manner and form as those regulations or rules specify, a statement that it falls below such

standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by federal regulations or rules of the board as provided by Section 431.245, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as those regulations or rules specify, a statement that it falls below such standard;

(j) unless its label bears:

(1) the common or usual name of the food, if any;
and

(2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of the fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under Section 706(c) of the federal Act, other than those sold as such, may be designated as spices, flavorings, and colors, without naming each; provided that, to the extent that compliance with the requirements of this subdivision is impractical or results in deception or unfair competition, exemptions shall be established by rules of the board;

(k) if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the board determines to be, and by rule prescribed, as necessary in order to fully inform purchasers as to its value for such uses;

(l) if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; provided that, to the extent that compliance with the requirements of this subsection is impracticable, exemptions shall be established by rules of the board. The provisions of this subsection and Subsections (h) and (j) with respect to artificial coloring do not apply in the case of butter, cheese, and ice cream;

(m) if it is a raw agricultural commodity that is the produce of the soil and bears or contains a pesticide chemical

applied after harvest, unless the shipping container of the commodity bears labeling that declares the presence of the chemical in or on the commodity and the common or usual name and the function of the chemical, except that the declaration is not required while the commodity, after removal from the shipping container, is being held or displayed for sale at retail out of the container in accordance with the custom of the trade;

(n) if it is a product intended as an ingredient of another food and if used according to the directions of the purveyor will result in the final food product being adulterated or misbranded;

(o) if it is a color additive, unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to the color additive as may be contained in regulations issued under Section 706 of the federal Act;

(p) if its packaging or labeling is in violation of an applicable regulation issued under Section 3 or 4 of the Federal Poison Prevention Packaging Act of 1970 (15 U.S.C. 1491 et seq.);

(q) if it contains saccharin, unless its label and labeling and retail display comply with the requirements of Sections 403(o) and 403(p) of the federal Act;

(r) if it contains saccharin and is offered for sale, but not for immediate consumption, at a retail establishment, unless the retail establishment displays prominently, where the food is held for sale, notice that is provided by the manufacturer of the food under Section 403(o)(2) of the federal Act for consumers concerning the information required by Section 403(p) of the federal Act to be on food labels and labeling;

(s)(1) if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides:

(A)(i) the serving size that is an amount customarily consumed and that is expressed in a common household measure that is appropriate to the food; or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food;

(B) the number of servings or other units of measure per container;

(C) the total number of calories in each serving size or other unit of measure that are:

(i) derived from any source; and

(ii) derived from fat;

(D) the amount of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugar, dietary fiber, and total protein contained in each serving size or other unit of measure; and

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under the federal Act; or

(2)(A) if it is a food distributed at retail in bulk display cases, or a food received in bulk containers, unless it has nutrition labeling prescribed by the secretary; and

(B) if the secretary determines it is necessary, nutrition labeling will be mandatory for raw fruits, vegetables, and fish, including freshwater or marine finfish, crustaceans, mollusks including shellfish, amphibians, and other forms of aquatic animal life, except that:

(3)(A) Subdivisions (1) and (2) do not apply to food:

(i) that is served in restaurants or other establishments in which food is served for immediate human consumption or that is sold for sale or use in those establishments;

(ii) that is processed and prepared primarily in a retail establishment, that is ready for human consumption, that is of the type described in Subparagraph (i), that is offered for sale to consumers but not for immediate human consumption in the establishment, and that is not offered for sale outside the establishment;

(iii) that is an infant formula subject to Section 412 of the federal Act;

(iv) that is a medical food as defined in Section 5(b) of the Orphan Drug Act (21 U.S.C. Section 360ee(b));
or

(v) that is described in Section 405, clause (2), of the federal Act;

(B) Subdivision (1) does not apply to the label of a food if the secretary determines by regulation that compliance with that subdivision is impracticable because the package of the food is too small to comply with the requirements of that subdivision and if the label of that food does not contain any nutrition information;

(C) if the secretary determines that a food contains insignificant amounts of all the nutrients required by Subdivision (1) to be listed in the label or labeling of food, the requirements of Subdivision (1) do not apply to the food if the label, labeling, or advertising of the food does not make any claim with respect to the nutritional value of the food, provided that if the secretary determines that a food contains insignificant amounts of more than half the nutrients required by Subdivision (1) to be in the label or labeling of the food, the amounts of those nutrients shall be stated in a simplified form prescribed by the secretary;

(D) if a person offers food for sale and has annual gross sales made or business done in sales to consumers that is not more than \$500,000 or has annual gross sales made or business done in sales of food to consumers that is not more than \$50,000, the requirements of this subsection do not apply to food sold by that person to consumers unless the label or labeling of food offered by that person provides nutrition information or makes a nutrition claim;

(E) if foods are subject to Section 411 of the federal Act, the foods shall comply with Subdivisions (1) and (2) in a manner prescribed by the rules; and

(F) if food is sold by a food distributor, Subdivisions (1) and (2) do not apply if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and the food distributor does not manufacture, process, or repackage the food it sells;

(t) if it is a food intended for human consumption and is offered for sale, and a claim is made on the label, labeling, or

retail display relating to the nutrient content or a nutritional quality of the food to a specific disease or condition of the human body, except as permitted by Section 403(r) of the federal Act; or

(u) if it is a food intended for human consumption and its label, labeling, and retail display do not comply with the requirements of Section 403(r) of the federal Act pertaining to nutrient content and health claims.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 156, eff. Sept. 1, 1991; Acts 1993, 73rd Leg., ch. 459, Sec. 3, eff. Sept. 1, 1993.

Sec. 431.083. FOOD LABELING EXEMPTIONS. (a) Except as provided by Subsection (c), the board shall adopt rules exempting from any labeling requirement of this chapter:

(1) small open containers of fresh fruits and fresh vegetables; and

(2) food that is in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on conditions that the food is not adulterated or misbranded under the provisions of this chapter when removed from the processing, labeling, or repacking establishment.

(b) Food labeling exemptions adopted under the federal Act apply to food in this state except as modified or rejected by rules adopted by the board.

(c) The board may not adopt rules under Subsection (a) to exempt foods from the labeling requirements of Sections 403(q) and (r) of the federal Act.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1993, 73rd Leg., ch. 459, Sec. 4, eff. Sept. 1, 1993.

Sec. 431.084. EMERGENCY PERMITS FOR FOODS CONTAMINATED WITH MICROORGANISMS. (a) The commissioner shall provide for the issuance of temporary permits to a manufacturer, processor, or packer of a class of food in any locality that provides conditions for the manufacture, processing, or packing for the class of food as necessary to protect the public health only if the commissioner

finds after investigation that:

(1) the distribution in this state of a class of food may, because the food is contaminated with microorganisms during the manufacture, processing, or packing of the food in any locality, be injurious to health; and

(2) the injurious nature of the food cannot be adequately determined after the food has entered commerce.

(b) The board by rule shall establish standards and procedures for the enforcement of this section.

(c) During the period for which permits are issued for a class of food determined by the commissioner to be injurious under Subsection (a), a person may not introduce or deliver for introduction into commerce the food unless the person is a manufacturer, processor, or packer who has a permit issued by the commissioner as authorized by rules adopted under this section.

(d) The commissioner may immediately suspend a permit issued under this section if a condition of the permit is violated. An immediate suspension is effective on notice to the permit holder.

(e) A holder of a permit that has been suspended may at any time apply for the reinstatement of the permit. Immediately after a hearing and an inspection of the permit holder's establishment, the commissioner shall reinstate the permit if adequate measures have been taken to comply with and maintain the conditions of the permit as originally issued or as amended.

(f) A permit holder shall provide access to the permit holder's factory or establishment to an authorized agent to allow the agent to determine whether the permit holder complies with the conditions of the permit. Denial of access is grounds for suspension of the permit until the permit holder freely provides the access.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

SUBCHAPTER E. DRUGS AND DEVICES

Sec. 431.111. ADULTERATED DRUG OR DEVICE. A drug or device shall be deemed to be adulterated:

(a)(1) if it consists in whole or in part of any filthy,

putrid, or decomposed substance; or

(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

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

(3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(4) if it:

(A) bears or contains, for purposes of coloring only, a color additive that is unsafe under Section 431.161(a); or

(B) is a color additive, the intended use of which in or on drugs or devices is for purposes of coloring only, and is unsafe under Section 431.161(a); or

(5) if it is a new animal drug that is unsafe under Section 512 of the federal Act;

(b) if it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under the authority of the federal Act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standards of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. 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;

(c) if it is not subject to the provision of Paragraph (b) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess;

(d) if it is a drug and any substance has been:

(1) mixed or packed therewith so as to reduce its quality or strength; or

(2) substituted wholly or in part therefor;

(e) if it is, or purports to be or is represented as, a device that is subject to a performance standard established under Section 514 of the federal Act, unless the device is in all respects in conformity with the standard;

(f)(1) if it is a class III device:

(A)(i) that is required by a regulation adopted under Section 515(b) of the federal Act to have an approval under that section of an application for premarket approval and that is not exempt from Section 515 as provided by Section 520(g) of the federal Act; and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the United States Food and Drug Administration by the 90th day after the date of adoption of the regulation; or

(II) for which that application was filed and approval was denied or withdrawn, for which that notice was filed and was declared incomplete, or for which approval of the device under the protocol was withdrawn;

(B) that was classified under Section 513(f) of the federal Act into class III, which under Section 515(a) of the federal Act is required to have in effect an approved application for premarket approval, that is not exempt from Section 515 as provided by Section 520(g) of the federal Act, and that does not have the application in effect; or

(C) that was classified under Section 520(l) of the federal Act into class III, which under that section is required to have in effect an approved application under Section 515 of the

federal Act, and that does not have the application in effect, except that:

(2)(A) in the case of a device classified under Section 513(f) of the federal Act into class III and intended solely for investigational use, Subdivision (1)(B) does not apply to the device during the period ending on the 90th day after the date of adoption of the regulations prescribing the procedures and conditions required by Section 520(g)(2) of the federal Act; and

(B) in the case of a device subject to a regulation adopted under Section 515(b) of the federal Act, Subdivision (1) does not apply to the device during the period ending on whichever of the following dates occurs later:

(i) the last day of the 30-day calendar month beginning after the month in which the classification of the device into class III became effective under Section 513 of the federal Act; or

(ii) the 90th day after the date of adoption of the regulation;

(g) if it is a banned device;

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

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

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1993, 73rd Leg., ch. 440, Sec. 2, eff. Sept. 1, 1993.

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)(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) 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) 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) as to the name by which the drug or its ingredients shall be designated, the requirements of Subsection (d) prevail;

(g) 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) 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) 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) 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);

(k) 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), 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); 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;

(l) 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;

(m) 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 Poison Prevention Packaging Act of 1970 (15 U.S.C. 1472 or 1473);

(n) 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;

(o) 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;

(p) 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;

(q) 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

(r) 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.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1997, 75th Leg., ch. 282, Sec. 4, eff. Sept. 1, 1997; Acts 2003, 78th Leg., ch. 111, Sec. 4, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 1099, Sec. 2, eff. Sept. 1, 2003.

Sec. 431.113. EXEMPTION FOR CERTAIN DRUGS AND DEVICES.

(a) The board is directed to adopt rules exempting from any labeling or packaging requirement of this chapter drugs and devices that are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at

establishments other than those where originally processed or packaged on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter on removal from such processing, labeling, or repacking establishment.

(b) Drugs and device labeling or packaging exemptions adopted under the federal Act shall apply to drugs and devices in this state except insofar as modified or rejected by rules of the board.

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

(A) 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) 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), and (h)(3), and the packaging requirements of Sections 431.112(f), (g), and (m), 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) 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." 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.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 2003, 78th Leg., ch. 111, Sec. 5, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 1099, Sec. 3, eff. Sept. 1, 2003.

Sec. 431.114. NEW DRUGS. (a) A person shall not sell, deliver, offer for sale, hold for sale or give away any new drug unless:

(1) an application with respect thereto has been approved and the approval has not been withdrawn under Section 505 of the federal Act; and

(2) a copy of the letter of approval or approvability issued by the Federal Food and Drug Administration is on file with the commissioner if the product is manufactured in this state.

(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) of the federal Act.

(c) This section shall not apply:

(1) to any drug that is not a new drug as defined in the federal Act;

(2) to any drug that is licensed under the Public Health Services Act of July 1, 1944 (42 U.S.C. 201 et seq.); or

(3) to any drug approved by the commissioner by the authority of any prior law.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 157, eff. Sept. 1, 1991; Acts 2003, 78th Leg., ch. 111, Sec. 6, eff. Sept. 1, 2003.

Sec. 431.115. NEW ANIMAL DRUGS. (a) A new animal drug shall, with respect to any particular use or intended use of the drug, be deemed unsafe for the purposes of this chapter unless:

(1) there is in effect an approval of an application filed pursuant to Section 512(b) of the federal Act with respect to the use or intended use of the drug; and

(2) the drug, its labeling, and the use conforms to the approved application.

(b) A new animal drug shall not be deemed unsafe for the purposes of this chapter if the article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under Section 512(j) of the federal Act.

(c) This section does not apply to any drug:

(1) licensed under the virus-serum-toxin law of March 4, 1913 (21 U.S.C. 151-159);

(2) approved by the United States Department of Agriculture; or

(3) approved by the commissioner by the authority of any prior law.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 158, eff. Sept. 1, 1991.

Sec. 431.116. AVERAGE MANUFACTURER PRICE. (a) In this section, "average manufacturer price" has the meaning assigned by 42 U.S.C. Section 1396r-8(k), as amended.

(b) A person who manufactures a drug, including a person who manufactures a generic drug, that is sold in this state shall file with the department:

(1) the average manufacturer price for the drug; and

(2) the price that each wholesaler in this state pays the manufacturer to purchase the drug.

(c) The information required under Subsection (b) must be filed annually or more frequently as determined by the department.

(d) The department and the attorney general may investigate the manufacturer to determine the accuracy of the information provided under Subsection (b). The attorney general may take action to enforce this section.

(e) Repealed by Acts 2005, 79th Leg., Ch. 349, Sec. 29, eff. September 1, 2007.

(f) Notwithstanding any other state law, pricing information disclosed by manufacturers or labelers under this section may be provided by the department only to the Medicaid vendor drug purchase program for its sole use. The Medicaid vendor drug purchase program may use the information only as necessary to administer its drug programs, including Medicaid drug programs.

(g) Notwithstanding any other state law, pricing information disclosed by manufacturers or labelers under this section is confidential and, except as necessary to permit the attorney general to enforce state and federal laws, may not be disclosed by the Health and Human Services Commission or any other state agency in a form that discloses the identity of a specific manufacturer or labeler or the prices charged by a specific manufacturer or labeler for a specific drug.

(h) The attorney general shall treat information obtained under this section in the same manner as information obtained by the attorney general through a civil investigative demand under Section 36.054, Human Resources Code.

(i) Notwithstanding any other state law, the penalties for unauthorized disclosure of confidential information under Chapter 552, Government Code, apply to unauthorized disclosure of confidential information under this section.

Added by Acts 2001, 77th Leg., ch. 1003, Sec. 2, eff. Sept. 1, 2001.

Amended by Acts 2003, 78th Leg., ch. 198, Sec. 2.199, eff. Sept. 1, 2003.

Amended by:

Acts 2005, 79th Leg., Ch. 349, Sec. 29, eff. September 1,

2007.

Sec. 431.117. PRIORITY FOR HEALTH CARE PROVIDERS IN DISTRIBUTION OF INFLUENZA VACCINE. The executive commissioner of the Health and Human Services Commission shall study the wholesale distribution of influenza vaccine in this state to determine the feasibility of implementing a system that requires giving a priority in filling orders for influenza vaccine to physicians and other licensed health care providers authorized to administer influenza vaccine over retail establishments. The executive commissioner may implement such a system if it is determined to be feasible.

Added by Acts 2007, 80th Leg., R.S., Ch. 922, Sec. 2, eff. June 15, 2007.

SUBCHAPTER F. COSMETICS

Sec. 431.141. ADULTERATED COSMETIC. A cosmetic shall be deemed to be adulterated:

(a) if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual; provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon; "Caution: This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness"; and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this subsection and Subsection (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes;

(b) if it consists in whole or in part of any filthy, putrid, or decomposed substance;

(c) if it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to

health;

(d) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(e) if it is not a hair dye and it is, or it bears or contains, a color additive that is unsafe within the meaning of Section 431.161(a).

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.142. MISBRANDED COSMETIC. (1) A cosmetic shall be deemed to be misbranded:

(a) if:

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

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

(b) if in 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, which statement shall be separately and accurately stated in a uniform location on the principal display panel of the label; provided, that under Subdivision (2) reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by rules adopted by the board;

(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 its container is so made, formed, or filled as to be misleading;

(e) if it is a color additive, unless its packaging and labeling are in conformity with the packaging and labeling requirements, applicable to the color additive, prescribed under

Section 706 of the federal Act. This subsection shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes, as defined by Section 431.141(a); or

(f) if its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 3 or 4 of the Federal Poison Prevention Packaging Act of 1970 (15 U.S.C. 1472 or 1473).

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

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 159, eff. Sept. 1, 1991.

SUBCHAPTER G. POISONOUS OR DELETERIOUS SUBSTANCES

Sec. 431.161. POISONOUS OR DELETERIOUS SUBSTANCES.

(a) Any poisonous or deleterious substance, food additive, pesticide chemical in or on a raw agricultural commodity, or color additive shall, with respect to any particular use or intended use, be deemed unsafe for the purpose of Section 431.081(a)(2) with respect to any food, Section 431.111(a) with respect to any drug or device, or Section 431.141 with respect to any cosmetic. However, if a rule adopted under Section 431.181 or Subsection (b) is in effect that limits the quantity of that substance, and if the use or intended use of that substance conforms to the terms prescribed by the rule, a food, drug, or cosmetic shall not, by reason of bearing or containing that substance in accordance with the rules, be considered adulterated within the meaning of Section 431.081(a)(1), 431.111, or 431.141.

(b) The board, whenever public health or other considerations in the state so require or on the petition of an interested party, may adopt rules prescribing tolerances for any added, poisonous, or deleterious substances, food additives, pesticide chemicals in or on raw agricultural commodities, or color additives, including zero tolerances and exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities. The rule may prescribe the conditions under which a food additive or a color additive may be safely used and may prescribe exemptions if the food additive or color additive is to be used solely for investigational or experimental purposes. Rules adopted under this section limiting the quantity of poisonous or deleterious substances in food must provide equal or stricter standards than those adopted by the federal Food and Drug Administration or its successor. A person petitioning for the adoption of a rule shall establish by data submitted to the board that a necessity exists for the rule and that its effect will not be detrimental to the public health. If the data furnished by the petitioner are not sufficient to allow the board to determine whether the rules should be adopted, the board may require additional data to be submitted. The petitioner's failure to comply with the request is sufficient grounds to deny the request. In adopting rules relating to those substances, the board shall consider, among other relevant factors, the following information furnished by the petitioner, if any:

(1) the name and all pertinent information concerning the substance, including, if available, its chemical identity and composition, a statement of the conditions of the proposed use, directions, recommendations, and suggestions, specimens of proposed labeling, all relevant data bearing on the physical or other technical effect, and the quantity required to produce that effect;

(2) the probable composition of any substance formed in or on a food, drug, or cosmetic resulting from the use of that substance;

(3) the probable consumption of that substance in the diet of man and animals, taking into account any chemically or

pharmacologically related substance in the diet;

(4) safety factors that, in the opinion of experts qualified by scientific training and experience to evaluate the safety of those substances for the use or uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data;

(5) the availability of any needed practicable methods of analysis for determining the identity and quantity of:

(A) that substance in or on an article;

(B) any substance formed in or on an article because of the use of that substance; and

(C) the pure substance and all intermediates and impurities; and

(6) facts supporting a contention that the proposed use of that substance will serve a useful purpose.

(c) Notwithstanding Sections 11.013 and 12.001, the commissioner may adopt emergency rules under Chapter 2001, Government Code to establish tolerance levels of poisonous or deleterious substances in food.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995.

SUBCHAPTER H. FAIR PACKAGING AND LABELING; FALSE ADVERTISING

Sec. 431.181. FAIR PACKAGING AND LABELING. (a) All labels of consumer commodities, as defined by this chapter, shall conform with the requirements for the declaration of net quantity of contents of Section 4 of the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.) and the regulations promulgated pursuant thereto; provided, that consumer commodities exempted from the requirements of Section 4 of the Fair Packaging and Labeling Act shall also be exempt from this subsection.

(b) The label of any package of a consumer commodity that bears a representation as to the number of servings of the commodity contained in the package shall bear a statement of the net quantity (in terms of weight, measure, or numerical count) of each serving.

(c) No person shall distribute or cause to be distributed in commerce any packaged consumer commodity if any qualifying words or

phrases appear in conjunction with the separate statement of the net quantity of contents required by Subsection (a), but nothing in this subsection shall prohibit supplemental statements at other places on the package describing in nondeceptive terms the net quantity of contents; provided, that the supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the commodity contained in the package.

(d) Whenever the board determines that rules containing prohibitions or requirements other than those prescribed by Subsection (a) are necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity, the board shall adopt with respect to that commodity rules effective to:

(1) establish and define standards for the characterization of the size of a package enclosing any consumer commodity, which may be used to supplement the label statement of net quantity of contents of packages containing such commodity, but this paragraph shall not be construed as authorizing any limitation on the size, shape, weight, dimensions, or number of packages that may be used to enclose any commodity;

(2) regulate the placement on any package containing any commodity, or on any label affixed to the commodity, of any printed matter stating or representing by implication that such commodity is offered for retail sale at a price lower than the ordinary and customary retail sale price or that a retail sale price advantage is accorded to purchasers thereof by reason of the size of that package or the quantity of its contents;

(3) require that the label on each package of a consumer commodity (other than one which is a food within the meaning of Section 431.002(15)) bear:

(A) the common or usual name of the consumer commodity, if any; and

(B) in case the consumer commodity consists of two or more ingredients, the common or usual name of each ingredient listed in order of decreasing predominance, but nothing in this paragraph shall be deemed to require that any trade secret be

divulged; or

(4) prevent the nonfunctional slack-fill of packages containing consumer commodities. For the purpose of this subdivision, a package shall be deemed to be nonfunctionally slack-filled if it is filled of substantially less than its capacity for reasons other than:

(A) protection of the contents of the package;

or

(B) the requirements of the machine used for enclosing the contents in the package.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.182. FALSE ADVERTISEMENT. (a) An advertisement of a food, drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(b) The advertising of a food that incorporates a health claim not in conformance with or defined by Section 403(r) of the federal Act is deemed to be false or misleading for the purposes of this chapter.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1993, 73rd Leg., ch. 386, Sec. 5, eff. Sept. 1, 1993.

Sec. 431.183. FALSE ADVERTISEMENT OF DRUG OR DEVICE.

(a) An advertisement of a drug or device is false if the advertisement represents that the drug or device affects:

(1) infectious and parasitic diseases;

(2) neoplasms;

(3) endocrine, nutritional, and metabolic diseases and immunity disorders;

(4) diseases of blood and blood-forming organs;

(5) mental disorders;

(6) diseases of the nervous system and sense organs;

(7) diseases of the circulatory system;

(8) diseases of the respiratory system;

(9) diseases of the digestive system;

(10) diseases of the genitourinary system;

(11) complications of pregnancy, childbirth, and the

puerperium;

(12) diseases of the skin and subcutaneous tissue;

(13) diseases of the musculoskeletal system and connective tissue;

(14) congenital anomalies;

(15) certain conditions originating in the perinatal period;

(16) symptoms, signs, and ill-defined conditions; or

(17) injury and poisoning.

(b) Subsection (a) does not apply to an advertisement of a drug or device if the advertisement does not violate Section 431.182 and is disseminated:

(1) to the public for self-medication and is consistent with the labeling claims permitted by the federal Food and Drug Administration;

(2) only to members of the medical, dental, and veterinary professions and appears only in the scientific periodicals of those professions; or

(3) only for the purpose of public health education by a person not commercially interested, directly or indirectly, in the sale of the drug or device.

(c) The board by rule shall authorize the advertisement of a drug having a curative or therapeutic effect for a disease listed under Subsection (a) if the board determines that an advance in medical science has made any type of self-medication safe for the disease. The board may impose conditions and restrictions on the advertisement of the drug necessary in the interest of public health.

(d) This section does not indicate that self-medication for a disease other than a disease listed under Subsection (a) is safe or effective.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 160, eff. Sept. 1, 1991.

SUBCHAPTER I. WHOLESALE DISTRIBUTORS

OF NONPRESCRIPTION DRUGS

Sec. 431.201. DEFINITIONS. In this subchapter:

(1) "Nonprescription drug" means any drug that is not a prescription drug as defined by Section 431.401.

(2) "Place of business" means each location at which a drug for wholesale distribution is located.

(3) "Wholesale distribution" means distribution to a person other than a consumer or patient, and includes distribution by a manufacturer, repackager, own label distributor, broker, jobber, warehouse, or wholesaler.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Amended by:

Acts 2005, 79th Leg., Ch. 282, Sec. 3(b), eff. March 1, 2006.

Sec. 431.2011. APPLICABILITY OF SUBCHAPTER. This subchapter applies only to the wholesale distribution of nonprescription drugs.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(c), eff. March 1, 2006.

Sec. 431.202. LICENSE REQUIRED. (a) A person may not engage in wholesale distribution of nonprescription drugs in this state unless the person holds a wholesale drug distribution license issued by the department under this subchapter or Subchapter N.

(b) An applicant for a license under this subchapter must submit an application to the department on the form prescribed by the department or electronically on the TexasOnline Internet website.

(c) A license issued under this subchapter expires on the second anniversary of the date of issuance.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 161, eff. Sept. 1, 1991; Acts 1991, 72nd Leg., ch. 539, Sec. 5, eff. Sept. 1, 1991.

Amended by:

Acts 2005, 79th Leg., Ch. 282, Sec. 3(d), eff. March 1, 2006.

Text of section as repealed by Acts 2005, 79th Leg., R.S., Ch. 282,
Sec. 3 effective September 1, 2005

Sec. 431.2021. EXEMPTION FROM LICENSING.

Text of subsection as amended by Acts 2005, 79th Leg., R.S., Ch. 28,
Sec. 6

(a) A person who engages in wholesale distribution of prescription drugs in this state for use in humans is exempt from this subchapter if the person is exempt under:

(1) the Prescription Drug Marketing Act of 1987, as amended (21 U.S.C. Section 353(c)(3)(B));

(2) the regulations adopted by the secretary to administer and enforce that Act;

(3) the interpretations of that Act set out in the compliance policy manual of the United States Food and Drug Administration; or

(4) Section 562.154, Occupations Code.

(b) An exemption from the licensing requirements under this section does not constitute an exemption from the other provisions of this Act or the rules adopted by the board to administer and enforce this Act.

Added by Acts 1991, 72nd Leg., ch. 539, Sec. 6, eff. Sept. 1, 1991.

Amended by Acts 1993, 73rd Leg., ch. 375, Sec. 1, eff. June 2, 1993.

Amended by:

Acts 2005, 79th Leg., Ch. 28, Sec. 6, eff. September 1, 2005.

Acts 2005, 79th Leg., Ch. 282, Sec. 3(k), eff. September 1, 2005.

Sec. 431.203. CONTENTS OF LICENSE STATEMENT. The license statement must contain:

(1) the name under which the business is conducted;

(2) the address of each place of business that is licensed;

(3) the name and residence address of:

(A) the proprietor, if the business is a proprietorship;

(B) all partners, if the business is a partnership; or

(C) all principals, if the business is an

association;

(4) the date and place of incorporation, if the business is a corporation;

(5) the names and residence addresses of the individuals in an administrative capacity showing:

(A) the managing proprietor, if the business is a proprietorship;

(B) the managing partner, if the business is a partnership;

(C) the officers and directors, if the business is a corporation; or

(D) the persons in a managerial capacity, if the business is an association; and

(6) the residence address of an individual in charge of each place of business.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 539, Sec. 7, eff. Sept. 1, 1991.

Sec. 431.2031. EFFECT OF OPERATION IN OTHER JURISDICTIONS; REPORTS. (a) A person who engages in the wholesale distribution of drugs outside this state may engage in the wholesale distribution of drugs in this state if the person holds a license issued by the department.

(b) The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with this chapter and the minimum standards adopted under this chapter.

(c) The department may issue a license to a person who engages in the wholesale distribution of drugs outside this state to engage in the wholesale distribution of drugs in this state, if after an examination of the reports of the person's compliance history and current compliance record, the department determines that the person is in compliance with this subchapter and the board's rules.

(d) The department shall consider each licensing statement filed by a person who wishes to engage in wholesale distribution of drugs in this state on an individual basis.

Added by Acts 1991, 72nd Leg., ch. 539, Sec. 8, eff. Sept. 1, 1991.

Sec. 431.204. FEES. (a) The department shall collect fees for:

- (1) a license that is filed or renewed;
- (2) a license that is amended, including a notification of a change in the location of a licensed place of business required under Section 431.206; and
- (3) an inspection performed in enforcing this subchapter and rules adopted under this subchapter.

(b) The executive commissioner of the Health and Human Services Commission by rule shall set the fees in amounts that allow the department to recover the biennial expenditures of state funds by the department in:

- (1) reviewing and acting on a license;
- (2) amending and renewing a license;
- (3) inspecting a licensed facility; and
- (4) implementing and enforcing this subchapter, including a rule or order adopted or a license issued under this subchapter.

(c) Fees collected under this section shall be deposited to the credit of the food and drug registration fee account of the general revenue fund and appropriated to the department to carry out the administration and enforcement of this chapter.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 539, Sec. 9, eff. Sept. 1, 1991.

Amended by:

Acts 2005, 79th Leg., Ch. 282, Sec. 3(e), eff. March 1, 2006.

Sec. 431.206. CHANGE OF LOCATION OF PLACE OF BUSINESS.

(a) Not fewer than 30 days in advance of the change, the licensee shall notify the department in writing of the licensee's intent to change the location of a licensed place of business.

(b) The notice shall include the address of the new location, and the name and residence address of the individual in charge of the business at the new location.

(c) Not more than 10 days after the completion of the change of location, the licensee shall notify the department in writing to

confirm the completion of the change of location and provide verification of the information previously provided or correct and confirm any information that has changed since providing the notice of intent.

(d) The notice and confirmation required by this section are deemed adequate if the licensee sends the notices by certified mail, return receipt requested, to the central office of the department or submits them electronically through the TexasOnline Internet website.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 539, Sec. 9, eff. Sept. 1, 1991.

Amended by:

Acts 2005, 79th Leg., Ch. 282, Sec. 3(f), eff. March 1, 2006.

Sec. 431.207. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION OF LICENSE. (a) The commissioner of state health services may refuse an application for a license or may suspend or revoke a license if the applicant or licensee:

(1) has been convicted of a felony or misdemeanor that involves moral turpitude;

(2) is an association, partnership, or corporation and the managing officer has been convicted of a felony or misdemeanor that involves moral turpitude;

(3) has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) is an association, partnership, or corporation and the managing officer has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(5) has not complied with this chapter or the rules implementing this chapter;

(6) has violated Section 431.021(1)(3), relating to

the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(7) has violated Chapter 481 or 483;

(8) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or licensee to maintain; or

(9) fails to complete a license application or submits an application that contains false, misleading, or incorrect information or contains information that cannot be verified by the department.

(b) The executive commissioner of the Health and Human Services Commission by rule shall establish minimum standards required for the issuance or renewal of a license under this subchapter.

(c) The refusal to license an applicant or the suspension or revocation of a license by the department and the appeal from that action are governed by the procedures for a contested case hearing under Chapter 2001, Government Code.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 539, Sec. 9, eff. Sept. 1, 1991; Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995.

Amended by:

Acts 2005, 79th Leg., Ch. 282, Sec. 3(f), eff. March 1, 2006.

Sec. 431.208. REPORTING OF PURCHASE PRICE. (a) On the department's request, a person who engages in the wholesale distribution of drugs in this state shall file with the department information showing the actual price at which the wholesale distributor sells a particular drug to a retail pharmacy.

(b) The department shall adopt rules to implement this section.

(c) The department and the attorney general may investigate the distributor to determine the accuracy of the information provided under Subsection (a). The attorney general may take action to enforce this section.

(d) Repealed by Acts 2005, 79th Leg., Ch. 349, Sec. 29, eff.

September 1, 2007.

Added by Acts 2001, 77th Leg., ch. 1003, Sec. 3, eff. Sept. 1, 2001.

Amended by:

Acts 2005, 79th Leg., Ch. 349, Sec. 29, eff. September 1, 2007.

SUBCHAPTER J. FOOD MANUFACTURERS, FOOD WHOLESALERS, AND WAREHOUSE
OPERATORS

Sec. 431.221. DEFINITIONS. In this subchapter:

(1) "Place of business" means:

(A) each location where:

(i) a person manufactures food; or

(ii) food for wholesale is distributed; or

(B) a warehouse where food is stored.

(2) "Food manufacturer" means a person who combines, purifies, processes, or packages food for sale through a wholesale outlet. The term also includes a retail outlet that packages or labels food before sale and a person that represents itself as responsible for the purity and proper labeling of an article of food by labeling the food with the person's name and address. The term does not include a restaurant that provides food for immediate human consumption to a political subdivision or to a licensed nonprofit organization if the restaurant would not otherwise be considered a food manufacturer under this subdivision.

(3) "Food wholesaler" means a person who distributes food for resale, either through a retail outlet owned by that person or through sales to another person. The term "food wholesaler" shall not include:

(A) a commissary which distributes food primarily intended for immediate consumption on the premises of a retail outlet under common ownership;

(B) an establishment engaged solely in the distribution of nonalcoholic beverages in sealed containers; or

(C) a restaurant that provides food for immediate human consumption to a political subdivision or to a licensed nonprofit organization if the restaurant would not otherwise be considered a food wholesaler under this subdivision.

(4) Deleted by Acts 1997, 75th Leg., ch. 629, Sec. 2, eff. Sept. 1, 1997

(5) "Direct seller" means an individual:

(A) who is not affiliated with a permanent retail establishment and who engages in the business of:

(i) in-person sales of prepackaged nonperishable foods, including dietary supplements, to a buyer on a buy-sell basis, a deposit-commission basis, or a similar basis for resale in a home; or

(ii) sales of prepackaged nonperishable foods, including dietary supplements, in a home;

(B) who receives substantially all remuneration for a service, whether in cash or other form of payment, which is directly related to sales or other output, including the performance of the service, and not to the number of hours worked; and

(C) who performs services under a written contract between the individual and the person for whom the service is performed, and the contract provides that the individual is not treated as an employee with respect to federal tax purposes.

(6) "Licensed nonprofit organization" means an organization that is licensed under any statutory authority of the State of Texas and is exempt from federal income taxation under Section 501(a), Internal Revenue Code of 1986, and its subsequent amendments, as an organization described in Section 501(c)(3) of that code.

(7) "Warehouse operator" means a person that operates a warehouse where food is stored.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1993, 73rd Leg., ch. 713, Sec. 1, eff. Sept. 1, 1993; Acts 1995, 74th Leg., ch. 348, Sec. 1, eff. Aug. 28, 1995; Acts 1995, 74th Leg., ch. 1047, Sec. 1, eff. Sept. 1, 1995; Acts 1997, 75th Leg., ch. 629, Sec. 2, eff. Sept. 1, 1997; Acts 1997, 75th Leg., ch. 1378, Sec. 1, eff. Sept. 1, 1997; Acts 2003, 78th Leg., ch. 334, Sec. 1, eff. June 18, 2003; Acts 2003, 78th Leg., ch. 383, Sec. 5, eff. Sept. 1, 2003.

Amended by:

Acts 2005, 79th Leg., Ch. 728, Sec. 23.001(51), eff. September 1, 2005.

Sec. 431.2211. APPLICATION OF SUBCHAPTER. (a) A person is not required to hold a license under this subchapter if the person is:

(1) a person, firm, or corporation that only harvests, packages, washes, or ships raw fruits or vegetables;

(2) an individual who only sells prepackaged nonperishable foods, including dietary supplements, from a private home as a direct seller;

(3) a person who holds a license under Chapter 432 and who only engages in conduct within the scope of that license; or

(4) a restaurant that provides food for immediate human consumption to a political subdivision or to a licensed nonprofit organization if the restaurant would not otherwise be required to hold a license under this subchapter.

(a-1) A person is not required to hold a license under this subchapter if the person holds a license under Chapter 440 and is engaging in conduct within the scope of that license.

(a-2) A person is not required to hold a license under this subchapter if the person holds a permit under Chapter 435 related to the processing, producing, bottling, receiving, transferring, or transporting of Grade A milk or milk products and is engaging in conduct within the scope of that permit.

(b) An exemption from the licensing requirements prescribed by this subchapter does not exempt the person from other provisions prescribed by this subchapter or from rules adopted by the board to administer and enforce those provisions.

(c) This subchapter does not apply to the distribution of beverages in sealed containers by holders of licenses or permits issued under Chapter 19, 20, 21, 23, 64, or 65, Alcoholic Beverage Code. The provisions of the Alcoholic Beverage Code prevail to the extent of any conflict with this chapter.

(d) A food wholesaler is not required to obtain a license under this subchapter for a place of business if all of the food distributed from that place of business will be stored in a

warehouse licensed under this subchapter.

(e) A food wholesaler that is not required to obtain a license for a place of business under Subsection (d) shall register that place of business with the department. The department shall adopt rules for the registration of food wholesalers under this section.

Amended by Acts 1993, 73rd Leg., ch. 713, Sec. 1, eff. Sept. 1, 1993; Acts 1995, 74th Leg., ch. 348, Sec. 2, eff. Aug. 28, 1995; Acts 1997, 75th Leg., ch. 629, Sec. 3, eff. Sept. 1, 1997; Acts 1997, 75th Leg., ch. 1378, Sec. 2, eff. Sept. 1, 1997; Acts 2001, 77th Leg., ch. 262, Sec. 3, eff. Sept. 1, 2001; Acts 2003, 78th Leg., ch. 112, Sec. 2, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 334, Sec. 2, eff. June 18, 2003; Acts 2003, 78th Leg., ch. 383, Sec. 6, eff. Sept. 1, 2003; Acts 2003, 78th Leg., ch. 757, Sec. 2, eff. Sept. 1, 2003.

Sec. 431.222. LICENSE REQUIRED; LICENSING FEES.

(a) Except as provided by Section 431.2211, a food manufacturer, food wholesaler, or warehouse operator in this state must apply for and obtain from the department each year a license for each place of business that the food manufacturer, food wholesaler, or warehouse operator operates in this state. The food manufacturer, food wholesaler, or warehouse operator must pay a licensing fee for each establishment.

(b) The department shall require a food manufacturer that distributes only food manufactured by that firm to obtain only a license as a food manufacturer. A person that does not manufacture food and serves only as a food wholesaler must obtain only a food wholesaler's license. A person that distributes both its own manufactured food and food it does not manufacture must obtain only a food manufacturer's license. A warehouse operator who also distributes food is required to obtain only a warehouse operator license.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 162, eff. Sept. 1, 1991; Acts 1993, 73rd Leg., ch. 713, Sec. 1, eff. Sept. 1, 1993; Acts 2003, 78th Leg., ch. 383, Sec. 7, eff. Sept. 1, 2003.

Sec. 431.223. CONTENTS OF LICENSE APPLICATION. (a) The person applying for a license under this subchapter must provide, at a minimum, the following information in a license application:

(1) the name under which the food manufacturer, wholesale distributor, or warehouse operator conducts business;

(2) the address of each place of business in this state that is licensed;

(3) if the food manufacturer, wholesale distributor, or warehouse operator is an individual, a partnership, or an association, the name or names of:

(A) the proprietor, if the business is a sole proprietorship;

(B) all partners, if the business is a partnership; or

(C) all principals, if the business is an association;

(4) if the food manufacturer, wholesale distributor, or wholesale operator is a corporation, the date and place of incorporation and the name and address of its registered agent in this state;

(5) the names and residences of the individuals in an administrative capacity, showing:

(A) the managing proprietor, if the business is a sole proprietorship;

(B) the managing partner, if the business is a partnership;

(C) the officers and directors, if the business is a corporation; or

(D) the persons in a managerial capacity, if the business is an association; and

(6) the residence address of a person in charge of each place of business.

(b) The license application must be signed, verified, and filed on a form furnished by the department according to the rules adopted by the board.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended

by Acts 1993, 73rd Leg., ch. 713, Sec. 1, eff. Sept. 1, 1993; Acts 2003, 78th Leg., ch. 383, Sec. 8, eff. Sept. 1, 2003.

Sec. 431.224. FEES. (a) The board shall collect fees for:

- (1) a license that is filed or renewed;
- (2) a license that is amended, including a notification of a change in the location of a licensed place of business required under Section 431.2251; and
- (3) an inspection performed to enforce this subchapter and rules adopted under this subchapter.

(b) The board may charge annual fees.

(c) The board by rule shall set the fees in amounts that allow the department to recover at least 50 percent of the annual expenditures of state funds by the department in:

- (1) reviewing and acting on a license;
- (2) amending and renewing a license;
- (3) inspecting a licensed facility; and
- (4) implementing and enforcing this subchapter, including a rule or order adopted or a license issued under this subchapter.

(d) The department shall use not less than one-half of license fees collected for inspecting a licensed place of business or enforcing this subchapter, and the remainder for the administration of this subchapter.

(e) All license fees received by the department under this subchapter shall be deposited in the state treasury to the credit of the food and drug license fee fund.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 163, eff. Sept. 1, 1991; Acts 1993, 73rd Leg., ch. 713, Sec. 1, eff. Sept. 1, 1993.

Sec. 431.2245. PROCESSING OF LICENSING FEES. (a) The commissioner shall establish a system for processing licensing fees under this chapter, including vended water facility licensing fees.

(b) Under the fee processing system, the maximum time for processing a fee payment made by a negotiable instrument may not exceed 48 hours, beginning at the time that the negotiable

instrument is first received by the department and ending at the time that the fee payment is submitted for deposit by the department to the treasury division of the office of the comptroller.

(c) The comptroller shall cooperate with the commissioner in developing the fee processing system.

Added by Acts 1999, 76th Leg., ch. 697, Sec. 1, eff. Aug. 30, 1999.

Sec. 431.225. EXPIRATION DATE. (a) The board by rule may provide that licenses expire on different dates during the year.

(b) For the year in which the license expiration date is changed, license fees payable on or before September 1 shall be prorated so that each license holder pays only that portion of the license fee allocable to the number of months during which the license is valid. On renewal of the license on the new expiration date, the total license renewal fee is payable.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 164, eff. Sept. 1, 1991; Acts 1993, 73rd Leg., ch. 713, Sec. 1, eff. Sept. 1, 1993.

Sec. 431.2251. CHANGE IN LOCATION OF PLACE OF BUSINESS. Not later than the 31st day before the date of the change, the license holder shall notify in writing the commissioner or the commissioner's designee of the license holder's intent to change the location of a licensed place of business. The notice shall include the address of the new location and the name and residence address of the individual in charge of the place of business. Not later than the 10th day after the completion of the change of location, the license holder shall forward to the commissioner or the commissioner's designee the name and residence address of the individual in charge of the new place of business. Notice is considered adequate if the license holder provides the intent and verification notices to the commissioner or the commissioner's designee by certified mail, return receipt requested, mailed to the central office of the department.

Added by Acts 1993, 73rd Leg., ch. 713, Sec. 1, eff. Sept. 1, 1993.

Sec. 431.226. REFUSAL TO GRANT LICENSE; SUSPENSION OR

REVOCAION OF LICENSE. (a) The commissioner may refuse an application for a license or may suspend or revoke a license.

(b) The board by rule shall establish minimum standards for granting and maintaining a license.

(c) The refusal or the suspension or revocation of a license by the commissioner and the appeal from that action are governed by the procedures for a contested case hearing under Chapter 2001, Government Code.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1993, 73rd Leg., ch. 713, Sec. 1, eff. Sept. 1, 1993; Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995.

SUBCHAPTER K. GENERAL ADMINISTRATIVE PROVISIONS AND RULEMAKING
AUTHORITY

Sec. 431.241. RULEMAKING AUTHORITY. (a) The board may adopt rules for the efficient enforcement of this chapter.

(b) The board may conform its rules, if practicable, with regulations adopted under the federal Act.

(c) The enumeration of specific federal laws and regulations in Sections 431.244 and 431.245 does not limit the general authority granted to the board in Subsection (b) to conform its rules to those adopted under the federal Act.

(d) The board may adopt the federal regulations issued by the secretary pursuant to the Prescription Drug Marketing Act of 1987 (21 U.S.C. Sections 331, 333, 353, and 381), as necessary or desirable so that the state wholesale drug distributor licensing program in Subchapter I of this chapter may achieve compliance with that Act.

(e) The board and the Texas Department of Human Services shall not establish a drug formulary that restricts by any prior or retroactive approval process a physician's ability to treat a patient with a prescription drug that has been approved and designated as safe and effective by the United States Food and Drug Administration, in compliance with federal law and subject to review by the Texas Department of Human Services, Vendor Drug Advisory Subcommittee.

(f) Nothing in this section shall effect a prior approval

program in operation on the effective date of this section nor shall any portion of this chapter prohibit a prior approval process on any federally exempted products.

(g) The department may assess a fee for the issuance of a certificate of free sale and another certification issued under this chapter. The board by rule shall set each fee in an amount sufficient to recover the cost to the department of issuing the particular certificate.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 539, Sec. 11, eff. Sept. 1, 1991; Acts 1993, 73rd Leg., ch. 675, Sec. 7, eff. Sept. 1, 1993.

Sec. 431.242. CONTESTED CASE HEARINGS AND APPEALS. A hearing under this chapter or an appeal from a final administrative decision shall be conducted under Chapter 2001, Government Code.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995.

Sec. 431.243. PERSONS TO CONDUCT HEARINGS. The commissioner or an officer, agent, or employee designated by the commissioner shall conduct a hearing authorized or required under this chapter.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.244. FEDERAL REGULATIONS ADOPTED AS STATE RULES.

(a) A regulation adopted by the secretary under the federal Act concerning pesticide chemicals, food additives, color additives, special dietary use, processed low acid food, acidified food, infant formula, bottled water, or vended bottled water is a rule for the purposes of this chapter, unless the board modifies or rejects the rule.

(b) A regulation adopted under the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.) is a rule for the purposes of this chapter, unless the board modifies or rejects the rule. The board may not adopt a rule that conflicts with the labeling requirements for the net quantity of contents required under Section 4 of the Fair Packaging and Labeling Act (15 U.S.C. 1453)

and the regulations adopted under that Act.

(c) A regulation adopted by the secretary under Sections 403(b) through (i) of the federal Act is a rule for the purposes of this chapter unless the board modifies or rejects the rule. The board may not adopt a rule that conflicts with the limitations provided by Sections 403(q) and (r) of the federal Act.

(d) A federal regulation that this section provides as a rule for the purposes of this chapter is effective:

(1) on the date that the regulation becomes effective as a federal regulation; and

(2) whether or not the department has fulfilled the rulemaking provisions of Chapter 2001, Government Code.

(e) If the board modifies or rejects a federal regulation, the board shall comply with the rulemaking provisions of Chapter 2001, Government Code.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1991, 72nd Leg., ch. 539, Sec. 12, eff. Sept. 1, 1991; Acts 1993, 73rd Leg., ch. 459, Sec. 6, eff. Sept. 1, 1993; Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995.

Sec. 431.245. DEFINITION OR STANDARD OF IDENTITY, QUALITY, OR FILL OF CONTAINER. (a) A definition or standard of identity, quality, or fill of container of the federal Act is a definition or standard of identity, quality, or fill of container in this chapter, except as modified by board rules.

(b) The board by rule may establish definitions and standards of identity, quality, and fill of container for a food if:

(1) a federal regulation does not apply to the food; and

(2) the board determines that adopting the rules will promote honest and fair dealing in the interest of consumers.

(c) A temporary permit granted for interstate shipment of an experimental pack of food that varies from the requirements of federal definitions and standards of identity is automatically effective in this state under the conditions of the permit.

(d) The commissioner may issue additional permits if the commissioner determines that:

(1) it is necessary for the completion of an otherwise adequate investigation; and

(2) the interests of consumers are safeguarded.

(e) A permit issued under Subsection (d) is subject to the terms and conditions of board rules.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.246. REMOVAL OF ADULTERATED ITEM FROM STORES. The board shall adopt rules that provide a system for removing adulterated items from the shelves of a grocery store or other retail establishment selling those items.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.247. DELEGATION OF POWERS OR DUTIES. (a) The board by rule may delegate a power or duty imposed on the commissioner by this chapter to a designee of the board, including the power or duty to issue an emergency rule, an emergency manufacturing permit, or an order or to render a final administrative decision.

(b) A health authority may, unless otherwise restricted by law, delegate a power or duty imposed on the health authority by this chapter to an employee of the local health department, the local health unit, or the public health district in which the health authority serves.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.2471. TEXAS DEPARTMENT OF HEALTH PEACE OFFICERS.

(a) The department may employ a peace officer to administer and enforce this chapter.

(b) The department may not employ a peace officer under this section unless:

(1) the employee will enforce the food and drug portions of this chapter;

(2) the Commission on Law Enforcement Officer Standards and Education certifies the employee as qualified to be a peace officer;

(3) the commissioner recommends the employee to the

department as being qualified to enforce the food and drug laws within the jurisdiction of the department; and

(4) the employee also serves simultaneously as the director of the food and drugs division of the department.

(c) A person employed as a peace officer under this section has the powers, privileges, and immunities of a peace officer while carrying out the employee's duties under this chapter.

Added by Acts 1993, 73rd Leg., ch. 339, Sec. 1, eff. Sept. 1, 1993.

Sec. 431.248. MEMORANDUM OF UNDERSTANDING WITH DEPARTMENT OF AGRICULTURE. (a) The department and the Department of Agriculture shall execute a memorandum of understanding that:

(1) requires each agency to disclose to the other agency any positive results of testing conducted by the agency for pesticides in food; and

(2) specifies how each agency will assist the other in performing its duties regarding pesticides in food.

(b) The department and the Department of Agriculture shall adopt the memorandum of understanding as a rule.

(c) The department and the Department of Agriculture shall request the federal Food and Drug Administration to join in execution of the memorandum of understanding.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 431.249. DISSEMINATION OF INFORMATION. (a) The commissioner may publish reports summarizing the judgments, decrees, and court orders rendered under this chapter, including the nature and disposition of the charge.

(b) The commissioner may disseminate information regarding a food, drug, device, or cosmetic in a situation that the commissioner determines to involve imminent danger to health or gross deception of consumers.

(c) This section does not prohibit the commissioner from collecting, reporting, and illustrating the results of an investigation by the commissioner.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

SUBCHAPTER L. DEVICE DISTRIBUTORS AND MANUFACTURERS

Sec. 431.271. DEFINITIONS. In this subchapter:

(1) "Distributor" means a person who furthers the marketing of a finished domestic or imported device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. The term includes an importer or an own-label distributor. The term does not include a person who repackages a finished device or who otherwise changes the container, wrapper, or labelling of the finished device or the finished device package.

(2) "Finished device" means a device, or any accessory to a device, that is suitable for use, without regard to whether it is packaged or labelled for commercial distribution.

(3) "Importer" means any person who initially distributes a device imported into the United States.

(4) "Manufacturer" means a person who manufactures, fabricates, assembles, or processes a finished device. The term includes a person who repackages or relabels a finished device. The term does not include a person who only distributes a finished device.

(5) "Place of business" means each location at which a finished device is manufactured or held for distribution.

Added by Acts 1993, 73rd Leg., ch. 440, Sec. 3, eff. Sept. 1, 1993.
Amended by Acts 1995, 74th Leg., ch. 1047, Sec. 2, eff. Sept. 1, 1995.

Sec. 431.272. LICENSE REQUIRED; MINIMUM STANDARDS.

(a) Except as provided by Section 431.273, a person may not operate as a distributor or manufacturer of devices in this state unless the person has a license from the commissioner for each place of business.

(b) A distributor or manufacturer of devices in this state must comply with the minimum requirements specified in the federal Act and in this chapter.

Added by Acts 1993, 73rd Leg., ch. 440, Sec. 3, eff. Sept. 1, 1993.
Amended by Acts 1995, 74th Leg., ch. 1047, Sec. 2, eff. Sept. 1, 1995.

Sec. 431.273. EXEMPTION FROM LICENSING. (a) A person is exempt from licensing under this subchapter if the person engages only in the following types of device distribution:

- (1) intracompany sales;
- (2) distribution from a place of business located outside of this state; or
- (3) the sale, purchase, or trade of a distressed or reconditioned device by a salvage broker or a salvage operator licensed under Chapter 432 (Texas Food, Drug, Device, and Cosmetic Salvage Act).

(b) An exemption from the licensing requirements under this section does not constitute an exemption from the other provisions of this chapter or the rules adopted by the board to administer and enforce this chapter.

Added by Acts 1993, 73rd Leg., ch. 440, Sec. 3, eff. Sept. 1, 1993.
Amended by Acts 1995, 74th Leg., ch. 1047, Sec. 3, eff. Sept. 1, 1995.

Sec. 431.274. LICENSE APPLICATION. (a) A person applying for a license under this subchapter shall provide, at a minimum, the following information on a license application form furnished by the commissioner:

- (1) the name under which the business is conducted;
- (2) the address of each place of business that is licensed;
- (3) the name and residence address of:
 - (A) the proprietor, if the business is a proprietorship;
 - (B) all partners, if the business is a partnership; or
 - (C) all principals, if the business is an association;
- (4) the date and place of incorporation if the business is a corporation;
- (5) the names and residence addresses of the individuals in an administrative capacity showing:

(A) the managing proprietor, if the business is a proprietorship;

(B) the managing partner, if the business is a partnership;

(C) the officers and directors, if the business is a corporation; or

(D) the persons in a managerial capacity, if the business is an association; and

(6) the residence address of an individual in charge of each place of business.

(b) The license application must be signed, verified, and completed in a manner described in the rules adopted by the board.

(c) A person applying for a license under this subchapter must pay a licensing fee for each place of business.

Added by Acts 1993, 73rd Leg., ch. 440, Sec. 3, eff. Sept. 1, 1993.

Sec. 431.275. ADVISORY COMMITTEE. (a) The board shall appoint a committee to:

(1) advise the board in the development of standards and procedures relating to the licensing of distributors and manufacturers of devices under this subchapter;

(2) make recommendations to the board relating to the content of the rules adopted to implement this subchapter; and

(3) perform any other functions requested by the board in implementing and administering this subchapter.

(b) The advisory committee is composed of:

(1) one person representing a distributor of devices;

(2) two persons representing manufacturers of devices; and

(3) two public members.

(c) A person is not eligible for appointment as a public member if the person or the person's spouse:

(1) is licensed by an occupational regulatory agency in the health care field;

(2) is employed by a manufacturer or distributor of devices, by a health care facility, corporation, or agency, or by a corporation authorized to underwrite health care insurance;

(3) governs or administers a manufacturer or distributor of devices or a health care facility, corporation, or agency;

(4) has a financial interest, other than a consumer's interest, in a manufacturer or distributor of devices or a health care facility, corporation, or agency; or

(5) would qualify for appointment under Subsection (b)(1) or (2).

(d) The advisory committee members serve staggered three-year terms.

(e) A vacancy on the advisory committee is filled by the board in the same manner as other appointments to the advisory committee.

(f) A member of the advisory committee is not entitled to compensation, but is entitled to reimbursement of the member's travel expenses as provided in the General Appropriations Act for state employees.

(g) The advisory committee may elect a chair, vice chair, and secretary from among its members and may adopt rules for the conduct of its own activities.

(h) The advisory committee will have an opportunity to review and comment on the board's rules to carry out this subchapter before the rules are proposed.

Added by Acts 1993, 73rd Leg., ch. 440, Sec. 3, eff. Sept. 1, 1993.
Amended by Acts 1995, 74th Leg., ch. 1047, Sec. 4, eff. Sept. 1, 1995.

Sec. 431.276. FEES. (a) The department shall collect fees for:

(1) a license that is filed or renewed;

(2) a license that is amended, including notification of a change of location of a licensed place of business required under Section 431.278, a change of the name of an association or corporation, or a change in the ownership of the licensee; and

(3) an inspection performed to enforce this subchapter and rules adopted under this subchapter.

(b) The board may charge annual fees.

(c) The board by rule shall set the fees in amounts that allow the department to recover at least 50 percent of the annual expenditures of state funds by the department in:

- (1) reviewing and acting on a license or renewal license;
- (2) amending a license;
- (3) inspecting a licensed facility; and
- (4) implementing and enforcing this subchapter, including a rule or order adopted or a license issued under this subchapter.

(d) At least half of the licensing fees collected shall be used to inspect an applicant or licensed place of business.

(e) Fees collected under this section shall be deposited to the credit of the food and drug registration fee account of the general revenue fund and may be appropriated to the department only to carry out this chapter.

Added by Acts 1993, 73rd Leg., ch. 440, Sec. 3, eff. Sept. 1, 1993.

Sec. 431.277. LICENSE EXPIRATION. (a) The board by rule may provide that licenses expire on different dates during the year.

(b) If the board changes a license expiration date, the board shall prorate the license fee payable on or before September 1 so that the licensee is required to pay only that portion of the fee that is allocable to the number of months during which the license is valid.

(c) The total renewal license fee is payable when the license is renewed on the new expiration date.

Added by Acts 1993, 73rd Leg., ch. 440, Sec. 3, eff. Sept. 1, 1993.

Sec. 431.278. CHANGE OF LOCATION OF PLACE OF BUSINESS.

(a) Not fewer than 30 days in advance of the change, the licensee shall notify the commissioner or the commissioner's designee in writing of the licensee's intent to change the location of a licensed place of business. The notice shall include the address of the new location and the name and residence address of the individual in charge of the business at the new location.

(b) Not later than the 10th day after the date of completion of the change of location, the licensee shall notify the commissioner or the commissioner's designee in writing to verify the change of location, the address of the new location, and the name and residence address of the individual in charge of the business at the new address.

(c) Notice is adequate if the licensee provides the intent and verification notices to the commissioner or the commissioner's designee by certified mail, return receipt requested, mailed to the central office of the department.

Added by Acts 1993, 73rd Leg., ch. 440, Sec. 3, eff. Sept. 1, 1993.

Sec. 431.279. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION OF LICENSE. (a) The commissioner may refuse an application or may suspend or revoke a license if the applicant or licensee:

(1) has been convicted of a felony or misdemeanor that involves moral turpitude;

(2) is an association, partnership, or corporation and the managing officer has been convicted of a felony or misdemeanor that involves moral turpitude;

(3) has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) is an association, partnership, or corporation and the managing officer has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs; or

(5) has not complied with this chapter or the board's rules implementing this chapter.

(b) The commissioner may refuse an application for a license or may suspend or revoke a license if the commissioner determines from evidence presented during a hearing that the applicant or licensee:

(1) has violated Section 431.021(1)(3), relating to the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(2) has violated Chapter 481 (Texas Controlled Substances Act) or 483 (Dangerous Drugs); or

(3) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or licensee to maintain.

(c) The refusal to license an applicant or the suspension or revocation of a license by the commissioner and the appeal from that action are governed by the board's formal hearing procedures and the procedures for a contested case hearing under Chapter 2001, Government Code.

Added by Acts 1993, 73rd Leg., ch. 440, Sec. 3, eff. Sept. 1, 1993.
Amended by Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995.

SUBCHAPTER M. DRUG DONATION PROGRAM

Sec. 431.321. DEFINITIONS. (a) "Charitable medical clinic" means a clinic, including a licensed pharmacy that is a community pharmaceutical access program provider, that provides medical care or drugs without charge or for a substantially reduced charge, complies with the insurance requirements of Chapter 84, Civil Practice and Remedies Code, and is exempt from federal income tax under Section 501(a) of the Internal Revenue Code of 1986 by being listed as an exempt organization in Section 501(c)(3) or 501(c)(4) of the code and is operated exclusively for the promotion of social welfare by being primarily engaged in promoting the common good and general welfare of the people in a community.

(b) "Seller" means a person, other than a charitable drug donor, as defined in Chapter 82, Civil Practice and Remedies Code.

(c) "Manufacturer" means a person, other than a charitable drug donor, as defined in Chapter 82, Civil Practice and Remedies Code.

(d) "Charitable drug donor" means a licensed convalescent or nursing home or related institution, licensed hospice, hospital,

physician, pharmacy, or a pharmaceutical seller or manufacturer that donates drugs pursuant to a qualified patient assistance program, that donates drugs to a charitable medical clinic.

(d-1) In this subchapter, "community pharmaceutical access program" means a program offered by a licensed pharmacy under which the pharmacy assists financially disadvantaged persons to access prescription drugs at no charge or at a substantially reduced charge.

(e) In this subchapter, "patient assistance program" means a qualified program offered by a pharmaceutical manufacturer under which the manufacturer provides drugs to financially disadvantaged persons at no charge or at a substantially reduced cost. The term does not include the provision of a drug as part of a clinical trial.

Added by Acts 2001, 77th Leg., ch. 1138, Sec. 1, eff. Jan. 1, 2002.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 820, Sec. 2, eff. June 15, 2007.

Sec. 431.322. DONATION OF UNUSED DRUGS TO CHARITABLE MEDICAL CLINIC. (a) A charitable drug donor may donate certain unused prescription drugs to a charitable medical clinic, and a charitable clinic may accept, dispense, or administer the donated drugs in accordance with this subchapter.

(b) A seller or manufacturer of a drug may not donate drugs to a charitable medical clinic except pursuant to a qualified patient assistance program. A seller or manufacturer of a drug that donates drugs through a qualified patient assistance program shall be considered a charitable drug donor.

(c) The charitable drug donor shall use appropriate safeguards established by the board to ensure that the drugs are not compromised or illegally diverted while being stored or transported to the charitable medical clinic.

(d) The charitable medical clinic may not accept the donated drugs unless:

(1) the charitable drug donor certifies that the drugs have been properly stored while in the possession of the donor or of

the person for whom the drugs were originally dispensed;

(2) the charitable drug donor provides the clinic with a verifiable address and telephone number; and

(3) the person transferring possession of the drugs presents the charitable medical clinic with photographic identification.

Added by Acts 2001, 77th Leg., ch. 1138, Sec. 1, eff. Jan. 1, 2002.

Sec. 431.323. CIRCUMSTANCES UNDER WHICH DONATED DRUGS MAY BE ACCEPTED AND DISPENSED. (a) A charitable medical clinic may accept and dispense or administer donated drugs only in accordance with this subchapter.

(b) The donated drugs must be drugs that require a prescription. A donated drug may not be a controlled substance under Chapter 481.

(c) The donated drugs must be approved by the federal Food and Drug Administration and:

(1) be sealed in the manufacturer's unopened original tamper-evident packaging and either:

(A) individually packaged; or

(B) packaged in unit-dose packaging;

(2) be oral or parenteral medication in sealed single-dose containers approved by the federal Food and Drug Administration;

(3) be topical or inhalant drugs in sealed units-of-use containers approved by the federal Food and Drug Administration; or

(4) be parenteral medication in sealed multiple-dose containers approved by the federal Food and Drug Administration from which no doses have been withdrawn; and

(5) must not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer.

(d) The charitable medical clinic may dispense or administer the donated drugs only:

(1) before the expiration date or within the recommended shelf life of the donated drugs, as applicable; and

(2) after a licensed pharmacist has determined that the drugs are of an acceptable integrity.

(e) The donated drugs may be accepted and dispensed or administered by the charitable medical clinic only in accordance with rules adopted by the department.

Added by Acts 2001, 77th Leg., ch. 1138, Sec. 1, eff. Jan. 1, 2002.

Sec. 431.324. RULES. The department shall adopt rules to implement this subchapter that are designed to protect the public health and safety.

Added by Acts 2001, 77th Leg., ch. 1138, Sec. 1, eff. Jan. 1, 2002.

Sec. 431.325. LIMITATION ON LIABILITY. (a) Charitable drug donors, charitable medical clinics, and their employees are not liable for harm caused by the accepting, dispensing, or administering of drugs donated in strict compliance with this subchapter unless the harm is caused by:

(i) willful or wanton acts of negligence;

(ii) conscious indifference or reckless disregard for the safety of others; or

(iii) intentional conduct.

(b) This section does not limit, or in any way affect or diminish, the liability of a drug seller or manufacturer pursuant to Chapter 82, Civil Practice and Remedies Code.

(c) This section shall not apply where harm results from the failure to fully and completely comply with the requirements of this subchapter.

(d) This section shall not apply to a charitable medical clinic that fails to comply with the insurance provisions of Chapter 84, Civil Practice and Remedies Code.

Added by Acts 2001, 77th Leg., ch. 1138, Sec. 1, eff. Jan. 1, 2002.

SUBCHAPTER N. WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

Sec. 431.401. DEFINITIONS. In this subchapter:

(1) "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree for the drug has

occurred.

(2) "Authorized distributor of record" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products in accordance with Section 431.4011.

(3) "Pharmacy warehouse" means a location for which a person holds a wholesale drug distribution license under this subchapter, that serves as a central warehouse for drugs or devices, and from which intracompany sales or transfers of drugs or devices are made to a group of pharmacies under common ownership and control.

(3-a) "Co-licensed product partner" means one of two or more parties that have the right to engage in the manufacturing or marketing of a prescription drug consistent with the United States Food and Drug Administration's regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293).

(3-b) "Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, or by the manufacturer's co-licensed product partner, third-party logistics provider, or exclusive distributor, in which:

(A) the wholesale distributor takes title but not physical possession of the prescription drug;

(B) the wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the drug to a patient; and

(C) the pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer or the manufacturer's third-party logistics provider or exclusive distributor.

(4) "Logistics provider" means a person that receives prescription drugs only from the original manufacturer, delivers the prescription drugs at the direction of that manufacturer, and does not purchase, sell, trade, or take title to any prescription drug.

(4-a) "Manufacturer" means a person licensed or

approved by the United States Food and Drug Administration to engage in the manufacture of drugs or devices, consistent with the federal agency's definition of "manufacturer" under the agency's regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293). The term does not include a pharmacist engaged in compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Section 562.154, Occupations Code.

(4-b) "Manufacturer's exclusive distributor" means a person who holds a wholesale distributor license under this subchapter, who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, and who takes title to, but does not have general responsibility to direct the sale or disposition of, the manufacturer's prescription drug. A manufacturer's exclusive distributor must be an authorized distributor of record to be considered part of the normal distribution channel.

(5) "Normal distribution channel" means a chain of custody for a prescription drug, either directly or by drop shipment, from the manufacturer of the prescription drug, the manufacturer to the manufacturer's co-licensed product partner, the manufacturer to the manufacturer's third-party logistics provider, or the manufacturer to the manufacturer's exclusive distributor, to:

(A) a pharmacy to:

- (i) a patient; or
- (ii) another designated person authorized by law to dispense or administer the drug to a patient;

(B) an authorized distributor of record to:

- (i) a pharmacy to a patient; or
- (ii) another designated person authorized by law to dispense or administer the drug to a patient;

(C) an authorized distributor of record to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy;

(D) a pharmacy warehouse to the pharmacy

warehouse's intracompany pharmacy or another designated person authorized by law to dispense or administer the drug to a patient;

(E) a person authorized by law to prescribe a prescription drug that by law may be administered only under the supervision of the prescriber; or

(F) an authorized distributor of record to one other authorized distributor of record to a licensed practitioner for office use.

(6) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of a prescription drug, from sale by a manufacturer, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the prescription drug.

(7) "Place of business" means each location at which a drug for wholesale distribution is located.

(8) "Prescription drug" has the meaning assigned by 21 C.F.R. Section 203.3.

(9) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling of a drug to further the distribution of a prescription drug. The term does not include repackaging by a pharmacist to dispense a drug to a patient.

(10) "Repackager" means a person who engages in repackaging.

(10-a) "Third-party logistics provider" means a person who holds a wholesale distributor license under this subchapter, who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, and who does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third-party logistics provider must be an authorized distributor of record to be considered part of the normal distribution channel.

(11) "Wholesale distribution" means distribution of prescription drugs to a person other than a consumer or patient. The term does not include:

(A) intracompany sales of prescription drugs,

which means transactions or transfers of prescription drugs between a division, subsidiary, parent, or affiliated or related company that is under common ownership and control, or any transaction or transfer between co-license holders of a co-licensed product;

(B) the sale, purchase, distribution, trade, or transfer of prescription drugs or the offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

(C) the distribution of prescription drug samples by a representative of a manufacturer;

(D) the return of drugs by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. Section 203.23;

(E) the sale of reasonable quantities by a retail pharmacy of a prescription drug to a licensed practitioner for office use;

(F) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription;

(G) the sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(H) the sale, purchase, or trade of a drug, or the offer to sell, purchase, or trade a drug, for emergency medical reasons, including a transfer of a prescription drug by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(I) the delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; or

(J) the sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third-party returns processor.

(12) "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including a manufacturer, repackager, own-label distributor, private-label distributor, jobber, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, authorized distributor of record, drug wholesaler or distributor, independent wholesale drug trader, specialty wholesale distributor, third-party logistics provider, retail pharmacy that conducts wholesale distribution, and pharmacy warehouse that conducts wholesale distribution.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 3, eff. September 1, 2007.

Sec. 431.4011. ONGOING RELATIONSHIP. In this subchapter, "ongoing relationship" means an association that exists when a manufacturer and distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute the manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Sec. 431.4012. APPLICABILITY OF SUBCHAPTER. This subchapter applies only to the wholesale distribution of prescription drugs.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Sec. 431.402. LICENSE REQUIRED. (a) A person may not engage in wholesale distribution of prescription drugs in this state unless the person holds a wholesale drug distribution license

under this subchapter for each place of business.

(b) A license issued under this subchapter expires on the second anniversary of the date of issuance.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Sec. 431.403. EXEMPTION FROM LICENSING. (a) A person who engages in wholesale distribution of prescription drugs in this state for use in humans is exempt from this subchapter if the person is exempt under:

(1) the Prescription Drug Marketing Act of 1987 (21 U.S.C. Section 353(c)(3)(B));

(2) the regulations adopted by the secretary to administer and enforce that Act; or

(3) the interpretations of that Act set out in the compliance policy manual of the United States Food and Drug Administration.

(b) An exemption from the licensing requirements under this section does not constitute an exemption from the other provisions of this chapter or the rules adopted under this chapter to administer and enforce the other provisions of this chapter.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Sec. 431.4031. EXEMPTION FROM CERTAIN PROVISIONS FOR CERTAIN WHOLESALE DISTRIBUTORS. A wholesale distributor that distributes prescription drugs that are medical gases or a wholesale distributor that is a manufacturer or a third-party logistics provider on behalf of a manufacturer is exempt from Sections 431.404(a)(5) and (6), (b), and (c), 431.4045(2), 431.405, 431.407, and 431.408.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 4, eff. September 1, 2007.

Sec. 431.404. LICENSE APPLICATION. (a) An applicant for a license under this subchapter must submit an application to the department on the form prescribed by the department. The application must contain:

(1) the name, full business address, and telephone number of the applicant;

(2) all trade or business names under which the business is conducted;

(3) the address, telephone number, and name of a contact person for each of the applicant's places of business;

(4) the type of business entity and:

(A) if the business is a sole proprietorship, the name of the proprietor;

(B) if the business is a partnership, the name of the partnership and each of the partners; or

(C) if the business is a corporation, the name of the corporation, the place of incorporation, and the name and title of each corporate officer and director;

(5) the name and telephone number of, and any information necessary to complete a criminal history record check on, a designated representative of each place of business; and

(6) a list of all licenses and permits issued to the applicant by any other state under which the applicant is permitted to purchase or possess prescription drugs.

(b) Each person listed in Subsection (a)(5) shall provide the following to the department:

(1) the person's places of residence for the past seven years;

(2) the person's date and place of birth;

(3) the person's occupations, positions of employment, and offices held during the past seven years;

(4) the business name and address of any business, corporation, or other organization in which the person held an office under Subdivision (3) or in which the person conducted an occupation or held a position of employment;

(5) a statement of whether during the preceding seven years the person was the subject of a proceeding to revoke a license

or a criminal proceeding and the nature and disposition of the proceeding;

(6) a statement of whether during the preceding seven years the person has been enjoined, either temporarily or permanently, by a court from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, including the details concerning the event;

(7) a written description of any involvement by the person as an officer or director with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were named as a party;

(8) a description of any misdemeanor or felony offense for which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere;

(9) a description of any criminal conviction of the person under appeal, a copy of the notice of appeal for that criminal offense, and a copy of the final written order of an appeal not later than the 15th day after the date of the appeal's disposition; and

(10) a photograph of the person taken not earlier than 180 days before the date the application was submitted.

(c) The information submitted under Subsection (b) must be attested to under oath.

(d) An applicant or license holder shall submit to the department any change in or correction to the information required under this section in the form and manner prescribed by the department.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 5, eff. September 1, 2007.

Sec. 431.4045. INSPECTION REQUIRED. The department may not issue a wholesale distributor license to an applicant under this subchapter unless the department:

(1) conducts a physical inspection of the place of business at the address provided by the applicant under Section 431.404 or determines that an inspection is unnecessary after thoroughly evaluating the information in the application, the compliance history of the applicant and the applicant's principals, and the risk of counterfeiting in the applicant's product; and

(2) determines that the designated representative of the place of business meets the qualifications required by Section 431.405.

Added by Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 6, eff. September 1, 2007.

Sec. 431.405. QUALIFICATIONS FOR LICENSE. (a) The department may not issue a wholesale distributor license to an applicant without considering the minimum federal information and related qualification requirements published in federal regulations at 21 C.F.R. Part 205, including:

(1) factors in reviewing the qualifications of persons who engage in wholesale distribution, 21 C.F.R. Section 205.6;

(2) appropriate education and experience for personnel employed in wholesale distribution, 21 C.F.R. Section 205.7; and

(3) the storage and handling of prescription drugs and the establishment and maintenance of prescription drug distribution records, 21 C.F.R. Section 205.50.

(b) In addition to meeting the minimum federal requirements as provided by Subsection (a), to qualify for the issuance or renewal of a wholesale distributor license under this subchapter, the designated representative of an applicant or license holder must:

(1) be at least 21 years of age;

(2) have been employed full-time for at least three years by a pharmacy or a wholesale distributor in a capacity related to the dispensing or distributing of prescription drugs, including

recordkeeping for the dispensing or distributing of prescription drugs;

(3) be employed by the applicant full-time in a managerial-level position;

(4) be actively involved in and aware of the actual daily operation of the wholesale distributor;

(5) be physically present at the applicant's place of business during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

(6) serve as a designated representative for only one applicant at any one time, except in a circumstance, as the department determines reasonable, in which more than one licensed wholesale distributor is colocated in the same place of business and the wholesale distributors are members of an affiliated group, as defined by Section 1504, Internal Revenue Code of 1986;

(7) not have been convicted of a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or the distribution of controlled substances; and

(8) not have been convicted of a felony under a federal, state, or local law.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 7, eff. September 1, 2007.

Sec. 431.406. EFFECT OF OPERATION IN OTHER JURISDICTIONS; REPORTS. (a) A person who engages in the wholesale distribution of drugs outside this state may engage in the wholesale distribution of drugs in this state if the person holds a license issued by the department.

(b) The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with this subchapter and the minimum standards adopted under this subchapter.

(c) The department may issue a license to a person who

engages in the wholesale distribution of drugs outside this state to engage in the wholesale distribution of drugs in this state if, after an examination of the reports of the person's compliance history and current compliance record, the department determines that the person is in compliance with this subchapter and the rules adopted under this subchapter.

(d) The department shall consider each license application and any related documents or reports filed by or in connection with a person who wishes to engage in wholesale distribution of drugs in this state on an individual basis.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Sec. 431.407. CRIMINAL HISTORY RECORD INFORMATION. The department shall submit to the Department of Public Safety the fingerprints provided by a person with an initial or a renewal license application to obtain the person's criminal history record information and may forward the fingerprints to the Federal Bureau of Investigation for a federal criminal history check.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Sec. 431.408. BOND. (a) A wholesale distributor applying for or renewing a license shall submit payable to this state a bond or other equivalent security acceptable to the department, including an irrevocable letter of credit or a deposit in a trust account or financial institution, in the amount of \$100,000 payable to this state.

(a-1) A pharmacy warehouse that is not engaged in wholesale distribution is exempt from the bond requirement under Subsection (a).

(b) The bond or equivalent security submitted under Subsection (a) shall secure payment of any fines or penalties imposed by the department or imposed in connection with an enforcement action by the attorney general, any fees or other enforcement costs, including attorney's fees payable to the attorney general, and any other fees and costs incurred by this

state related to that license holder, that are authorized under the laws of this state and that the license holder fails to pay before the 30th day after the date a fine, penalty, fee, or cost is assessed.

(c) The department or this state may make a claim against a bond or security submitted under Subsection (a) before the first anniversary of the date a license expires or is revoked under this subchapter.

(c-1) A single bond is sufficient to cover all places of business operated by a wholesale distributor in this state.

(d) The department shall deposit the bonds and equivalent securities received under this section in a separate account.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 8, eff. September 1, 2007.

Sec. 431.409. FEES. (a) The department shall collect fees for:

- (1) a license that is filed or renewed;
- (2) a license that is amended, including a notification of a change in the location of a licensed place of business required under Section 431.410; and
- (3) an inspection performed in enforcing this subchapter and rules adopted under this subchapter.

(b) The executive commissioner of the Health and Human Services Commission by rule shall set the fees in amounts that are reasonable and necessary and allow the department to recover the biennial expenditures of state funds by the department in:

- (1) reviewing and acting on a license;
- (2) amending and renewing a license;
- (3) inspecting a licensed facility; and
- (4) implementing and enforcing this subchapter, including a rule or order adopted or a license issued under this subchapter.

(c) Fees collected under this section shall be deposited to

the credit of the food and drug registration fee account of the general revenue fund and appropriated to the department to carry out this chapter.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Sec. 431.4095. RENEWAL NOTIFICATION; CHANGE OR RENEWAL.

(a) Before the expiration of a license issued under this subchapter, the department shall send to each licensed wholesale distributor a form containing a copy of the information the distributor provided to the department under Section 431.404.

(b) Not later than the 30th day after the date the wholesale distributor receives the form under Subsection (a), the wholesale distributor shall identify and state under oath to the department any change in or correction to the information.

Added by Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 9, eff. September 1, 2007.

Sec. 431.410. CHANGE OF LOCATION OF PLACE OF BUSINESS.

(a) Not fewer than 30 days in advance of the change, the license holder shall notify the department in writing of the license holder's intent to change the location of a licensed place of business.

(b) The notice shall include the address of the new location and the name and residence address of the individual in charge of the business at the new location.

(c) Not more than 10 days after the completion of the change of location, the license holder shall notify the department in writing to confirm the completion of the change of location and provide verification of the information previously provided or correct and confirm any information that has changed since providing the notice of intent.

(d) The notice and confirmation required by this section are considered adequate if the license holder sends the notices by certified mail, return receipt requested, to the central office of the department or submits the notices electronically through the TexasOnline Internet website.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Sec. 431.411. MINIMUM RESTRICTIONS ON TRANSACTIONS. (a) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or pharmacy warehouse in accordance with the terms and conditions of the agreement between the wholesale distributor and the pharmacy or pharmacy warehouse. An expired, damaged, recalled, or otherwise nonsalable prescription drug that is returned to the wholesale distributor may be distributed by the wholesale distributor only to either the original manufacturer or a third-party returns processor. The returns or exchanges, salable or otherwise, received by the wholesale distributor as provided by this subsection, including any redistribution of returns or exchanges by the wholesale distributor, are not subject to the pedigree requirement under Section 431.412 if the returns or exchanges are exempt from pedigree under:

(1) Section 503, Prescription Drug Marketing Act of 1987 (21 U.S.C. Section 353(c)(3)(B));

(2) the regulations adopted by the secretary to administer and enforce that Act; or

(3) the interpretations of that Act set out in the compliance policy guide of the United States Food and Drug Administration.

(a-1) Each wholesale distributor and pharmacy shall administer the process of drug returns and exchanges to ensure that the process is secure and does not permit the entry of adulterated or counterfeit drugs into the distribution channel.

(a-2) Notwithstanding any provision of state or federal law to the contrary, a person that has not otherwise been required to obtain a wholesale license under this subchapter and that is a pharmacy engaging in the sale or transfer of expired, damaged, returned, or recalled prescription drugs to the originating wholesale distributor or manufacturer and pursuant to federal statute, rules, and regulations, including the United States Food and Drug Administration's applicable guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293), is

exempt from wholesale licensure requirements under this subchapter.

(b) A manufacturer or wholesale distributor may distribute prescription drugs only to a person licensed by the appropriate state licensing authorities or authorized by federal law to receive the drug. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor must verify that the person is legally authorized by the appropriate state licensing authority to receive the prescription drugs or authorized by federal law to receive the drugs.

(c) Except as otherwise provided by this subsection, prescription drugs distributed by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license. A manufacturer or wholesale distributor may distribute prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(1) the identity and authorization of the recipient is properly established; and

(2) delivery is made only to meet the immediate needs of a particular patient of the authorized person.

(d) Prescription drugs may be distributed to a hospital pharmacy receiving area if a pharmacist or an authorized receiving person signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor not later than the next business day after the date of delivery to the pharmacy receiving area.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 10, eff. September 1, 2007.

Sec. 431.412. PEDIGREE REQUIRED. (a) A person who is

engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer, shall provide a pedigree for each prescription drug for human consumption that leaves or at any time has left the normal distribution channel and is sold, traded, or transferred to any other person.

(b) A pharmacy that sells a drug to a person other than the final consumer shall provide a pedigree to the person acquiring the prescription drug. The sale of a reasonable quantity of a drug to a practitioner for office use is not subject to this subsection.

(b) Repealed by Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 14.

(b-1) A retail pharmacy or pharmacy warehouse is required to comply with this section only if the pharmacy or warehouse engages in the wholesale distribution of a prescription drug.

(c) The sale, trade, or transfer of a prescription drug between license holders with common ownership or for an emergency is not subject to this section.

(c) Repealed by Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 14.

(d) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager, but excluding the original manufacturer of the finished form of a prescription drug, and who is in possession of a pedigree for a prescription drug must verify before distributing the prescription drug that each transaction listed on the pedigree has occurred.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 11, eff. September 1, 2007.

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 14.

Sec. 431.413. PEDIGREE CONTENTS. (a) A pedigree must include all necessary identifying information concerning each sale in the product's chain of distribution from the manufacturer, through acquisition and sale by a wholesale distributor or

repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At a minimum, the chain of distribution information must include:

(1) the name, address, telephone number, and, if available, the e-mail address of each person who owns the prescription drug and each wholesale distributor of the prescription drug;

(2) the name and address of each location from which the product was shipped, if different from the owner's name and address;

(3) the transaction dates; and

(4) certification that each recipient has authenticated the pedigree.

(b) The pedigree must include, at a minimum, the:

(1) name of the prescription drug;

(2) dosage form and strength of the prescription drug;

(3) size of the container;

(4) number of containers;

(5) lot number of the prescription drug; and

(6) name of the manufacturer of the finished dosage form.

(c) Each pedigree statement must be:

(1) maintained by the purchaser and the wholesale distributor for at least three years; and

(2) available for inspection and photocopying not later than the second business day after the date a request is submitted by the department or a peace officer in this state.

(d) The executive commissioner of the Health and Human Services Commission shall adopt rules to implement this section.

(e) The department shall:

(1) conduct a study on the implementation of electronic pedigrees; and

(2) in conducting the study under Subdivision (1), consult with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drugs in this state.

(e-1) If, after consulting with manufacturers,

distributors, and pharmacies responsible for the sale and distribution of prescription drugs in this state, the department determines that electronic track and trace pedigree technology is universally available across the entire prescription pharmaceutical supply chain, the department shall establish a targeted implementation date for electronic track and trace pedigree technology. After the department has established a targeted implementation date, the department may revise the date. The targeted implementation date may not be earlier than July 1, 2010.

(f) Subsection (e) and this subsection expire January 1, 2009.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 12, eff. September 1, 2007.

Sec. 431.414. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION OF LICENSE. (a) The commissioner of state health services may refuse an application for a license or may suspend or revoke a license if the applicant or license holder:

(1) has been convicted of a felony or misdemeanor that involves moral turpitude;

(2) is an association, partnership, or corporation and the managing officer has been convicted of a felony or misdemeanor that involves moral turpitude;

(3) has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) is an association, partnership, or corporation and the managing officer has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other

dangerous or habit-forming drugs;

(5) has not complied with this subchapter or the rules implementing this subchapter;

(6) has violated Section 431.021(1)(3), relating to the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(7) has violated Chapter 481 or 483; or

(8) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or license holder to maintain.

(a-1) The commissioner of state health services may suspend or revoke a license if the license holder no longer meets the qualifications for obtaining a license under Section 431.405.

(b) The executive commissioner of the Health and Human Services Commission by rule shall establish minimum standards required for the issuance or renewal of a license under this subchapter.

(c) The department shall deny a license application that is incomplete, contains false, misleading, or incorrect information, or contains information that cannot be verified by the department.

(d) The refusal to license an applicant or the suspension or revocation of a license by the department and the appeal from that action are governed by the procedures for a contested case hearing under Chapter 2001, Government Code.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1, 2006.

Amended by:

Acts 2007, 80th Leg., R.S., Ch. 980, Sec. 13, eff. September 1, 2007.

Sec. 431.415. ORDER TO CEASE DISTRIBUTION. (a) The commissioner of state health services shall issue an order requiring a person, including a manufacturer, distributor, or retailer of a prescription drug, to immediately cease distribution of the drug if the commissioner determines there is a reasonable probability that:

(1) a wholesale distributor has:
 (A) violated this subchapter;
 (B) falsified a pedigree; or
 (C) sold, distributed, transferred,
manufactured, repackaged, handled, or held a counterfeit
prescription drug intended for human use that could cause serious
adverse health consequences or death; and

(2) other procedures would result in unreasonable
delay.

(b) An order under Subsection (a) must provide the person
subject to the order with an opportunity for an informal hearing on
the actions required by the order to be held not later than the 10th
day after the date of issuance of the order.

(c) If, after providing an opportunity for a hearing, the
commissioner of state health services determines that inadequate
grounds exist to support the actions required by the order, the
commissioner shall vacate the order.

Added by Acts 2005, 79th Leg., Ch. 282, Sec. 3(g), eff. March 1,
2006.