CHAPTER 913

H.B. No. 1732

An Act relating to the regulation and manufacture of certain foods, drugs, devices, and cosmetics; providing penalties.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. The Texas Food, Drug and Cosmetic Act (Article 4476-5, Vernon's Texas Civil Statutes) is amended to read as follows:

Sec. 1. *SHORT TITLE.* This Act may be cited as the Texas Food, Drug and Cosmetic Act.

Sec. 2. *DEFINITIONS. In* [~~For the purpose of~~] this Act:

(1) [~~(a) The term~~] "Commissioner [~~of Health~~]" means the Commissioner of Health of the State of Texas.

(2) "*Person*" [~~(b) The term "person"~~] includes individual, partnership, corporation, and association.

(3) "*Food*" [~~(c) The term "food"~~] means:

(A) [~~(1)~~] articles used for food or drink for man;

(B)[~~; (2)~~] chewing gum; [~~;~~] and

(C) [~~(3)~~] articles used for components of any such article.

(4) "Drug" [~~(d) The term "drug"~~] means [~~(1)~~] articles recognized in the official United States Pharmacopoeia [~~, official Homeopathic Pharmacopoeia of the United States, or official~~] National Formulary, or any supplement to *it,* [~~any of them; and (2)~~] articles designed or intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, [~~; and (3)~~] articles (other than food) intended to affect the structure of any function of the body of man or other animals, [~~;~~] and [~~(4)~~] articles intended for use as a component of any article specified in *this subdivision. The term* [~~clause (1), (2) or (3), but~~] does not include devices or their components, parts or accessories.

(5) "Device," [~~(e) The term "devices,"~~] except when used in *Subdivision (11)* [~~Paragraph (k)~~] of this section and in Sections *3(i)*[~~(g)~~], *11(g)* [~~(f)~~], *16* [~~15~~] (c) and *21* [~~18~~] (c), means *an instrument* [~~instruments~~], apparatus [~~and contrivances~~], *implement, machine, contrivance, implant, in vitro reagent, or other similar or related article,* including *any component, part, or accessory, that is:* [~~their components, parts, accessories, designed or intended~~]

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

(B) intended [~~(1)~~] 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 [~~(2)~~] 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.*

(6) "Cosmetic" [~~(f) The term "cosmetic"~~] means [~~(1)~~] articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for *cleaning* [~~cleansing~~], beautifying, promoting attractiveness, or altering the appearance, and [~~(2)~~] articles intended for use as a component of *those* [~~such~~] articles. *The* [~~; except that such~~] term *does* [~~shall~~] not include soap.

(7) "Official [~~(g) The term "official~~] compendium" means the official United States Pharmacopoeia [~~, official Homeopathic Pharmacopoeia of the United States, official~~] National Formulary, or any supplement to *it* [~~any of them~~].

(8) "Label" [~~(h) The term "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 Act that any word, statement, or other information *that appears* [~~appearing~~] on the label shall not be considered to be complied with unless *the* [~~such~~] word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of *the* [~~such~~] article, or is easily legible through the outside container or wrapper.

(9) "Immediate [~~(i) The term "immediate~~] container" does not include package liners.

(10) "Labeling" [~~(j) The term "labeling"~~] means all labels and other written, printed or graphic matter *that is on* [~~(1) upon~~] an article or any of *the* [~~its~~] containers or wrappers *that accompany the* [~~; or (2) accompanying such~~] article.

(11) [~~(k)~~] 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 [~~in~~] any combination thereof, but also the extent to which the labeling *or advertising* fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling *or advertising* relates under the conditions of use prescribed in the labeling *or advertising* thereof, or under such conditions of use as are customary or usual.

(12) "Advertising" [~~(l) The term "advertisement"~~] means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(13) [~~(m)~~] The representation of a drug, in its labeling [~~or advertisement~~], as an antiseptic shall be considered to be a representation that *the drug* [~~it~~] is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(14) "New [~~(n) The term "new~~] drug" means:

(A) [~~(1)~~] 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 the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, and if at that time its labeling contained the same representations concerning the conditions of its use)*; or

(B) [~~(2)~~] 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.

(15) "Contaminated with filth" [~~(o) The term "contaminated"~~] 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.

(16) [~~(p)~~] The provisions of this Act regarding the selling of food, drugs, devices, or cosmetics, shall be considered to include the manufacture, production, processing, *packaging,* [~~packing,~~] 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.

(17) [~~(q) The term~~] "Federal Act" means the Federal Food, Drug and Cosmetic Act (Title 21 U.S.C. 301 et seq. [~~; 52 Stat. 1040 et seq.~~]).

(18) "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

[~~(r) The term "butter" shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, containing not less than eighty per centum (80%) by weight of milk fat, all tolerances having been allowed for.~~

[~~(s) The word "package" shall include, and be construed to include,~~] 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 Act of August 3, 1912, or the Act of March 4, 1915.

(19) "Pesticide [~~(t) The term "pesticide"~~] chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is *a "pesticide"* [~~an "economic poison"~~] within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., *Sec. 136(u)* [~~secs. 135/135K~~]) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(20) "Raw [~~(u) The term "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.

(21) "Food [~~(v) The term "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 [~~such~~] 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 [~~(1) A~~] pesticide chemical in or on a raw agricultural commodity; [~~or~~]

(B) a [~~(2) 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; [~~or~~]

(C) a color additive;

(D) any [~~(3) Any~~] substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the Federal [~~Food, Drug and Cosmetic~~] Act, the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.* [~~and the following~~]) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260) as amended and extended (21 U.S.C. 71 *et seq.* [~~and the following~~]); *or*

(E) a new animal drug.

(22) "Animal feed," as used in Subdivision (31) of this section, in Section 512 of the Federal Act, and in provisions of this Act 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.

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

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

(25)(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) of this subdivision 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.

(26) "Consumer commodity," except as otherwise provided by this subdivision, means any food, drug, device, or cosmetic, as those terms are defined by this Act 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 or the provisions of the eighth paragraph under the heading "Bureau of Animal Industry" of the Act of March 4, 1913, commonly known as the Virus-Serum-Toxin Act;

(C) a drug subject to the provisions of Section 17(c)(1) or 16(k) of this Act, or Section 503(b)(1) or 506 of the Federal Act;

(D) a beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act; 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.

(27) "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.

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

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

(30) "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.

(31) "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, chloratetracycline, chloramphenicol, or bacitracin, or any derivative of those substances, unless:

(i) a published order of the secretary of health and human services 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.

(32) "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.

(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.

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

(36) "Vended water device" means any self-service device that dispenses unit measures of water into a container without the necessity of refilling the machine between each operation.

Sec. 3. *UNLAWFUL AND PROHIBITED ACTS.* The following acts and the causing thereof within the State of Texas are hereby declared unlawful and prohibited:

(a) *the introduction or delivery for introduction into commerce* [~~The manufacture, sale, or delivery, holding or offering for sale~~] of any food, drug, device, or cosmetic that is adulterated or misbranded;

(b) *the* [~~The~~] adulteration or misbranding of any food, drug, device, or cosmetic *in commerce*;

(c) *the* [~~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, as defined in this Act, 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 Act and of rules adopted under authority of this Act; 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 [~~(d) The sale, delivery for sale, holding for sale, or offering for sale~~] of any article in violation of *Section 12, 18, or 19 of this Act* [~~Sections 12 or 16~~];

(f) the [~~(e) The~~] dissemination of any false advertisement; [~~. By false advertising is meant all misrepresentations disseminated in any manner or by any means other than the labeling for the purpose of inducing or which are likely to induce directly or indirectly the purchase of food, drugs, devices or cosmetics;~~]

(g) the [~~(f) 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* [~~samples,~~] as authorized by Section *25* [~~21~~]; *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 the State of Texas of any food, drug, device, or cosmetic that is adulterated or misbranded;

(i) the [~~(g) The~~] giving of a guaranty or undertaking *referred to in Section 5 of this Act*, 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 the *State of Texas* [~~United States~~] from whom he received in good faith the food, drug, device, or cosmetic; *or the giving of a guaranty or undertaking referred to in Section 5 of this Act, which guaranty or undertaking is false;*

(j) the [~~(h) The~~] removal or disposal of a detained *or embargoed* article in violation of Section 6 *of this Act*;

(k) the [~~(i) 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;

(l)(1) forging [~~(j) 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 Act or the* regulations promulgated under the provisions of *the Federal* [~~this~~] 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 his 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 Act, of any information acquired under authority of this Act concerning any method or process which as a trade secret is entitled to protection;

(n) the [~~(k) The~~] using, on the labeling of any drug *or device* or in any *ad advertising* [~~advertisement~~] 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* [~~effective~~] under Section *18 of this Act or Section 505, 515, or 520(g) of the Federal Act, as the case may be* [~~16~~], or that such drug *or device* complies with the provisions of such *sections* [~~Section~~];

(o) the using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with Section 25 of this Act 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 thereof 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 Act;

(q)(1) placing or causing to be placed on any drug or device or container thereof, 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 thereof, 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 thereof 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 Act 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.

[~~(l) The acceptance by any person of an unused prescription or drug, in whole or in part, after it has been originally dispensed or sold, for the purpose of resale to any person.~~]

Sec. 4. *INJUNCTION. (a) If the commissioner, an authorized agent, or a health authority finds that a person has violated, or is violating or threatening to violate any provision of Section 3 of this Act and the violation or threat of violation creates an immediate threat to the health and safety of the public, the commissioner, an authorized agent, or a health authority may petition the district court for a temporary restraining order to restrain continuing violations or threat of violation.*

(b) If a person has violated, or is violating or threatening to violate any provision of Section 3 of this Act, the commissioner, an authorized agent, or a health authority may petition the district court for an injunction to prohibit the person from continuing the violation or threat of violation.

(c) On application for injunctive relief and a finding that a person is violating or threatening to violate any provision of Section 3 of this Act, the district court shall grant any injunctive relief warranted by the facts.

(d) Venue for a suit brought under this section is in the county in which the violation or the threat of violation is alleged to have occurred or in Travis County. [~~In addition to the remedies hereinafter provided the Commissioner of Health is hereby authorized to apply to any district court where the offense occurred for, and such court shall have jurisdiction after due notice and show cause hearing to grant, a temporary or permanent injunction restraining any person from violating any provision of Section 3, irrespective of whether or not there exists an adequate remedy at law.~~]

Sec. 5 *VIOLATION A MISDEMEANOR; PENALTIES.* (a) *A* [~~Any~~] person *commits an offense if the person* [~~who~~] violates any of the provisions of Section 3 *of this Act relating to unlawful or prohibited acts. An offense under this subsection is a Class A misdemeanor* [~~shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not less than Twenty/five Dollars ($25.00) nor more than Two Hundred Dollars ($200.00), and for the second or subsequent offense shall be subject to a fine of not less than One Hundred Dollars ($100.00) nor more than One Thousand Dollars ($1,000.00), or imprisonment in the county jail for a period of not more than one year, or both such fine and imprisonment~~].

(b) No person shall be subject to the penalties of Subsection (a) of this Section:

(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 3(a) or *(e)* [~~(c)~~] if *the person* [~~he~~] establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in *this state* [~~the United States~~] from whom *the person* [~~he~~] received in good faith the article, to the effect that:

(A) in the case of an alleged violation of Section 3(a), the [~~such~~] article is not adulterated or misbranded within the meaning of this Act; *and*

(B) in the case of an alleged violation of Section 3(e), the article is not an article that may not, under the provisions of Section 404 or 405 of the Federal Act or Section 12 or 18 of this Act, be introduced into commerce;

(3) for having violated Section 3(l) of this Act, 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 3(b), (c), or (k) of this Act by failure to comply with Section 16(j) of this Act 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 3(l)(2) of this Act 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 3(l)(3) of this Act 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) No 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, shall be liable under this Section *for* [~~by reason of~~] the dissemination [~~by him~~] of *the* [~~such~~] false advertisement, unless *the person* [~~he~~] has refused, on the request of the *commissioner* [~~Commissioner of Health~~] to furnish the *commissioner* [~~Commissioner of Health~~] the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency, residing in *this state* [~~the United States~~] who caused *the person* [~~him~~] disseminate *the* [~~such~~] advertisement.

(d) No person shall be subject to the penalties of Subsection (a) of this section for a violation of Section 3 of this Act involving misbranded food if the violation exists solely because the food is misbranded under Section 11 of this Act because of its advertising, and no person shall be subject to the penalties of Subsection (a) of this section for such a violation unless the violation is committed with the intent to defraud or mislead.

Sec. 5A. ADMINISTRATIVE PENALTIES. (a) If a person violates any provision of Section 3 of this Act or an order adopted or registration issued under this Act, the commissioner may assess an administrative penalty against that person as provided by this section.

(b) The penalty may be in an amount not to exceed $25,000 a day for each violation. Each day a violation continues may be considered a separate violation for purposes of penalty assessment.

(c) In determining the amount of the penalty, the commissioner shall consider the person's history of previous violations, the seriousness of the violation, any hazard to the health and safety of the public, and the demonstrated good faith of the person charged.

(d) The administrative penalty may be assessed only after the person charged with the violation described in Subsection (a) of this section has been given the opportunity for a hearing.

(e) If a hearing has been held, the commissioner shall make findings of fact and shall issue a written decision as to the occurrence of the violation and the amount of the penalty that is warranted incorporating, when appropriate, an order requiring that the penalty be paid.

(f) If appropriate, the commissioner may consolidate a hearing held under this section with other proceedings.

(g) If the person charged with the violation fails to request a hearing, an administrative penalty may be assessed by the commissioner after the commissioner has determined that a violation occurred and the amount of the penalty that is warranted.

(h) After making a determination under Subsection (g) of this section, the commissioner shall issue an order requiring that the penalty be paid.

(i) On the issuance of an order finding that a violation has occurred, the commissioner within 30 days shall inform the person charged of the amount of the penalty.

(j) Within the 30-day period immediately following the day on which the decision or order is final as provided in Subsection (c), Section 16, Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes), the person charged with the penalty must:

(1) pay the penalty in full; or

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

(A) forward the amount to the commissioner for placement in an escrow account; or

(B) in lieu of payment into escrow, post with the commissioner a bond for the amount of the penalty, in a form approved by the commissioner, that is effective until all judicial review of the order or decision is final.

(k) If after judicial review of the decision or order it is determined that a violation did not occur, that a penalty should not be assessed, or that the amount of the penalty should be reduced, the commissioner shall, not later than the 30th day after the date of the determination, if the penalty has been paid to the department, remit the appropriate amount to the person, with accrued interest. If a bond has been posted, the department shall execute a release of the bond.

(l) Failure to forward the money to the commissioner within the time provided by Subsection (j) of this section results in a waiver of all rights to contest the violation or the amount of the penalty.

(m) Judicial review of the order or decision of the commissioner assessing the penalty is in accordance with the substantial evidence rule and shall be instituted by filing a petition with the district court of Travis County, as provided for in Section 19, Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes).

(n) Administrative penalties owed under this section may be recovered in a civil action brought by the attorney general at the request of the commissioner.

(o) A penalty collected under this section shall be deposited in the state treasury to the credit of the general revenue fund.

Sec. 6. *DETENTION AND CONDEMNATION OF PRODUCT.* (a) Whenever *the commissioner or an* [~~a duly~~] authorized agent [~~of the Commissioner of Health~~] finds or has *probable cause* [~~good reason~~] to believe, that any food, drug, device, [~~or~~] cosmetic, *or consumer commodity* is adulterated, *is* [~~or~~] so misbranded as to be dangerous *or fraudulent* within the meaning of this Act, *or violates Section 12, 18, or 19 of this Act, the commissioner or agent* [~~he~~] shall affix to *the* [~~such~~] article a tag or other appropriate marking, giving notice that *the* [~~such~~] article is, or is suspected of being, adulterated or misbranded and has been detained *or embargoed*, and warning all persons not to remove *the article* from the premises or dispose of *the* [~~such~~] article by sale or otherwise until permission for removal or disposal is given by *the commissioner, the* [~~such~~] agent, or the court. It shall be unlawful for any person to remove *the article* from the premises or dispose of *the* [~~such~~] detained *or embargoed* article by sale or otherwise without such permission. In the case of perishable goods, *the* [~~such~~] goods may be moved with the permission of the *commissioner* [~~Commissioner of Health,~~] or *an authorized* [~~his~~] agent [;] to a place suitable for proper storage.

(b) *If the article is on display for sale to the public at large or any member of the public, the commissioner may order the claimant of the article or the claimant's agent to remove the article to a secure area approved by the commissioner or an authorized agent. The removal order shall be in writing and shall be signed by the commissioner. The removal order may be issued before or in conjunction with the affixing of the tag or other appropriate marking in Subsection (a) of this section. The removal order shall remain in effect until the order expires by its own terms, is withdrawn by the commissioner, or is removed by the court in an order denying condemnation in accordance with Subsection (c) of this section. The claimant of the article or the claimant's agent shall pay the costs of the removal and storage of the detained article. If the claimant of the article or the claimant's agent fails or refuses to carry out the removal order in a timely manner, the commissioner may cause the article to be removed. The costs of the removal shall be assessed against the claimant of the article or the claimant's agent.*

(c) When an article is adulterated or misbranded or is in violation of Section 12, 18, or 19 of this Act, the article may be proceeded against by petition to the judge of any court in whose jurisdiction the article is located, detained, or embargoed for the condemnation of the article. When the commissioner or an authorized agent has found that an article that is embargoed or detained is not adulterated or misbranded, the commissioner or authorized agent shall remove the tag or other marking from the article. [~~When an article detained under Subsection (a) has been found by such agent to be adulterated, or misbranded, the Commissioner of Public Health or his agent shall petition the judge of the county or district court in whose jurisdiction the article is detained for an order for condemnation of such article. When such agent has found that an article so detained is not adulterated or misbranded, he shall promptly remove the tag or other marking.~~]

(d) [~~(c)~~] If the court finds that *sampled,* detained *or embargoed* article is adulterated or misbranded, *the* [~~such~~] article shall, after entry of the decree, be destroyed at the expense of the claimant *of the article* [~~thereof~~], under the supervision of *an authorized* [~~such~~] agent, and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of *the* [~~such~~] article or *the claimant's* [~~his~~] agent. *If* [~~; provided, that when~~] the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after *the* [~~such~~] costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that *the* [~~such~~] article shall be so labeled or processed, has been executed, may by order direct that *the* [~~such~~] article be delivered to the claimant [~~thereof~~] for *the* [~~such~~] labeling or processing under the supervision of an agent of the *commissioner or an authorized agent. The claimant is liable for the costs of the supervision. The article shall be returned to the claimant and the bond shall be discharged on the representation to the court by the commissioner or an authorized agent that the article is no longer in violation of this Act and that the expenses of the supervision have been paid.* [~~Commissioner of Health. Such bond shall be returned to the claimant of the article on representation to the court by the Commissioner of Health that the article is no longer in violation of this Act.~~]

(e) [~~(d)~~] Whenever the *comissioner* [~~Commissioner of Health~~] or *an* [~~any of his~~] authorized *agent* [~~agents~~] shall find in any room, building, vehicle of transportation or other structure, any meat, sea food, poultry, vegetable, [~~or~~] fruit *or other perishable article* which is unsound, *that contains* [~~or contain~~] any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the *commissioner* [~~Commissioner of Health,~~] or *an* [~~his~~] authorized agent, shall forthwith condemn, or in any manner render the same unsalable as human food.

Sec. 7. *CRIMINAL PROCEEDINGS; NOTICE.* [~~(a)~~] It shall be the duty of *the attorney general and* each district [~~attorney or~~] county, *or city* attorney, to whom the *commissioner, an authorized agent, or a health authority* [~~Commissioner of Health~~] reports any violation of this Act, to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.

[~~(b) If it is found that the detained article is adulterated or misbranded and such article is voluntarily destroyed or decreed to be destroyed, no criminal proceeding shall follow against the owner or claimant thereof before such person shall be given appropriate notice and an opportunity to present his views before the Commissioner of Health and show cause either orally or in writing why such criminal action should not be instituted.~~]

Sec. 8. *MINOR VIOLATIONS; NOTICE OR WARNING.* Nothing in this Act shall be construed as requiring the *commissioner, an authorized agent, or a health authority* [~~Commissioner of Health~~] to report for *prosecution or* the institution of proceedings under this Act, minor violations of this Act, whenever the *commissioner, an authorized agent, or a health authority* [~~Commissioner of Health~~] believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

Sec. 9. *RULES; DUTY TO ADOPT. (a) Definitions and standards of identity, quality, and fill of container of the Federal Act are the definitions and standards of identity, quality, and fill of container in this Act, except as modified by rules of the board.* Whenever in the *board's* judgment [~~of the Commissioner of Health~~] such action will promote honesty and fair dealing in the interest of consumers, the *board may adopt rules establishing definitions and standards of identity, quality, and fill of container for foods to which no federal regulations apply.*

(b) Temporary permits granted for interstate shipment of experimental packs of food varying from the requirements of federal definitions and standards of identity are automatically effective in this state under the conditions provided in those permits. In addition, the commissioner may issue additional permits if necessary for the completion of an otherwise adequate investigation and where the interests of consumers are safeguarded. Those permits are subject to the terms and conditions of the rules adopted by the board. [~~Commissioner of Health shall promulgate regulations of general application fixing and establishing for any food or class of food a reasonable definition and standard of identity, and/or reasonable standard of quality and/or fill of container. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Commissioner of Health shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label.~~]

Sec. 10. *ADULTERATED FOOD.* A food shall be deemed to be adulterated:

(a)(1) If 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* [~~such~~] food shall not be considered adulterated under this *subdivision* [~~clause~~] if the quantity of *the* [~~such~~] substance in *the* [~~such~~] food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance *other than one that is* [~~except~~] a pesticide chemical in or on a raw agricultural commodity, [~~and except~~] a food additive *a color additive, or a new animal drug* [~~;~~] which is unsafe within the meaning of Section *14 of this Act* [~~13~~]; or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section *14(a) of this Act* [~~13~~], or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of Section *14(a) of this Act* [~~13~~]; 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 *14(a) of this Act* [~~13~~], 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 *14 of this Act and Section 409 of the Federal Act* [~~13 and clause (C) of this Section~~], 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) if it 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) if 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) 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 *diseased, unwholesome, or* injurious to health; or (5) if it is *in whole or in part,* the product of a diseased animal [~~or~~] 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) 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 (7) if 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)(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if 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) if it contains saccharin, dulcin, glucin, or other sugar substitutes except in dietary foods, and when so used shall be declared; or (6) if 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 Bureau of Animal Industry or *by rules of the board* [~~the Commissioner of Health~~].

(c) If it is *or* [~~confectionery and~~] it bears or contains *a color additive that is unsafe under Section 14(a) of this Act* [~~any alcohol or non-nutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of one per centum, harmless natural gum, and pectin; provided, that this paragraph shall not apply to any confectionery by reason of its containing less than one-half of one per~~

~~centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless non/nutritive masticatory substances~~].

(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 one-half of one percent (0.5%) by volume derived solely from the use of flavoring extracts; 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 Act; 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. [~~If it bears or contains a coal/tar color other than one certified under authority of the Federal Act.~~]

Sec. 11. *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 22 of this Act*;

(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) [~~(c)(1)~~] If it is an imitation of another food, unless its label bears, *in prominent type of uniform size,* the word "imitation" [; ~~(2) In type of uniform size and prominence~~] and immediately thereafter the name of the food imitated; [~~(3) Except in cases of mixtures and compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced. No one administering this law may constitute oleomargarine as an imitation of butter,~~]

(e) [~~(d)~~] If its container is so made, formed, or filled as to be misleading;

(f) [~~(e)~~] If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; (2) an accurate statement *in a uniform location on the principal display panel of the label,* of the quantity of the *contents* [~~content~~] in terms of weight, measure, or numerical count; provided, that under [~~clause (2) of~~] this *subsection* [~~paragraph~~] reasonable variations shall be permitted, and exemptions as to small packages shall be established, by *rules adopted* [~~regulations prescribed~~] by the *board* [~~Commissioner of Health~~];

(g) [~~(f)~~] If any word, statement, or other information required by or under authority of this Act 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) [~~(g)~~] 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 9, 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* [~~such~~] regulations *or rules*, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(i) [~~(h)~~] 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 9, and its quality falls below such standard unless its label bears, in such manner and form as *those* [~~such~~] 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 9, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as *those* [~~such~~] regulations *or rules* specify, a statement that it falls below such standard;

(j) [~~(i)~~] If it is not subject to the provisions of *Subsection (h)* [~~paragraph (g)~~] of this Section, unless *its label* [~~it~~] bears [~~labeling clearly giving~~] (1) the common or usual name of the food, if

any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such *ingredient* [~~ingredients~~]; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings, without naming each; provided that, to the extent that compliance with the requirements of *Subdivision* [~~clause~~] (2) of this *subsection* [~~paragraph~~] is impractical or results in deception or unfair competition, exemptions shall be established by *rules of the board* [~~regulations promulgated by the Commissioner of Health, provided further, that the requirements in paragraphs (e)(2), and (e)(1) shall not apply to any bottled carbonated drinks or still soft drinks and, provided further, that clause (2) of paragraph (i) shall not apply to any bottled carbonated drinks or still soft drinks or the dispensing of carbonated soft drinks or still soft drinks in single service cups. Nothing in this law shall be construed as requiring proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredients to disclose their trade formulas except in so far as the provisions of this law require to secure freedom of adulteration or misbranding~~];

(k) [~~(j)~~] 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* [~~Commissioner of Health~~] determines to be, and by *rule* [~~regulations~~] prescribed, as necessary in order to fully inform purchasers as to its value for such uses;

(l) [~~(k)~~] If it bears or contains any artificial *flavoring* [~~flavorings~~], 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* [~~paragraph~~] is impracticable, exemptions shall be established by *rules of the board* [~~regulations promulgated by the Commissioner of Health~~]. The provisions of this *subsection* [~~paragraph~~] and *Subsections (h)* [~~paragraph (g)~~] and *(j)* [~~(i)~~] with respect to artificial coloring *are* [~~is~~] not to apply in the case of butter, cheese and ice cream.

Sec. 12. EMERGENCY PERMIT CONTROL. (a) *The board shall adopt rules establishing standards and procedures for the enforcement of this section.* Whenever the *commissioner* [~~Commissioner of Health~~] finds after investigation that the distribution in Texas of any class of food may, by reason of contamination with microorganisms during *the* manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered commerce, *the commissioner* [~~it~~] then, and in such case only, shall *provide for the issuance* [~~promulgate regulations providing for the issuance~~], to manufacturers, processors, or packers of such class of food in such locality, *of* [~~or~~] permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such *rules* [~~regulations~~], and during such temporary period, no person shall introduce or deliver for introduction into commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the *commissioner* [~~Commissioner of Health~~] as provided by such *rules* [~~regulations~~].

(b) The *commissioner* [~~Commissioner of Health~~] is authorized to suspend immediately upon notice any permit issued under authority of this Section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the *commissioner* [~~Commissioner of Health~~] shall, immediately after [~~prompt~~] hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued, or as amended.

(c) Any *authorized agent* [~~officer or employee duly designated by the Commissioner of Health~~] shall have access to any factory or establishment, the operator of which holds a permit from the *commissioner* [~~Commissioner of Health~~] for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be *grounds* [~~ground~~] for suspension of the permit until such access is freely given by the operator.

Sec. 13. *FOOD LABELING EXEMPTIONS. (a) The board shall adopt rules exempting from any labeling requirement of this Act:*

(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 Act when removed from the processing, labeling, or repacking establishment.

(b) Food labeling exemptions adopted under the Federal Act apply to food in Texas except insofar as modified or rejected by rules adopted by the board.

Sec. 14. FOOD; TOLERANCES FOR ADDED POISONOUS INGREDIENTS. (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 10(a)(2) of this Act with respect to any food, Section 15(a) of this Act with respect to any drug or device, or Section 20 of this Act with respect to any cosmetic. However, if a rule adopted under Section 22 of this Act or Subsection (b) of this section 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 10(a)(1), 15, or 20 of this Act.

(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 the provisions of Section 1.05, Article 4414b, Revised Statutes, the commissioner may adopt emergency rules under the Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes) to establish tolerance levels of poisonous or deleterious substances in food. [~~Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof, cannot be avoided by good manufacturing practice, or serves a useful purpose, shall be deemed to be unsafe for purposes of the application of clause (2) of Section 10(a); but when such substance is so required, cannot be so avoided, or serves a useful purpose, the Commissioner of Health shall promulgate regulations limiting the quantity therein or thereon to such extent as the Commissioner of Health finds necessary for the protection of public health; and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of Section 10(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1), Section 10(a). In determining the quantity of such added substance to be tolerated in or on different articles of food, the Commissioner of Health shall take into account the extent to which the use of such substance is required, cannot be avoided in the production of~~

~~each such article, or serves a useful purpose, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.~~]

Sec. *15. DRUGS AND DEVICES; ADULTERATION DEFINED* [~~14~~]. 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 defective material~~]; or (2)(A) if it has been [~~produced,~~] prepared, packed, or held under insanitary conditions whereby it may have been contaminated *with filth*, or whereby it may have been rendered injurious to health [~~; or whereby it may have become or have been rendered incapable of, or unsuitable for, the purpose for which it was designed or intended~~]; *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 Act 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 [~~it is a drug and~~] 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)* [~~is a drug and it~~] bears or contains, for purposes of coloring only, a *color additive that is unsafe under Section 14(a) of this Act; 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 14(a) of this Act; or (5) if it is a new animal drug that is unsafe under Section 512 of the Federal Act;* [~~coal/tar color other than one from a batch certified under the authority 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* [~~standard~~] 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 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* [~~standard~~] of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such *standards* [~~standard~~] is plainly stated on its label. Whenever a drug is recognized in [~~both~~] the United States Pharmacopoeia *National Formulary,* [~~and the Homeopathic Pharmacopoeia of the United States~~] it shall be subject to the requirements of the United States Pharmacopoeia *National Formulary* [~~unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia~~];

(c) If it is not subject to the provision of paragraph (b) of this Section 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) If it is a banned device;

(g) 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

(h) 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 [~~provided, that this Subsection shall not apply to registered pharmacists compounding and dispensing physicians' prescriptions~~].

Sec. *16. DRUGS AND DEVICES; MISBRANDING DEFINED* [~~15~~]. A drug or device shall be deemed to be misbranded:

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

(2) If its labeling or packaging fails to conform with the requirements of Section 22 of this Act;

(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* [~~clause~~] (2) of this *subsection* [~~paragraph~~] 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* [~~established by regulations prescribed by the Commissioner of Health~~];

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

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

(e)*(1)* If it is a drug [~~and is not designated solely by a name recognized in an official compendium~~] 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 Subsection (e)(3) of this section) of the drug, if such there be; and

(ii) [~~its label bears (1) the common or usual name of the drug, if such there be; and (2)~~] in case it is fabricated from two or more ingredients, the *established name and quantity* [~~common or usual name~~] of each active ingredient, including the *quantity, kind, and proportion* [~~kind and quantity or 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* [~~glucosines~~], 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 Paragraph (B) of this subdivision 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) of this subsection) 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) of this subsection, 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) of this subdivision applies, then the common or usual name, if any, of such drug or of such ingredient; provided further, that where Paragraph (B) of this subdivision 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) of this subsection, 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) of this subdivision applies, then any common or usual name of such device; [~~to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemption shall be established by regulations promulgated by the Commissioner of Health;~~]

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to

health, or against unsafe dosage or methods or *durations* [~~duration~~] 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* [~~; provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Commissioner of Health shall promulgate regulations exempting such drug or device from such requirements~~];

(g) If it purports to be a drug the name of which is recognized in *an* [~~the~~] 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* [~~; provided, that the method of packing may be modified with the consent of the Commissioner of Health~~]. Whenever a drug is recognized in [~~both~~] the United States Pharmacopoeia *National Formulary* [~~and the Homeopathic Pharmacopoeia of the United States~~], 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 (e) of this section as to the name by which the drug or its ingredients shall be designated, the requirements of Subsection (e) of this section prevail* [~~unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia~~];

(h) If it has been found by the *secretary* [~~Commissioner of Health~~] 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* [~~Commissioner of Health~~] shall by regulations require as necessary for the protection of public health [~~: No such regulation shall be established for any drug recognized in an official compendium until the Commissioner of Health shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements~~];

(i)(1) If it is a drug [~~or device~~] and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug [~~or device~~]; or (3) if it is offered for sale under the name of another drug [~~or device~~];

(j) If it is dangerous to health when used in the dosage, *or manner* or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

(k) *If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless:*

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

(2) such certificate or release is in effect with respect to such drug; [~~(1) If it is a drug sold at retail and contains any quantity of amidopyrine, barbituric acid, pituitary, thyroid, or their derivatives; or (2) if it is a drug or device sold at retail and its label bears a statement that it is to be dispensed or sold only by or on the prescription of a physician, dentist or veterinarian licensed to practice in this state, unless it is sold on a prescription by a member of the medical, dental, or veterinary profession who is licensed by law to administer such drug or device, and its label bears the name and place of business of the seller, the serial number and date of such prescription, and the name of such member of the medical, dental or veterinary profession. Such prescription shall not be refilled except on the authorization of the prescribing physician, dentist or veterinarian. This Subsection shall not apply to a drug containing one or more of the derivatives of barbituric acid and in addition a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of barbituric derivative to cause an hypnotic or somnifacient effect.~~]

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

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

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

(m) If it is a color additive, the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in rules issued under Section 14(b) of this Act;

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

(1) the established name as defined in Section 16(e) of this Act, 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 Section 16(e) of this Act; 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;

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

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued under Section 3 or 4 of the Federal Poison Prevention Packaging Act of 1970;

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

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

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

(2) it is sold, distributed, or used in violation of regulations prescribed under Section 16(e) of this Act;

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

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

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

(t) If it is a device subject to a performance standard established under Section 514 of the Federal Act, unless it bears such labeling as may be prescribed in such performance standard;

(u) If it is a device and there was a failure or refusal:

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

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

Sec. 17. EXEMPTIONS IN CASE OF DRUGS AND DEVICES. (a) The board is hereby directed to adopt rules exempting from any labeling or packaging requirement of this Act 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 Act 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 Texas except insofar as modified or rejected by rules of the board.

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

(A) is a habit-forming drug to which Section 16(d) of this Act applies; or

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

(C) is limited by an approved application under Section 505 of the Federal Act to use under the professional supervision of a practitioner licensed by law to administer such drug shall be dispensed only:

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

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

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

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of Section 16 of this Act, except Subsections (a)(1), (i)(2), (i)(3), (k), and (l), Section 16, of this Act and the packaging requirements of Subsections (g), (h), and (p), Section 16, of this Act 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) of this subsection;

(3) The board may, by rule, remove drugs subject to Section 16(d) of this Act and Section 505 of the Federal Act from the requirements of Subdivision (1) of this subsection when such requirements are not necessary for the protection of the public health;

(4) A drug that is subject to Subdivision (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription," or "Caution: State Law Prohibits Dispensing Without Prescription." A drug to which Subdivision (1) of this subsection 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.

~~[Sec. 15A. A drug or device is misbranded if it is a drug or device which is required by Federal Law to bear the statement "Caution: Federal Law prohibits dispensing without prescription," and it does not bear the statement.]~~

Sec. *18* [~~16~~]. *NEW DRUGS* (a) *A* [~~No~~] 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* [~~said~~] approval has not been withdrawn under Section 505 of the Federal Act, *and* [~~or~~] (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* [~~when not subject to the Federal Act, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Commissioner of Health a complete application setting forth (a) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (b) a full list of the articles used as components of such drug; (c) a full statement of the composition of such drug; (d) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (e) such samples of such drug and of the articles used as components thereof as the Commissioner of Health may require; and (f) specimens of the labeling proposed to be used for such drug. The Texas Board of Health shall adopt rules prescribing the requirements of a complete application and prescribing procedures for filing new drug applications~~].

(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 Section 312.1 of Title 21 of the Code of Federal Regulations (1980) and the exemption has not been terminated. The drug shall be plainly labeled in compliance with Section 505(i) or 507(d) of the Federal Act.* ~~[A complete application provided for in Subsection (a)(2) shall become effective on the one hundred eightieth day after the filing thereof, except that if the Commissioner of Health finds, after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.]~~

(c) ~~[An order refusing to permit an application under this section to become effective may be revoked by the Commissioner of Health.~~

~~[(d)]~~ This section shall not apply--

(1) to *any* [~~a~~] drug *that is not a new drug as defined in the Federal Act* ~~[intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug is plainly labeled in compliance with regulations issued by the Commissioner of Health or pursuant to Section 505(i) or 507(d) of the Federal Act~~]; or

(2) to *any drug that is licensed under the Public Health Services Act of July 1, 1944, or under the virus-serum-toxin law of March 4, 1913* [~~a drug sold in this state at any time prior to the enactment of this Act or introduced into interstate commerce at any time prior to the enactment of the Federal Act~~]; or

(3) to any drug *approved by the commissioner by authority of any law, including this section.* [~~which is licensed under the virus, serum, and toxin Act of July 1, 1902 (U.S.C. 1058 ed. Title 42, Chapter 6A, Sec. 262.)~~

[~~(e) The provisions of Section 2(n) shall not apply to any drug which, on October 9, 1962, or on the date immediately preceding the enactment of this Subsection, (A) was commercially sold or used in this State or in the United States, (B) was not a new drug as defined by Section 2(n) as then in force, and (C) was not covered by an effective application under Section 16 of this Act or under Section 505 of the Federal Act, when such drug is intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug.~~

[~~(f) This section does not apply to dimethyl sulfoxide (DMSO).~~

[~~(g) A hospital or health care facility may not forbid or restrict the use of a drug prescribed or administered by a licensed physician having staff privileges at that hospital or facility if:~~

[~~(1) an application for the drug has been approved under this section;~~

[~~(2) the Commissioner of Health has not issued an order refusing to permit an application relating to the drug to become effective under this section; or~~

[~~(3) a court of competent jurisdiction has declared that an application relating to the drug has become effective and has authorized the manufacture, sale, delivery, offer for sale, holding for sale, or gift of the drug under this section.~~

[~~(h) The Texas Department of Health may enter into any necessary contracts with federal or state agencies or institutions of higher education for review of technical and clinical data submitted under this section.~~]

Sec. 19. 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 Act 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 Act 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 approved by the commissioner by authority of any law, including Section 16 of this Act.

Sec. *20. COSMETICS; ADULTERATION DEFINED* [~~17~~]. 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 [~~or advertisement~~] 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* [~~paragraph~~] and Subsection [~~paragraph~~] (e) *of this section* 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 *insanitary* [~~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 [~~coal/tar~~] color *additive that is unsafe within the meaning of Section 14(a) of this Act* [~~other than one certified under authority of the Federal Act~~].

Sec. *21. COSMETICS; MISBRANDING DEFINED* [~~18~~]. A cosmetic shall be deemed to be misbranded:

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

(2) if its labeling or packaging fails to conform with the requirements of Section 22 of this Act;

(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* [~~clause~~] (2) of this *subsection* [~~paragraph~~] reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by *rules adopted by the board* [~~the Commissioner of Health~~];

(c) If any word, statement, or other information required by or under authority of this Act 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;

(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.

(g) The board shall adopt rules exempting from any labeling requirement of this Act 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 Act on removal from the processing, labeling, or repacking establishment. Cosmetic labeling exemptions adopted under the Federal Act shall apply to cosmetics in Texas except insofar as modified or rejected by rules adopted by the board.

Sec. 22. FAIR PACKAGING AND LABELING PROVISIONS. (a) All labels of consumer commodities, as defined by this Act, 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) of this section, 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) of this section 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 2(3) of this Act) 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.

Sec. *23. FALSE ADVERTISING* [~~10~~]. (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) For the purpose of this Act the advertisement of a drug or device representing it to have any effect in:

(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 [~~albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diptheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia, venereal disease,~~] shall also be deemed to be false, except that no advertisement not in violation of Subsection (a) *of this section* shall be deemed to be false under this *subsection* [~~Subsection~~] if *it is disseminated to the public for the purpose of self-medication and is consistent with the labeling claims permitted by the United States Food and Drug Administration,* it is disseminated only to members of the medical, dental, *and* [~~or~~] veterinary professions, [~~or~~] appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices; provided, that whenever the *board* [~~Commissioner of Health~~] determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the *board* [~~Commissioner of Health~~] shall by *rule* [~~regulation~~] authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the *board* [~~Commissioner of Health~~] may deem necessary in the interest of public health; provided, that this *subsection* [~~Subsection~~] shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

Sec. *24* [~~20~~]. *RULES; HEARINGS; UNIFORMITY WITH FEDERAL LAW. (a) The authority to adopt rules for the enforcement of this Act is vested in the board. The board is authorized to make the rules adopted under this Act conform, insofar as practicable, with those promulgated under the Federal Act. A violation of a rule adopted under this Act shall be deemed to be a violation of the Act.*

(b) Administrative hearings authorized or required by this Act and appeals from final administrative decisions shall be conducted pursuant to the applicable provisions of the Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes) and the board's rules for contested case hearings.

(c) All regulations adopted by the secretary pursuant to the Federal Act shall be the applicable rules for the purposes of this Act, except as they are modified or rejected by the board, for:

(1) pesticide chemicals;

(2) food additives;

(3) color additives;

(4) special dietary use;

(5) bottled water and vended bottled water; and

(6) infant formula.

(d) All regulations adopted under the Fair Packaging and Labeling Act shall be the rules in Texas except insofar as modified or rejected by rules adopted by the board; provided, that rules shall not be adopted that are contrary to the labeling requirements for the net quantity of contents required pursuant to Section 4 of the Fair Packaging and Labeling Act and the regulations promulgated thereunder.

(e)(1) Federal regulations that apply pursuant to Subsections (c) and (d) of this section take effect in this state on the date the regulations become effective as federal regulations. The department need not fulfill the requirements of the rulemaking provisions of the Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes) for the federal regulations to become effective in this state.

(2) If the board modifies or rejects any federal regulations, the board shall comply with the rulemaking provisions of the Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes).

(f) Notwithstanding the provisions of Section 1.05, Article 4414b, Revised Statutes, the commissioner or his designee may issue an emergency order, either mandatory or prohibitory in nature, regarding any activity of food, drug, device, or cosmetic manufacturing within the jurisdiction of the department if the commissioner or his designee determines that the activity is creating or posing an immediate and serious threat to human life or health and that other procedures available to the department to remedy or prevent the occurrence of the situation will result in unreasonable delay. The order may be issued without notice and hearing as the commissioner or his designee deems practicable under the circumstances. If an emergency order is issued under this authority without a hearing, the department shall fix a time and place for a hearing to be held in accordance with departmental rules so as to affirm, modify, or set aside the emergency order.

(g)(1) The department and the department of agriculture shall execute a memorandum of understanding that:

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

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

(2) The department and the department of agriculture shall adopt the memorandum of understanding as a rule.

(3) The department and the department of agriculture shall request the Federal Food and Drug Administration to join in execution of the memorandum of understanding.

(h) The board by rule may delegate any power or responsibility imposed on the commissioner in this Act, including the power or duty to issue emergency rules, emergency manufacturing permits, or orders or to render a final administrative decision to a designee of the board.

(i) A health authority may delegate any power or duty imposed on the health authority in this Act to an employee of the local health department, the local health unit, or the public health district in which the health authority serves, unless otherwise restricted by law. [~~(a) The authority to promulgate reasonable and necessary regulations, not inconsistent with any provision of this Act, for the efficient enforcement of this Act is hereby vested in the Commissioner of Health. The violation of a regulation promulgated under this Act shall be deemed to be a violation of this Act.~~

[~~(b) Hearings authorized or required by this Act shall be conducted by the Commissioner of Health or such officer, agent, or employee as the Commissioner of Health may designate for the purpose.~~

[~~(c) Before promulgating any regulations, the Commissioner of Health shall give thirty (30) days notice of the proposal and of the time and place for a hearing thereon by publishing such notice in a newspaper of general circulation within the state and the Commissioner of Health shall place any person, firm or corporation so desiring said notices on a state mailing list which said list shall entitle said holder to a copy of any notice of any regulation to be promulgated. To be entitled to receive such notices, said holder shall first pay in advance, an annual service charge to be determined by the Commissioner of Health, which same shall not be more than Five Dollars ($5.00), except that the public hearing on regulations under Section 12 may be held at a time, to be fixed by the Commissioner of Health, after notice thereof. The regulation so promulgated shall become effective on a date fixed by the Commissioner of Health (which date shall not be prior to the ninetieth (90) day after its promulgation), except that if the Commissioner of Health finds that emergency conditions exist necessitating an earlier effective date, then the Commissioner of Health shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the~~

~~Commissioner of Health shall specify therein to meet the emergency. Such regulation may be amended or repealed in the same manner as is provided for its adoption, except that in the case of a regulation amending or repealing any such regulation the Commissioner of Health, to such an extent as he deems necessary in order to prevent undue hardship, may disregard the foregoing provisions regarding notice, hearing, or effective date.~~

~~[(e/1) In all appeals prosecuted in any of the courts of this state pursuant to the provisions of this Act, such trials shall be de novo as that term is used and understood in appeals from justice of the peace courts to county courts. When such an appeal is filed and the court thereby acquires jurisdiction, all administrative or executive action taken prior thereto shall be null and void and of no force and effect, and the rights of the parties thereto shall be determined by the court upon a trial of the matters in controversy under rules governing the trial of other civil suits in the same manner and to the same extent as though the matter had been committed to the courts in the first instance and there had been no intervening administrative or executive action or decision. Under no circumstance shall the substantial evidence rule as interpreted and applied by the courts of Texas in other cases ever be used or applied to appeals prosecuted under the provisions of this Act. If this Section, or any part thereof, is for any reason ever held by any court to be invalid, unconstitutional or inoperative in any way, then in that event such appeals shall be as provided in Section 20(d) of this Act. It is specifically provided hereby that Section 20(d) of this Act shall not be operative unless and until the appeal as provided by Section 20(e/1) is held invalid, unconstitutional or inoperative.~~

~~[(d) If any party at interest be dissatisfied with any act, order, ruling or decision of the Commissioner of Health in connection with the administration of this Act, such party may file an action, naming the Commissioner of Health as defendant, in any of the district courts of Travis County to set aside the particular act, order, ruling or decision. The cause shall be tried by the court without a jury in the same manner as civil actions generally and all fact issues material to the validity of such act, order, ruling or decision shall be re/determined in such trial on the preponderance of the competent evidence but no evidence shall be admissible which was not either tendered to the Commissioner of Health or on file in his office while the matter was pending before him for decision. The burden of proof shall be on the plaintiff and judgment shall be entered by the court declaring the action, order, ruling or decision in question either valid or invalid. Appeals from any final judgment may be taken in the manner provided for in ordinary civil actions generally. No appeal bond shall be required by the Commissioner of Health. All acts, orders, rulings and decisions of the Commissioner of Health shall be final unless an action to set aside as herein authorized is filed within thirty (30) days after the action, order, ruling or decision is taken or made by the Commissioner of Health.]~~

Sec. *25. INSPECTIONS; EXAMINATIONS* ~~[21]~~. *(a) For purposes of the enforcement of this Act, the commissioner, authorized agents, or a health authority may on the presentation of appropriate credentials to the owner, operator, or agent in charge:*

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

(2) inspect at reasonable times, within reasonable limits, and in a reasonable manner such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein and thereon, and obtain samples necessary to the enforcement of this Act. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs or restricted devices that are adulterated or misbranded within the meaning of this Act or that may not be manufactured, introduced into commerce, or sold or offered for sale by reason of any provision of this Act have been or are being manufactured, processed, packed, transported, or held in any such place or otherwise bearing on a violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, and antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to Section 505(i) or (j) or Section 507(d) or (g), Section 519 or 520(g) of the Federal Act), and data relating to other drugs, or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to Section 505(j) of the Federal Act. Such inspection shall be commenced and completed with reasonable promptness.

(b) The provisions of Subsection (a) of this section shall not apply to:

(1) pharmacies that maintain establishments in conformance with the Texas Pharmacy Act (Article 4542a-1, Vernon's Texas Civil Statutes) regulating the practice of pharmacy and medicine and that are regularly engaged in dispensing prescription drugs, or devices on prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and that do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs or manufacture or process devices solely for use in the course of their professional practice;

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

(4) such other classes of persons as the board by rule may exempt from the application of this section on a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(c) An authorized agent or health authority making an inspection under this section for purposes of enforcing the requirements applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records:

(1) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of this Act; or

(2) required to be maintained under provisions of this Act.

(d) If the authorized agent or health authority making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, on completion of the inspection and prior to leaving the premises, he shall give to the owner, operator, or the owner's or operator's agent in charge a receipt describing the samples obtained.

(e) Every person required under this Act or Section 519 or 520(g) of the Federal Act to maintain records and every person who is in charge or custody of such records shall, on request of an authorized agent or a health authority, permit such authorized agent or health authority at all reasonable times to have access to and to copy and verify such records.

(f) For the purposes of enforcing the provisions of this Act, carriers engaged in commerce, and persons receiving food, drugs, devices, or cosmetics in commerce or holding such articles so received, shall, on the request of the authorized agent or a health authority, permit such authorized agent or health authority at reasonable times to have access to and to copy all records showing the movement in commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates; provided, that evidence obtained under this section or any evidence that is directly or indirectly derived from such evidence shall not be used in a criminal prosecution of the person from whom obtained; and provided further, that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers. [~~The Commissioner of Health or his duly authorized agent shall have free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, stored or held for introduction into commerce, or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in commerce, for the purpose:~~

[~~(1) of inspecting such factory, warehouse, establishment, or vehicle to determine if any of the provisions of this Act are being violated, and to determine whether the record keeping provisions of Chapter 425, Acts of the 56th Legislature, Regular Session, 1959, as amended (Article 726d, Vernon's Texas Penal Code), of the Texas Controlled Substances Act or of the regulations of the director of the Department of Public Safety are being violated; and~~

[~~(2) to secure samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for such samples. It shall be the duty of the Commissioner of Health to make or cause to be made examinations of samples secured under the provisions of this section to determine whether or not any provision of this Act is being violated. Whenever samples are secured by the Commissioner of Health or his agent, an equal amount of the product sampled, may upon request, be given to the person who has custody of the product sampled; payments shall be made only for that portion of the sample actually taken by the said Commissioner or agent.~~]

Sec. *26* [~~22~~]. *PUBLIC EDUCATION.* (a) The *commissioner* [~~Commissioner of Health~~] may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The *commissioner* [~~Commissioner of Health~~] may also cause to be disseminated such information regarding food, drugs, devices, *or* [~~and~~] cosmetics *in situations that, in the opinion of the commissioner, involve imminent danger to health or gross deception of the consumer* [~~as the Commissioner of Health deems necessary in the interest of public health and the protection of the consumer against fraud~~]. *This section does not prohibit the commissioner from collecting, reporting, and illustrating the results of an investigation of the commissioner.*

[~~Sec. 22A. (a) Prosecution had or pending by the Federal Government, or any of its agents, involving the first processing of agricultural products, against any person subject to federal jurisdiction in such matters, for criminal or civil penalties, shall constitute complete defense against prosecution by the State of Texas, or any of its agencies, against such person for violation of any provision of this Act involving substantially the same facts and the same subject matter as involved in such federal proceedings, regardless of similarity or dissimilarity as between the sanctions and penalties of the federal and state statutes or regulations, and regardless of the result of such federal prosecution or procedure.~~

~~(b) Proceedings pending or in active preparation through which the Federal Government seeks confiscation, destruction, decontamination, condemnation, or mutilation of agricultural products subject to such federal controls or procedures and subject to controls established in this Act, upon appropriate pleading will serve as abatement of any proceedings or cause of action for the same purpose involving the same person, or persons, and the same subject matter that may be brought by the State of Texas, or any of its agencies, through court or administrative proceedings.~~

~~(c) Compliance in good faith by any person subject to federal jurisdiction in such matters, with orders, directives or judgments issued or secured by or at the instance of the Federal Drug Administration, or any other federal agency, in respect to the acquirement, use, or operation of any product, process, plant, device, or machinery, used or useful in the first processing of agricultural products, shall constitute a bar to any criminal, civil, or administrative procedure brought by or at the instance of the Commissioner of Health, or other state agency, under or by virtue of provisions of this Act, to the extent that such state procedure may duplicate, overlap, or conflict with such federal orders, directives, or judgment.~~

~~(d) The provisions of this Section shall apply only to the business activity of cotton seed crushing and processing and to only those persons who are engaged in interstate commerce and subject to both federal and state inspection. Provided further, that the provisions of this Section shall apply only to situations where there is a conflict in the federal and state laws.~~]

Sec. *27* [~~23~~]. *WHOLESALE DRUG DISTRIBUTORS. (a)* [~~1.~~] No person shall engage in the wholesale distribution of drugs in this State without first filing a registration statement with the *commissioner* [~~Commissioner of Health~~].

The words "wholesale distribution" shall be defined as meaning distribution to other than the consumer or patient and shall include distribution by manufacturers, re-packers, own label distributors, jobbers, and wholesalers.

(b) [~~2.~~] The registration statement, which shall be signed and verified, shall be made on such forms as shall be furnished by the *commissioner* [~~Commissioner of Health~~] and shall provide the following information:

(1) [~~(a)~~] The name under which the business is conducted; [~~;~~]

(2) [~~(b)~~] The address of each place of business in the State being registered. A "place of business" means each location where drugs are located for wholesale distribution; [~~;~~]

(3) [~~(c)~~] If proprietorship, the name and resident address of the proprietor; if a partnership, the names and resident addresses of all partners; if a corporation, the date and place of incorporation; or if any other type of association, then the names and addresses of the principals of such association; [~~;~~]

(4) [~~(d)~~] The names and resident addresses of those individuals in actual administrative capacity which, in the case of proprietorship, shall be the managing proprietor; partnership, the managing partner; corporation, the officers and directors; or those in a managerial capacity in any other type of association; *and*[~~;~~]

(5) [~~(e)~~] For each place of business in the State, the resident address of the individuals in charge thereof.

(c) [~~3.~~] The registration statement shall be filed prior to commencing business as a wholesale drug distributor and annually thereafter [~~on or before the first day of September in each calendar year~~]. *The board by rule may adopt a system under which registrations expire on various dates during the year. For the year in which the registration expiration date is changed, registration fees payable before or on September 1 shall be prorated on a monthly basis so that each registrant shall pay only that portion of the registration fee that is allocable to the number of months during which the registration is valid. On renewal of the registration on the new expiration date, the total registration renewal fee is payable.*

(d) [~~4.~~] *The board shall adopt, charge, and collect fees for each registration filed, renewed, or amended under this section and for inspections performed in enforcing this section and rules adopted under this section. The fees may be charged on an annual basis. The amount of the fees shall be established by rule adopted by the board and must be set so that the department can recover not less than 50 percent of the actual annual expenditures of state funds by the department in:*

(1) reviewing and acting on registrations;

(2) amending and renewing registrations;

(3) inspecting registered facilities; and

(4) implementing and enforcing this section and rules and orders adopted and registrations issued under this section. [~~The initial and annual fee for registration which shall accompany the registration statement shall be Twenty/five Dollars ($25) for each place of business.~~]

(e) [~~5.~~] In the event the location of a registered place of business shall be changed, the registrant shall notify the *commissioner* [~~Commissioner of Health~~], in writing, of the address of such new location and the name and resident address of the individual in charge thereof. The fee to accompany such notification shall be *set by the board under Subsection (d) of this section* [~~Five Dollars ($5) unless it shall appear to the satisfaction of the Commissioner of Health that the change of location is of a temporary nature due to fire, flood, or other disaster~~].

(f) [~~6.~~] *After notice and a hearing pursuant to the applicable provisions of the Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes) and of the board's rules for the hearing of a contested case, the commissioner* [~~The Commissioner of Health~~] may[~~, after notice and hearing,~~] refuse to register or cancel, revoke, or suspend the registration of any wholesale drug distributor for any of the following reasons:

(1) [~~(a)~~] If the registrant has been convicted of a felony or misdemeanor which involves moral turpitude, or if the registrant be an association, partnership, or corporation, that the managing officer has been convicted of a felony or misdemeanor which involves moral turpitude;

(2) [~~(b)~~] That the registrant has been convicted in either a State or Federal court for 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 if the registrant be an association, partnership, or corporation, that the managing officer has been convicted in either 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;

(3) [~~(c)~~] That based on evidence presented during a hearing it is determined that the applicant or registrant has sold counterfeit drugs and medicines, or has violated any of the provisions of Chapter 425, Acts of the 56th Legislature, Regular Session, 1959 [~~, as amended~~] (Article 4476-14, Vernon's Texas Civil Statutes), of the Texas Controlled Substances Act [~~, as amended~~] (Article 4476-15, Vernon's Texas Civil Statutes), or of the regulations of the director of the Department of Public Safety including any significant discrepancy in the records required to be maintained by State law; *or*

(4) [~~(d)~~] Failure of the applicant or registrant to comply with this Act.

(g) [~~7.~~] Any registrant whose registration has been cancelled, revoked, or suspended by the *commissioner* [~~Commissioner of Health~~] pursuant to the preceding *subsection* [~~Section~~] shall have the right to *judicial review of the administrative decision pursuant to the applicable provisions of the Administrative Procedure and Texas Register Act (Article 6252-13a, Vernon's Texas Civil Statutes)* [~~appeal to a court of competent jurisdiction in his county of residence. Such appeal shall be de novo as appeals from justice courts to county courts, and the substantial evidence rule shall not apply~~].

(h) A [~~8. (a) Any~~] person *commits an offense if the person* [~~who~~] engages in the wholesale distribution of drugs *and* [~~who~~] does not comply with the requirements of this *section* [~~Section~~] by being registered with the *commissioner* [~~Commissioner of Health commits an offense~~].

[~~(b)~~] An offense under this *subsection* [~~Section~~] is a Class A misdemeanor.

(i) [~~9.~~] The fees provided for in Subsections *(d)*[~~4~~] and *(e)* [~~5~~] *of this section* shall be deposited in the State Treasury to the *credit of the food and drug registration fee general revenue* [~~Food~~

~~and Drug Registration Fee General Revenue~~] account and shall be available for carrying out the provisions of this Act.

Sec. *28. FOOD MANUFACTURERS. (a)* [~~23a. 1.~~] All manufacturers of foods in the state shall annually register [~~on or before September 1~~] with the *department* [~~Texas Department of Health and pay a fee set by the Texas Board of Health adequate to pay the cost of administering this program and not to exceed $25~~]. Where a manufacturer operates more than one establishment, then a separate registration and fee shall be required for each establishment operated.

(b) [~~2.~~] The registration statement, which shall be signed and verified, shall be made on forms furnished by the *department* [~~Texas Department of Health~~] and shall provide the following information:

(1) [~~(a)~~] the name under which the business is conducted;

(2) [~~(b)~~] the address of each place of business in the state being registered;

(3) [~~(c)~~] if a sole proprietorship, the name of the proprietor; if a partnership, the names of all partners; if a corporation, the date and place of incorporation and name and address of its registered agent in the state; or if any other type of association, then the names of the principals of such association; *and*

(4) [~~(d)~~] the names of those individuals in an actual administrative capacity which, in the case of a sole proprietorship shall be the managing proprietor; in a partnership, the managing partner; in a corporation, the officers and directors; in any other association, those in a managerial capacity.

(c) The board shall adopt, charge, and collect fees for each registration filed or renewed under this section and for inspections performed in enforcing this section and rules adopted under this section. The fees may be charged on an annual basis. The amount of the fees shall be established by rule adopted by the board and must be set so that the Texas Department of Health can recover not less than 50 percent of the actual annual expenditures of state funds by the department in:

(1) reviewing and acting on registrations;

(2) amending and renewing registrations;

(3) inspecting registered facilities; and

(4) implementing and enforcing this section and rules and orders adopted and registrations issued under this section.

(d) The board by rule may adopt a system under which registrations expire on various dates during the year. For the year in which the registration expiration date is changed, registration fees payable before or on September 1 shall be prorated on a monthly basis so that each registrant shall pay only that portion of the registration fee that is allocable to the number of months during which the registration is valid. On renewal of the registration on the new expiration date, the total registration renewal fee is payable.

(e) [~~3.~~] The term "manufacture" as used in this *Act* [~~article~~] shall mean the process of combining or purifying articles of food and packaging same for sale to the consumer, either by wholesale or retail. Any person, firm, or corporation who represents itself as responsible for the purity and the proper labeling of any article of food by placing or having placed its name and address upon the label of any food shall be deemed a manufacturer and shall be included within the meaning of this Section.

(f) [~~4.~~] All registration fees received by the *department* [~~Texas Department of Health~~] shall be deposited in the State Treasury to the credit of the *general revenue fund* [~~General Revenue Fund~~] and are appropriated to the department for the administration of this Act.

(g) [~~5.~~] The *commissioner* [~~Commissioner of Health~~] may, after notice and hearing, refuse to register or may cancel, revoke, or suspend the registration of any food manufacturer. The *board* [~~Texas Board of Health~~] shall adopt rules establishing minimum standards for registering, cancelling, revoking, and suspending registrations under this Section.

(h) [~~6.~~] Procedures for notice and hearing *and judicial review of a final administrative hearing* shall be governed by *the board's* [~~Texas Department of Health~~] rules for a contested case hearing and by the Administrative Procedure and Texas Register Act[~~, as amended~~] (Article 6252-13a, Vernon's Texas Civil Statutes).

(i) A [~~7. (a) Any~~] person *commits an offense if the person* [~~who~~] manufactures food in this state *and* [~~who~~] does not comply with the registration requirements of this Section [~~commits an offense~~].

[~~(b)~~] An offense under this section is a Class A misdemeanor.

SECTION 2. The following laws and parts of laws are repealed:

(1) Section 11, Chapter 42, Acts of the 40th Legislature, 1st Called Session, 1927 (Article 4465a, Vernon's Texas Civil Statutes);

(2) Article 4466, Revised Statutes;

(3) Article 4467, Revised Statutes;

(4) Article 4468, Revised Statutes;

(5) Article 4469, Revised Statutes;

(6) Chapter 199, Acts of the 48th Legislature, Regular Session, 1943 (Article 4476-1, Vernon's Texas Civil Statutes);

(7) Chapter 353, Acts of the 56th Legislature, Regular Session, 1959 (Article 4476-4, Vernon's Texas Civil Statutes); and

(8) Chapter 457, Acts of the 55th Legislature, Regular Session, 1957 (Article 4476-12, Vernon's Texas Civil Statutes).

SECTION 3. This Act takes effect on September 1, 1985.

SECTION 4. The importance of this legislation and the crowded condition of the calendars in both houses create an emergency and an imperative public necessity that the constitutional rule requiring bills to be read on three several days in each house be suspended, and this rule is hereby suspended.

Passed by the House on May 21, 1985, by the following vote: Yeas 141, Nays 2, 2 present, not voting; House concurred in Senate amendments to H.B. No. 1732 on May 27, 1985, by a non-record vote; passed by the Senate, with amendments, on May 26, 1985, by the following vote: Yeas 31, Nays 0.

Approved: June 15, 1985

Effective: September 1, 1985