

**Department of State Health Services  
Agenda Item for State Health Services Council  
May 12, 2006**

**Agenda Item Title:** New 25 TAC, Chapter 229, Subchapters D, O, and W, §§229.40-229.41, 229.241-229.252, 229.419-229.430 and repeal §§229.251-229.254, relating to the regulation of cosmetics; the licensing of wholesale distributors of nonprescription drugs, including good manufacturing practices; and the licensing of wholesale distributors of prescription drugs, including good manufacturing practices.

**Agenda Number:** 5a

**Recommended Council Action:**

For Discussion Only

For Discussion and Action by the Council

**Background:** The Drugs and Medical Devices Group of the Division for Regulatory Services regulates the manufacture and distribution of drugs in Texas. The legislature amended Health and Safety Code, Chapter 431, Subchapters I and N, relating to the licensing and regulation of nonprescription and prescription drugs. Licensing has been separated by class of drug (prescription vs. over-the-counter) and stricter requirements put in place for the distribution of prescription drugs.

**Summary:** The new rules set forth the licensing and regulation of manufacturers and distributors of nonprescription and prescription drugs, including: expanded application requirements, provisions for criminal history and background checks, new prohibited acts, and enforcement options.

**Summary of Stakeholder Input to Date (including advisory committees):** An informal work group of manufacturers and distributors was established and the work group provided input into the development of the rules. The stakeholder workgroup met on November 10, 2005, and May 5, 2006.

**Proposed Motion:** Motion to recommend to HHSC approval for publication of rules contained in agenda item # 5a.

**Agenda Item Approved by:** \_\_\_\_\_

**Date Submitted**

**Presented by:** Susan E. Tennyson

**Title:** Section Manager

**Program/Division:** Environmental and Consumer Safety Section, Regulatory Services

**Contact Name/Phone No.** Susan E. Tennyson/834-6770, Ext. 2600

## Title 25. HEALTH SERVICES

### Part 1. DEPARTMENT OF STATE HEALTH SERVICES

#### Chapter 229. Food and Drug

##### Subchapter D. Regulation of Cosmetics.

New §§229.40 - 229.41

##### Subchapter O. Licensing of Wholesale Distributors of Drugs--Including Good Manufacturing Practices.

Repeal §§229.251 - 229.254

##### Subchapter O. Licensing of Wholesale Distributors of Nonprescription Drugs--Including Good Manufacturing Practices.

New §§229.241 - 229.252

##### Subchapter W. Licensing of Wholesale Distributors of Prescription Drugs--Including Good Manufacturing Practices.

New §§229.419 - 229.430

#### Proposed Preamble

The Executive Commissioner of Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes new §§229.40 - 229.41, 229.241 - 229.252, and 229.419 - 229.430, and the repeal of §§229.251 - 229.254, concerning the regulation of cosmetics, the licensing of wholesale distributors of nonprescription drugs--including good manufacturing practices, and the licensing of wholesale distributors of prescription drugs--including good manufacturing practices, respectively.

#### BACKGROUND AND PURPOSE

The new sections are necessary to comply with amendments to Health and Safety Code, Chapter 431, Subchapters I and N, relating to the licensing and regulation of nonprescription and prescription drugs. Subchapter I of the statute sets forth the standards for the licensing and regulation of nonprescription drugs and requires the department to adopt rules to implement and enforce the subchapter. Existing Subchapter O of Chapter 229 of this title originally set forth the requirements for all drug and cosmetic manufacturers and distributors, but is now being proposed for repeal in order to separate the licensing and regulation of the various commodities.

#### SECTION-BY-SECTION SUMMARY

New §§229.40 - 229.41 reflect the regulations for cosmetic manufacturing and labeling, setting out the Scope and Purpose and adopting by reference the federal requirements for cosmetics.

New §§229.241 - 229.252 set forth the licensing and regulation of manufacturers and distributors of nonprescription drugs. Section 229.241 sets forth the purpose of the rules. Section 229.242 adopts by reference the federal requirement for nonprescription drugs. Section 229.243 sets forth the definitions used in the rules. Section 229.244 defines sale to include entire stream of possession of nonprescription drugs until possession by a consumer. Sections 229.245 – 229.248 set out the exemptions from licensing; licensing requirements; licensing procedures; and the requirements for reporting licensure changes. Section 229.249 sets out the licensing fees for each category of license. Section 229.250 sets forth the reasons for refusing to issue a license, for canceling, suspending, or revoking a license. Section 229.251 sets out the minimum standards for licensure, including good manufacturing practices. Section 229.252 sets out the enforcement and penalties provisions.

New §§229.419 - 229.430 set forth the licensing and regulation of manufacturers and distributors of prescription drugs. Section 229.419 sets forth the purpose of the rules. Section 229.420 adopts by reference the federal requirement for prescription drugs. Section 229.421 sets forth the definitions used in the rules. Section 229.422 defines sale to include entire stream of possession of prescription drugs until possession by a consumer. Section 229.423 sets out the exemptions from licensing. Section 229.424 outlines licensing requirements. Section 229.425 sets forth the licensing procedures, and §229.426 sets forth the requirements for reporting licensure changes. Section

229.427 sets out the licensing fees for each category of license. Section 229.428 sets forth the reasons for refusing to issue a license, for canceling, suspending, or revoking a license. Section 229.429 sets out the minimum standards for licensure, including good manufacturing practices. Section 229.430 outlines enforcement and penalties provisions.

#### FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each calendar year of the first five years the sections are in effect, there will be fiscal implications to the state as a result of enforcing or administering the sections as proposed. The effect on state government will be an estimated increase in revenue for the state of \$462,325 in fiscal year 2006, and \$462,325 in each of the fiscal years 2007 through 2010. These additional revenues will offset the increased costs associated with the legislative increase in pay, longevity pay, and travel reimbursement, as well as the costs of regulatory oversight. Implementation of the proposed sections will not result in any fiscal implications for local governments.

#### SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there are anticipated economic costs to small businesses or micro-businesses required to comply with the sections as proposed. There will be an increase in the licensing fees for businesses or persons required to maintain a prescription drug or nonprescription drug license. The probable economic cost to businesses or persons required to comply with the fee for the license will be an increase of approximately 30% to 35% for a two-year license. There is no anticipated negative impact on local employment.

#### PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is a reduction in the diversion of regulated products and in the amount of counterfeit prescription drugs in the marketplace.

#### REGULATORY ANALYSIS

The department has determined that this proposal is not a “major environmental rule” as defined by Government Code, §2001.0225. “Major environmental rule” is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

#### TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

#### PUBLIC COMMENT

Comments on the proposal may be submitted to Tom Brinck, Drugs and Medical Devices Group, Environmental and Consumer Safety Section, Division for Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, 512/719-0243, or by email to Tom.Brinck@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

#### LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Cathy Campbell, certifies that the proposed repeal and new rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

#### STATUTORY AUTHORITY

The proposed repeal and new sections are authorized by Health and Safety Code, §431.241, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules necessary for the implementation and enforcement of Chapter 431 by the department; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed repeal and new sections affect Health and Safety Code, Chapters 12, 431, and 1001; and Government Code, Chapter 531.

Legend: (Proposed New Rule)

Regular Print = Proposed new language

§229.40. Purpose.

(a) These sections set forth the requirements for the sale of cosmetics in this state.

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

§229.41. Applicable Laws and Regulations.

(a) The department adopts by reference the following laws and regulations:

(1) Federal Food, Drug, and Cosmetic Act, 21 United States Code, et seq., as amended;

(2) 21 Code of Federal Regulations (CFR), Part 700, General, as amended;

(3) 21 CFR, Part 701, Cosmetic Labeling, as amended; and

(4) 21 CFR, Part 740, Cosmetic Product Warning Statements, as amended.

(b) Copies of these laws and regulations are indexed and filed at the department, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours, 8:00 a.m. – 5:00 p.m. (except weekends and holidays). Electronic copies of these laws and regulations are available online at <http://www.dshs.state.tx.us/license.shtm>.

(c) Nothing in these sections shall relieve any person of the responsibility for compliance with other applicable Texas and federal laws and regulations.

§229.241. Purpose. These sections provide for the minimum licensing standards necessary to ensure the safety and efficacy of nonprescription drugs offered for sale by wholesale distributors.

§229.242. Applicable Laws and Regulations.

(a) The department adopts by reference the following laws and regulations:

(1) Federal Food, Drug, and Cosmetic Act, 21 United States Code, et seq., as amended;

(2) 9 Code of Federal Regulations (CFR), Part 113, Standard Requirements, as amended;

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(3) 21 CFR, Part 70, Color Additives, as amended;

(4) 21 CFR, Part 71, Color Additive Petitions, as amended;

(5) 21 CFR, Part 73, Listing of Color Additives Exempt From Certification, as amended;

(6) 21 CFR, Part 74, Listing of Color Additives Subject to Certification, as amended;

(7) 21 CFR, Part 80, Color Additive Certification, as amended;

(8) 21 CFR, Part 81, General Specifications and General Restrictions for Provisional Color Additives for use in Foods, Drugs, and Cosmetics, as amended;

(9) 21 CFR, Part 82, Listing of Certified Provisionally Listed Colors and Specifications, as amended;

(10) 21 CFR, Part 201, Labeling, as amended;

(11) 21 CFR, Part 206, Imprinting of Solid Oral Dosage Form Drug Products for Human Use, as amended;

(12) 21 CFR, Part 207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution, as amended;

(13) 21 CFR, Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, as amended;

(14) 21 CFR, Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals, as amended;

(15) 21 CFR, Part 225, Current Good Manufacturing Practice for Medicated Feeds, as amended;

(16) 21 CFR, Part 226, Current Good Manufacturing Practice for Type A Medicated Articles, as amended;

(17) 21 CFR, Part 250, Special Requirements For Specific Human Drugs, as amended;

(18) 21 CFR, Part 299, Drugs; Official Names and Established Names, as amended;  
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(19) 21 CFR, Part 300, General, as amended;

(20) 21 CFR, Part 310, New Drugs, as amended;

(21) 21 CFR, Part 312, Investigational New Drug Application, as amended;

(22) 21 CFR, Part 314, Applications for FDA Approval to Market a New Drug or an Antibiotic Drug, as amended;

(23) 21 CFR, Part 316, Orphan Drugs, as amended;

(24) 21 CFR, Part 320, Bioavailability and Bioequivalence Requirements, as amended;

(25) 21 CFR, Part 328, Over-the-Counter (OTC) Drug Products Intended for Oral Ingestion that Contain Alcohol, as amended;

(26) Part 330, Over-the-Counter (OTC) Human Drugs Which are Generally Recognized as Safe and Effective and Not Misbranded, as amended;

(27) 21 CFR, Part 331, Antacid Products for Over-the-Counter (OTC) Human Use, as amended;

(28) 21 CFR, Part 332, Antiflatulent Products for Over-the-Counter (OTC) Human Use, as amended;

(29) 21 CFR, Part 333, Topical Antimicrobial Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(30) 21 CFR, Part 335, Antidiarrheal Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(31) 21 CFR, Part 336, Antiemetic Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(32) 21 CFR, Part 338, Nighttime Sleep-aid Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(33) 21 CFR, Part 340, Stimulant Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(34) 21 CFR, Part 341, Cold, Cough, Allergy, Bronchodilator, and Anti-asthmatic Drug Products for Over-the-Counter (OTC) Human Use, as amended;

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(35) 21 CFR, Part 343, Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-The-Counter (OTC) Human Use, as amended;

(36) 21 CFR, Part 344, Topical OTIC Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(37) 21 CFR, Part 346, Anorectal Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(38) 21 CFR, Part 347, Skin Protectant Drug Products for Over-the-Counter (OTC) Human Use, as amended;

**(39) 21 CFR, Part 348, External Analgesic Drug Products for Over-the-Counter (OTC) Human Use, as amended;**

(40) 21 CFR, Part 349, Ophthalmic Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(41) 21 CFR, Part 350, Antiperspirant Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(42) 21 CFR, Part 352, Sunscreen Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(43) 21 CFR, Part 355, Anticaries Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(44) 21 CFR, Part 357, Miscellaneous Internal Drug Products for Over-the-Counter (OTC) Human Use, as amended;

(45) 21 CFR, Part 358, Miscellaneous External Drug Products for Over-the-Counter (OTC) Human Use, as amended; and

(46) 21 CFR, Part 369, Interpretive Statements Re: Warnings on Drugs and Devices for Over-the-Counter (OTC) Sales, as amended.

(b) Copies of these laws and regulations are indexed and filed at the department, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours, 8:00 a.m. – 5:00 p.m. (except weekends and holidays). Electronic copies of these laws and regulations are available online at <http://www.dshs.state.tx.us/license.shtm>.

(c) Nothing in these sections shall relieve any person of the responsibility for compliance with other applicable Texas and federal laws and regulations.

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§229.243. Definitions. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act -- The Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(2) Adulterated drug -- Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §431.111.

(3) Authorized agent -- An employee of the department who is designated by the commissioner to enforce the provisions of the Act.

(4) Change of ownership -- A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership; a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons; or if any other type of association, the removal, addition, or substitution of a person or persons as a principal of such association.

(5) Commissioner -- Commissioner of the Department of State Health Services.

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

(7) Department -- The Department of State Health Services.

(8) Device -- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is:

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

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

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

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(9) Drug -- Articles recognized in the official United States Pharmacopoeia National Formulary, or any supplement to it, articles designated or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, articles, other than food, intended to affect the structure or any function of the body of man or other animals, and articles intended for use as a component of any such article. The term does not include devices or their components, parts, or accessories. A food for which a claim is made in accordance with the Federal Act, §403(r), and for which the claim is approved by the U.S. Food and Drug Administration, is not a drug solely because the label or labeling contains such a claim.

(10) Federal Act -- Federal Food, Drug, and Cosmetic Act, 21 United States Code, et seq., as amended.

(11) Flea market -- A location at which booths or similar spaces are rented or otherwise made available temporarily to two or more persons and at which the persons offer tangible personal property for sale.

(12) Labeling -- All labels and other written, printed, or graphic matter:

(A) upon any drug or any of its containers or wrappers; or

(B) accompanying such drug.

(13) Manufacturer -- A person who manufactures, prepares, propagates, compounds, processes, packages, or repackages nonprescription drugs, or a person who changes the container, wrapper, or labeling of any nonprescription drug package.

(14) Misbranded drug -- Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §431.112.

(15) Nonprescription drug -- Any drug that is not a prescription drug, and includes the term “Over the Counter Drug.”

(16) Nonprescription drug product -- A finished dosage form, for example, tablet, capsule, solution, etc., that contains an active nonprescription drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo. Any nonprescription drug product that is also a cosmetic or device or component thereof is also subject to the applicable requirements of the Federal Act, Chapters V and VI, and Subchapters E and F; and Chapter 229 of this title, Subchapter D (relating to Regulation of Cosmetics) and Subchapter X (relating to Licensing of Device Distributors and Manufacturers).

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(17) Person -- An individual, corporation, business trust, estate, trust, partnership, association, or any other public or private legal entity.

(18) Place of business -- Each location at which a nonprescription drug for wholesale distribution is located.

(19) Prescription drug -- Any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to the Federal Act, §503(b).

(20) Wholesale distribution -- Distribution to a person other than a consumer or patient, including, but not limited to distribution to any person by a manufacturer, repackager, own label distributor, broker, jobber, warehouse, or wholesaler.

§229.244. Sale of Nonprescription Drugs. Any reference in these sections to the sale of nonprescription drugs shall be considered to include the manufacture, packaging, exposure, offer, possession, and holding of any nonprescription drug for sale; the sale, dispensing, and giving of any nonprescription drug; and supplying or applying of any nonprescription drug in the operation of any nonprescription drug place of business.

§229.245. Exemption.

(a) A person is exempt from licensing a place of business in accordance with §229.246 of this title (relating to Licensure Requirements) if the person holds a license for the place of business issued by the department under Subchapter W of this Chapter (relating to Licensing of Wholesale Distributors of Prescription Drugs).

(b) An exemption from the licensing requirement granted in subsection (a) of this section does not constitute an exemption from other applicable requirements for nonprescription drugs in these sections or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

§229.246. Licensure Requirements.

(a) General. Except as provided by §229.245 of this title (relating to Exemption), a person may not engage in the wholesale distribution of nonprescription drugs in Texas unless the person has a valid license from the department for each place of business.

(b) Out-of-state place of business. Except as provided by §229.245 of this title, a person who engages in the wholesale distribution of nonprescription drugs from outside this state may

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only engage in the wholesale distribution of nonprescription drugs in this state if the person holds a license as required under subsection (a) of this section.

(c) Combination product. If the United States Food and Drug Administration determines, with respect to a product that is a combination of a nonprescription drug and a device, that the primary mode of action of the product is as a nonprescription drug, a wholesale distributor of such a product is subject to licensure as described in this section.

(d) Display of license. The license shall be displayed in an open public area at each place of business.

(e) New place of business. Each person acquiring or establishing a place of business for the purpose of wholesale distribution of nonprescription drugs after the effective date of these sections shall apply to the department for a license of such business prior to beginning operation.

(f) Two or more places of business. If the wholesale distributor of nonprescription drugs operates more than one place of business, the wholesale distributor of nonprescription drugs shall license each place of business separately.

(g) Pre-licensing inspection. The applicant shall cooperate with any pre-licensing inspection by the department of the applicant's place of business. The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with the minimum standards in these sections for applicants located out-of-state.

(h) Issuance of license. In accordance with §229.281 of this title (relating to Processing License/Permit Applications Relating to Food and Drug Operations), the department may license a wholesale distributor of nonprescription drugs who meets the requirements of these sections, and pays all license fees in compliance with §229.249 of this title (relating to Licensure Fees).

(i) Transfer of license. Licenses shall not be transferable from one person to another or from one place of business to another.

(j) License term. Unless the license is amended as provided in subsection (k) of this section or suspended or revoked as provided in §229.250 of this title (relating to Refusal, Cancellation, Suspension, or Revocation of a License), the license is valid for two years.

(k) Amendment of license. A license that is amended, including a change of name, ownership, or a notification of a change in the location of a licensed place of business will require submission of an application as outlined in §229.247 of this title (relating to Licensing Procedures) and submission of fees as outlined in §229.249 of this title.

(l) Renewal of license.

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(1) The license application as outlined in §229.247 of this title and nonrefundable licensing fees as outlined in §229.249 of this title for each place of business shall be submitted to the department prior to the expiration date of the current license. A person who files a renewal application after the expiration date must pay an additional \$100 as a delinquency fee.

(2) A licensee who fails to submit a renewal application prior to the current licensure expiration date and continues operations may be subject to the enforcement and penalty provisions in §229.253 of this title (relating to Enforcement and Penalties), and/or the refusal, cancellation, suspension and revocation provisions in §229.250 of this title.

(3) A renewal license shall only be issued when all past due license fees and delinquency fees are paid.

§229.247. Licensing Procedures.

(a) License application forms. License application forms may be obtained from the department, 1100 West 49th Street, Austin, Texas, 78756, or online at <http://www.dshs.state.tx.us/license.shtm>.

(b) Contents of license application. The application for licensure as a wholesale distributor of nonprescription drugs shall be signed and verified, submitted on a license application form furnished by the department, and contain the following information:

(1) the name of the legal entity to be licensed, including the name under which the business is conducted;

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

(3) if a proprietorship, the name and residence address of the proprietor; if a partnership, the names and residence addresses of all partners; if a corporation, the date and place of incorporation and name and address of its registered agent in the state and corporation charter number; or if any other type of association, the names of the principals of such association;

(4) the name, residence address, and valid driver license number for each individual in an 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;

(5) for each place of business, the residence address of the individual in charge thereof;

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(6) a list of categories which must be marked and adhered to in the determination and payment of the fee; and

(7) a statement verified by the applicant's signature that acknowledges the applicant has read, understood, and agrees to abide by the provisions of these sections and those of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(c) Renewal license application. The renewal application for licensure as a wholesale distributor of nonprescription drugs shall be made on a license application form furnished by the department.

(d) Texas Online. Applicants may submit initial and renewal license applications under these sections electronically by the Internet through Texas Online at www.texasonline.state.tx.us. The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online.

§229.248. Report of Changes.

(a) Change in the content of a license application. The license holder shall notify the department in writing within ten days of any change which would render the information contained in the application for the license, reported pursuant to §229.247 of this title (relating to Licensing Procedures), no longer accurate. Failure to inform the department no later than ten days of a change in the information required in the application for a license may result in a suspension or revocation of the license.

(b) Change in location of place of business. Not fewer than 30 days in advance of the change, the licensee shall notify the department in writing of the licensee's intent to change the location of a licensed place of business. The notice shall include the address of the new location, and the name and residence address of the individual in charge of the business at the new location. Not more than 10 days after the completion of the change of location, the licensee shall notify the department in writing to confirm the completion of the change of location, and provide verification of the information previously provided or correct and confirm any information that has changed since providing the notice of intent. The notice and confirmation required by this subsection will be deemed adequate if the licensee sends the notices by certified mail, return receipt requested, to the department at 1100 West 49th Street, Austin, Texas 78756, or submits them electronically through the Texas Online Internet website.

§229.249. Licensure Fees.

(a) License fee. Except as provided by §229.245 of this title (relating to Exemption), no person may operate or conduct business as a wholesale distributor of nonprescription drugs without first obtaining a license from the department. All applicants for an initial wholesale

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distributor of nonprescription drugs license or a renewal license shall pay a licensing fee unless otherwise exempt as provided by subsection (c) of this section. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due license fees and delinquency fees are paid.

(1) In-state wholesale distributors of nonprescription drugs who are not manufacturers shall pay a two-year license fee based on the gross annual sales of all nonprescription drugs.

(A) For a wholesale distributor with gross annual nonprescription drug sales of \$0 - \$199,999.99, the fees are:

(i) \$1,040 for a two-year license;

(ii) \$1,040 for a two-year license that is amended due to a change of ownership; and

(iii) \$520 for a license that is amended during the current licensure period due to minor changes.

(B) For a wholesale distributor with gross annual nonprescription drug sales of \$200,000 - \$19,999,999.99, the fees are:

(i) \$1,690 for a two-year license;

(ii) \$1,690 for a two-year license that is amended due to a change of ownership; and

(iii) \$845 for a license that is amended during the current licensure period due to minor changes.

(C) For a wholesale distributor with gross annual nonprescription drug sales greater than or equal to \$20 million, the fees are:

(i) \$2,210 for a two-year license;

(ii) \$2,210 for a two-year license that is amended due to a change of ownership; and

(iii) \$1,105 for a license that is amended during the current licensure period due to minor changes.

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(2) In-state wholesale distributors of nonprescription drugs who are not manufacturers and who also are required to be licensed as a device distributor under §229.439(a) of this title (relating to Licensure Fees) or as a wholesale food distributor under §229.182(a)(3) of this title (relating to Licensing/Registration Fee and Procedures) shall pay a combined two-year license fee for each place of business. License fees are based on the combined gross annual sales of these regulated products (foods, drugs, and/or devices).

(A) For each place of business having combined gross annual sales of \$0 - \$199,999.99, the fees are:

(i) \$520 for a two-year license;

(ii) \$520 for a two-year license that is amended due to a change of ownership; and

(iii) \$260 for a license that is amended during the current licensure period due to minor changes.

(B) For each place of business having combined gross annual sales of \$200,000 - \$499,999.99, the fees are:

(i) \$780 for a two-year license;

(ii) \$780 for a two-year license that is amended due to a change of ownership; and

(iii) \$390 for a license that is amended during the current licensure period due to minor changes.

(C) For each place of business having combined gross annual sales of \$500,000 - \$999,999.99, the fees are:

(i) \$1,040 for a two-year license;

(ii) \$1,040 for a two-year license that is amended due to a change of ownership; and

(iii) \$520 for a license that is amended during the current licensure period due to minor changes.

(D) For each place of business having combined gross annual sales of \$1 million - \$9,999,999.99, the fees are:

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(i) \$1,300 for a two-year license;

(ii) \$1,300 for a two-year license that is amended due to a change of ownership; and

(iii) \$650 for a license that is amended during the current licensure period due to minor changes.

(E) For each place of business having combined gross annual sales greater than or equal to \$10 million, the fees are:

(i) \$1,950 for a two-year license;

(ii) \$1,950 for a two-year license that is amended due to a change of ownership; and

(iii) \$975 for a license that is amended during the current licensure period due to minor changes.

(3) In-state wholesale distributors of nonprescription drugs who are manufacturers shall pay a two-year license fee based on the gross annual sales of all nonprescription drugs.

(A) For a wholesale distributor with gross annual nonprescription drug sales of \$0 - \$199,999.99, the fees are:

(i) \$1,040 for a two-year license;

(ii) \$1,040 for a two-year license that is amended due to a change of ownership; and

(iii) \$520 for a license that is amended during the current licensure period due to minor changes.

(B) For a wholesale distributor with gross annual nonprescription drug sales of \$200,000 - \$19,999,999.99, the fees are:

(i) \$1,690 for a two-year license;

(ii) \$1,690 for a two-year license that is amended due to a change of ownership; and

(iii) \$845 for a license that is amended during the current licensure period due to minor changes.

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(C) For a wholesale distributor with gross annual nonprescription drug sales greater than or equal to \$20 million, the fees are:

(i) \$2,210 for a two-year license;

(ii) \$2,210 for a two-year license that is amended due to a change of ownership; and

(iii) \$1,105 for a license that is amended during the current licensure period due to minor changes.

(4) Out-of-state wholesale distributors of nonprescription drugs shall pay a two-year license fee based on all gross annual sales of nonprescription drugs delivered into Texas.

(A) For each wholesale distributor with gross annual nonprescription drug sales of \$0 - \$19,999,999, the fees are:

(i) \$1,300 for a two-year license;

(ii) \$1,300 for a two-year license that is amended due to a change of ownership; and

(iii) \$650 for a license that is amended during the current licensure period due to minor changes.

(B) For each wholesale distributor with gross annual nonprescription drug sales of greater than or equal to \$20 million, the fees are:

(i) \$1,950 for a two-year license;

(ii) \$1,950 for a two-year license that is amended due to a change of ownership; and

(iii) \$975 for a license that is amended during the current licensure period due to minor changes.

(b) Proration of license fees. A person that has more than one place of business may request a one-time proration of the license fees when applying for a license for each new place of business. Upon approval by the department, the license for the new place of business will have a renewal date that is the same as the firm's other licensed places of business.

(c) Exemption from license fees. A person is exempt from the license fees required by this section if the person is a charitable organization, as described in the Internal Revenue Code

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of 1986, §501(c)(3), or a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

§229.250. Refusal, Cancellation, Suspension or Revocation of License.

(a) The commissioner may refuse an application for a wholesale distributor of nonprescription drugs license or may suspend or revoke such a license if the applicant or licensee:

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

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

(3) is an association, partnership, or corporation and the managing officer and/or any officer or director of the corporation has been convicted of a felony or misdemeanor involving the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) has violated any of the provisions of the Texas, Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act) or these sections;

(5) has violated the Health and Safety Code, §431.021(1)(3), concerning the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(6) has violated the Health and Safety Code, Chapter 481 (Texas Controlled Substance Act), or the Health and Safety Code, Chapter 483 (Dangerous Drug Act);

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

(8) has failed to complete a license application or submits an application that contains false, misleading, or incorrect information or contains information that cannot be verified by the department;

(9) has failed to pay a license fee or a renewal fee for a license; or

(10) has obtained or attempted to obtain a license by fraud or deception.

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(b) The department may, after providing opportunity for hearing, refuse to license a wholesale distributor of nonprescription drugs, or may suspend or revoke a license for violations of the requirements in these sections or for any of the reasons described in the Act.

(c) Any hearings for the refusal, suspension, or revocation of a license are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(d) If the department suspends a license, the suspension shall remain in effect until the department determines that the reason for the suspension no longer exists. If the suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in §229.247 of this title (relating to Licensing Procedures); however, the department may choose not to renew the license until the department determines that the reason for suspension no longer exists.

(e) If the department revokes or does not renew a license, a person may reapply for a license by complying with the requirements and procedures in §229.247 of this title at the time of reapplication. The department may refuse to issue a license if the reason for revocation or non-renewal continues to exist.

(f) A license issued under these sections shall be returned to the department if the person's place of business:

(1) ceases business or otherwise ceases operation on a permanent basis;

(2) relocates; or

(3) changes name or ownership. For a corporation, an ownership change is deemed to have occurred, resulting in the necessity to return the license to the department, when 5.0% or more of the share of stock of a corporation is transferred from one person to another.

### **§229.251. Minimum Standards for Licensure.**

(a) General requirements. All persons engaged in the wholesale distribution of nonprescription drugs must comply with the applicable minimum standards in this section, in addition to the statutory requirements contained in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act) and those requirements adopted in §229.242 of this title (relating to Applicable Laws and Regulations). For the purpose of this section, the policies described in the United States Food and Drug Administration's (FDA's) Compliance Policy Guides as they apply to nonprescription drugs shall be the policies of the department.

(b) Federal establishment registration and drug listing. All persons who operate as nonprescription drug manufacturers in Texas shall meet the requirements in 21 Code of Federal Regulations (CFR), Part 207, titled "Registration of Producers of Drugs and Listing of Drugs in §229.251

Commercial Distribution." New nonprescription drugs offered for sale by wholesale distributors shall have met, if applicable, the requirements of 21 CFR, Part 314, titled "Applications for FDA Approval to Market a New Drug."

(c) Good manufacturing practices. Manufacturers of nonprescription drug products shall be in compliance with the applicable requirements in 21 CFR, Part 210, titled "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; 21 CFR, Part 211, titled "Current Good Manufacturing Practice for Finished Pharmaceuticals; General"; 21 CFR, Part 225, titled "Current Good Manufacturing Practice for Medicated Feeds"; and 21 CFR, Part 226, titled "Current Good Manufacturing Practice for Type A Medicated Article." The regulations in these parts govern the methods used in, and the facilities or controls used for, the manufacture, processing, packing, or holding of a drug to assure that each drug meets the requirements of the Federal Act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(d) Buildings and facilities.

(1) All manufacturing, processing, packing, or holding of drugs by nonprescription drug manufacturers shall take place in buildings and facilities described in subsection (c) of this section.

(2) No manufacturing, processing, packing, or holding of nonprescription drugs shall be conducted in any personal residence.

(3) No sale of nonprescription drugs shall be conducted in any flea market.

(4) Any place of business used by a wholesale distributor of nonprescription drugs who is not a manufacturer to store, warehouse, hold, offer, transport, or display drugs shall:

(A) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(B) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, and space;

(C) be maintained in a clean and orderly condition;

(D) be free from infestation by insects, rodents, birds, or vermin of any kind; and

(E) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated.

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(e) Storage of nonprescription drugs. All nonprescription drugs stored by wholesale distributors shall be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs.

(f) Operating procedures for wholesale distributors who are not manufacturers. Written procedures describing the holding of nonprescription drug products by wholesale distributors of nonprescription drugs who are not manufacturers shall be established and followed and shall include:

(1) a procedure for identifying and retrieving nonprescription drug products that are subject to a recall;  
and

(2) a quarantine procedure for nonprescription drug products that have expired; are subject to recall; or are otherwise determined to be adulterated or misbranded for the return, destruction, or other disposal of those items.

(g) Nonprescription drug labeling. Nonprescription drugs sold by wholesale distributors shall meet the labeling requirements of the Act and 21 CFR, Part 201, titled "Labeling."

(h) Nonprescription drugs that are combination products. Any nonprescription drug that is a combination product as described in §229.246(c) of this title (relating to Licensure Requirements) is also subject to the applicable requirements in Subchapter X of Chapter 229 of this title (relating to Licensing of Device Distributors and Manufacturers).

**(i) Nonprescription drugs that are also cosmetics. Any nonprescription drug that is also a cosmetic or component thereof is also subject to the applicable requirements of Subchapter D of Chapter 229 of this title (relating to Regulation of Cosmetics).**

#### **§229.252. Enforcement and Penalties.**

(a) Inspection. To enforce these sections or the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act), the commissioner, an authorized agent, or a health authority may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

(1) enter at reasonable times a place of business, including a factory or warehouse, in which a nonprescription drug is manufactured, packed, or held for introduction into commerce or held after the introduction;

(2) enter a vehicle being used to transport or hold a nonprescription drug in commerce; or

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

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

(c) Access to records.

(1) A person who is required to maintain records referenced in these sections or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act), or Federal Food, Drug, and Cosmetic Act (Federal Act), Chapter V, or a person who is in charge or custody of those records shall, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times access to and to copy and verify the records.

(2) A person, including a carrier engaged in commerce, or other person receiving a nonprescription drug in commerce or holding a nonprescription drug received in commerce shall, at the request of an authorized agent, permit the authorized agent at all reasonable times to have access to and to copy and verify all records showing:

(A) the movement in commerce of any nonprescription drug;

(B) the holding of any nonprescription drug after movement in commerce; and

(C) the quantity, shipper, and consignee of any nonprescription drug.

(d) Retention of records. Records required by these sections shall be maintained at the place of business or other location that is reasonably accessible for a period of at least three years following disposition of the nonprescription drug unless a greater period of time is required by laws and regulations adopted in §229.242 of this title (relating to Applicable Laws and Regulations).

(e) Adulterated and misbranded nonprescription drug. If the department identifies an adulterated or misbranded nonprescription drug, the department may impose the applicable provisions of Subchapter C of the Act including, but not limited to: detention, emergency order, recall, condemnation, destruction, injunction, civil penalties, criminal penalties, and/or administrative penalties. Administrative and civil penalties will be assessed using the Severity

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Levels contained in §229.251 of this title (relating to Minimum Standards for Licensure).

§229.419. Purpose. These sections provide for the minimum licensing standards necessary to ensure the safety and efficacy of prescription drugs offered for sale by wholesale distributors.

§229.420. Applicable Laws and Regulations.

(a) The department adopts by reference the following laws and regulations:

(1) Federal Food, Drug, and Cosmetic Act, 21 United States Code, et seq., as amended;

(2) 9 Code of Federal Regulations (CFR), Part 113, Standard Requirements, as amended;

(3) 21 CFR, Part 70, Color Additives, as amended;

(4) 21 CFR, Part 71, Color Additive Petitions, as amended;

(5) 21 CFR, Part 73, Listing of Color Additives Exempt From Certification, as amended;

(6) 21 CFR, Part 74, Listing of Color Additives Subject to Certification, as amended;

(7) 21 CFR, Part 80, Color Additive Certification, as amended;

(8) 21 CFR, Part 81, General Specifications and General Restrictions for Provisional Color Additives for use in Foods, Drugs, and Cosmetics, as amended;

(9) 21 CFR, Part 82, Listing of Certified Provisionally Listed Colors and Specifications, as amended;

(10) 21 CFR, Part 200, General, as amended;

(11) 21 CFR, Part 201, Labeling, as amended;

(12) 21 CFR, Part 202, Prescription Drug Advertising, as amended;

(13) 21 CFR, Part 203, Prescription Drug Marketing, as amended;

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- (14) 21 CFR, Part 205, Guidelines for State Licensing of Wholesale Prescription Drug Distributors, as amended;
- (15) 21 CFR, Part 206, Imprinting of Solid Oral Dosage Form Drug Products for Human Use, as amended;
- (16) 21 CFR, Part 207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution, as amended;
- (17) 21 CFR, Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, as amended;
- (18) 21 CFR, Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals, as amended;
- (19) 21 CFR, Part 216, Pharmacy Compounding, as amended;
- (20) 21 CFR, Part 225, Current Good Manufacturing Practice for Medicated Feeds, as amended;
- (21) 21 CFR, Part 226, Current Good Manufacturing Practice for Type A Medicated Articles, as amended;
- (22) 21 CFR, Part 250, Special Requirements For Specific Human Drugs, as amended;
- (23) 21 CFR, Part 290, Controlled Drugs, as amended;
- (24) 21 CFR, Part 299, Drugs; Official Names and Established Names, as amended;
- (25) 21 CFR, Part 300, General, as amended;
- (26) 21 CFR, Part 310, New Drugs, as amended;
- (27) 21 CFR, Part 312, Investigational New Drug Application, as amended;
- (28) 21 CFR, Part 314, Applications for FDA Approval to Market a New Drug or an Antibiotic Drug, as amended;
- (29) 21 CFR, Part 315, Diagnostic Radiopharmaceuticals, as amended;
- (30) 21 CFR, Part 316, Orphan Drugs, as amended;
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- (31) 21 CFR, Part 320, Bioavailability and Bioequivalence Requirements, as amended;
- (32) 21 CFR, Part 361, Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used In Research, as amended;
- (33) 21 CFR, Part 429, Drugs Composed Wholly or Partly of Insulin, as amended;

- (34) 21 CFR, Part 430, Antibiotic Drugs; General, as amended;
- (35) 21 CFR, Part 431, Certification of Antibiotic Drugs, as amended;
- (36) 21 CFR, Part 432, Packaging and Labeling of Antibiotic Drugs, as amended;
- (37) 21 CFR, Part 433, Exemptions from Antibiotic Certification and Labeling Requirements, as amended;
- (38) 21 CFR, Part 436, Tests and Methods of Assay of Antibiotic and Antibiotic-containing Drugs, as amended;
- (39) 21 CFR, Part 440, Penicillin Antibiotic Drugs, as amended;
- (40) 21 CFR, Part 441, Penem Antibiotic Drugs, as amended;
- (41) 21 CFR, Part 442, Cepha Antibiotic Drugs, as amended;
- (42) 21 CFR, Part 444, Oligosaccharide Antibiotic Drugs, as amended;
- (43) 21 CFR, Part 446, Tetracycline Antibiotic Drugs, as amended;
- (44) 21 CFR, Part 448, Peptide Antibiotic Drugs, as amended;
- (45) 21 CFR, Part 449, Antifungal Antibiotic Drugs, as amended;
- (46) 21 CFR, Part 450, Antitumor Antibiotic Drugs, as amended;
- (47) 21 CFR, Part 452, Macrolide Antibiotic Drugs, as amended;
- (48) 21 CFR, Part 453, Lincomycin Antibiotic Drugs, as amended;
- (49) 21 CFR, Part 455, Certain Other Antibiotic Drugs, as amended;

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- (50) 21 CFR, Part 460, Antibiotic Drugs Intended for Use in Laboratory Diagnosis of Disease, as amended;
- (51) 21 CFR, Part 500, General, as amended;
- (52) 21 CFR, Part 510, New Animal Drugs, as amended;
- (53) 21 CFR, Part 511, New Animal Drugs for Investigational Use, as amended;
- (54) 21 CFR, Part 514, New Animal Drug Applications, as amended;
- (55) 21 CFR, Part 515, Medicated Feed Mill License, as amended;
- (56) 21 CFR, Part 520, Oral Dosage Form New Animal Drugs, as amended;

- (57) 21 CFR, Part 522, Implantation or Injectable Dosage Form New Animal Drugs, as amended;
- (58) 21 CFR, Part 524, Ophthalmic and Topical Dosage Form New Animal Drugs, as amended;
- (59) 21 CFR, Part 526, Intramammary Dosage Forms, as amended;
- (60) 21 CFR, Part 529, Certain Other Dosage Form New Animal Drugs, as amended;
- (61) 21 CFR, Part 530, Extralabel Drug Use in Animals, as amended;
- (62) 21 CFR, Part 556, Tolerances for Residues of New Animal Drugs in Food, as amended;
- (63) 21 CFR, Part 558, New Animal Drugs for Use in Animal Feeds, as amended;
- (64) 21 CFR, Part 589, Substances Prohibited From Use in Animal Food or Feed, as amended;
- (65) 21 CFR, Part 600, Biological Products: General, as amended;
- (66) 21 CFR, Part 601, Licensing, as amended;
- (67) 21 CFR, Part 610, General Biological Products Standards, as amended;

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- (68) 21 CFR, Part 650, Additional Standards for Diagnostic Substances Dermal Test, as amended;
- (69) 21 CFR, Part 660, Additional Standards for Diagnostic Substances for Laboratory Tests, as amended;
- (70) 21 CFR, Part 680, Additional Standards for Miscellaneous Products, as amended; and
- (71) 21 CFR, Part 1302, Labeling and Packaging Requirements For Controlled Substances, as amended.

(b) Copies of these laws and regulations are indexed and filed at the department, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours. Electronic copies of these laws and regulations are available online at <http://www.dshs.state.tx.us/license.shtm>.

(c) Nothing in these sections shall relieve any person of the responsibility for compliance with other applicable Texas and federal laws and regulations.

§229.421. Definitions. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act -- The Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(2) Adulterated drug -- Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §431.111.

(3) Authorized agent -- An employee of the department who is designated by the commissioner to enforce the provisions of the Act.

(4) Change of ownership -- A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership; a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons; or if any other type of association, the removal, addition, or substitution of a person or persons as a principal of such association.

(5) Commissioner -- Commissioner of the Department of State Health Services.

(6) Department -- The Department of State Health Services.

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(7) Device -- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is:

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

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

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

(8) Drug -- Articles recognized in the official United States Pharmacopoeia National Formulary, or any supplement to it, articles designated or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, articles, other than food, intended to affect the structure or any function of the body of man or other animals, and articles intended for use as a component of any such article. The term does not include devices or their components, parts, or accessories. A food for which a claim is made in accordance with the Federal Act, §403(r), and for which the claim is approved by the U.S. Food and Drug Administration, is not a drug solely because the label or labeling contains such a claim.

(9) Emergency medical reasons -- Includes transfers of a prescription drug between a wholesale distributor or pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to alleviate a temporary shortage.

(10) Federal Act -- Federal Food, Drug, and Cosmetic Act, 21 United States Code, et seq., as amended.

(11) Flea market -- A location at which booths or similar spaces are rented or otherwise made available temporarily to two or more persons and at which the persons offer tangible personal property for sale.

(12) Labeling -- All labels and other written, printed, or graphic matter:

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(A) upon any drug or any of its containers or wrappers; or

(B) accompanying such drug.

(13) Manufacturer -- A person who manufactures, prepares, propagates, compounds, processes, packages, or repackages prescription drugs, or a person who changes the container, wrapper, or labeling of any prescription drug package. The term does not include compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Occupations Code, §562.154.

(14) Misbranded drug -- Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §431.112.

(15) Nonprescription drug -- Any drug that is not a prescription drug.

(16) Person -- An individual, corporation, business trust, estate, trust, partnership, association, or any other public or private legal entity.

(17) Place of business -- Each location at which a prescription drug for wholesale distribution is located.

(18) Prescription drug -- Any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to the Federal Act, §503(b).

(19) Repackage -- Repackaging or otherwise changing the container, wrapper, or labeling of a drug to further the distribution of a prescription drug. The term does not include repackaging by a pharmacist to dispense a drug to a patient or prepackaging in accordance with Occupations Code, §562.154.

(20) Repackager -- A person who engages in repackaging.

(21) Wholesale distribution -- Distribution to a person other than a consumer or patient, and includes distribution by a manufacturer, repackager, own label distributor, broker, jobber, warehouse, retail pharmacy that conducts wholesale distribution, or wholesaler. The term does not include:

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(A) intracompany sales of prescription drugs, which means transactions or transfers of prescription drugs between a division, subsidiary, parent, or affiliated or related company that is under common ownership and control of a corporate entity;

(B) the sale, purchase, distribution, trade, or transfer of prescription drugs or the offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

(C) the distribution of prescription drug samples by a representative of a manufacturer;

(D) the return of drugs by a hospital, health care entity, retail pharmacy, chain pharmacy warehouse, or charitable institution in accordance with 21 CFR, §203.23; or

(E) the delivery by a retail pharmacy of a prescription drug to a patient or a patient's agent under the lawful order of a licensed practitioner.

§229.422. Sale of Prescription Drugs. Any reference in these sections to the sale of prescription drugs shall be considered to include the manufacture, packaging, exposure, offer, possession, and holding of any prescription drug for sale; the sale, dispensing, and giving of any prescription drug; and supplying or applying of any prescription drug in the operation of any prescription drug place of business.

§229.423. Exemptions.

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

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

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

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

(4) the Occupations Code, §562.154.

(b) Exemptions from licensing. Persons who engage in the following types of distribution of prescription drugs for use in humans are exempt from the licensing requirements

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of these sections, to the extent that it does not violate provisions of the Texas Controlled Substances Act, Health and Safety Code, Chapter 481, or the Texas Dangerous Drug Act, Health and Safety Code, Chapter 483:

(1) intracompany sales;

(2) the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization, as described in the Internal Revenue Code of 1986, §501(c)(3), to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For the purpose of this subsection, “common control” means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, “emergency medical reasons” includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) the distribution of drug samples by manufacturers’ representatives or distributors’ representatives;  
or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.

(c) Applicability of other requirements. An exemption from the licensing requirements granted in subsection (b) of this section does not constitute an exemption from other applicable requirements for prescription drugs under these sections or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

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(d) Exemption from certain requirements for certain wholesale distributors. A wholesale distributor that distributes only prescription drugs that are medical gases is exempt from the requirements in §229.424(d) of this title (relating to Licensure Requirements), §229.425(c) and (d) of this title (relating to Licensing Procedures).

§229.424. Licensure Requirements.

(a) General. Except as provided in §229.423 of this title (relating to Exemptions), a person may not engage in the wholesale distribution of prescription drugs in Texas unless the person has a valid license from the commissioner of the department for each place of business.

(b) Out-of-state place of business.

(1) Except as provided by §229.423 of this title, a person who engages in the wholesale distribution of prescription drugs from outside this state may only engage in the wholesale distribution of prescription drugs in this state if the person holds a license as required in subsection (a) of this section.

(2) The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with the Act and these sections.

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

(4) The department shall consider each license application and any related documents or reports filed by or in connection with a person who wishes to engage in the wholesale distribution of prescription drugs in this state on an individual basis.

(c) Combination product. If the United States Food and Drug Administration determines, with respect to a product that is a combination of a prescription drug and a device, that the primary mode of action of the product is as a prescription drug, a wholesale distributor of such a product is subject to licensure as described in this section.

(d) Applicant qualifications. To qualify for the issuance or renewal of a wholesale distributor license under these sections, the designated representative of an applicant or license holder must:

(1) be at least 21 years of age;

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(2) have been employed full-time for at least three years by a pharmacy or a wholesale distributor in a capacity related to the dispensing or distributing of prescription drugs, including recordkeeping for the dispensing or distributing of prescription drugs;

(3) be employed by the applicant full-time in a managerial-level position;

(4) be actively involved in and aware of the actual daily operation of the wholesale distributor;

(5) be physically present at the applicant's place of business during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

(6) serve as a designated representative for only one applicant at any one time;

(7) not have been convicted of a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or the distribution of controlled substances; and

(8) not have been convicted of a felony under a federal, state, or local law.

(e) Display of license. The license shall be displayed in an open public area at each place of business.

(f) New place of business. Each person acquiring or establishing a place of business for the purpose of wholesale distribution of prescription drugs after the effective date of these sections shall apply to the department for a license of such business prior to beginning operation.

(g) Two or more places of business. If the wholesale distributor of prescription drugs operates more than one place of business, the wholesale distributor of prescription drugs shall license each place of business separately.

(h) Pre-licensing inspection. The applicant shall cooperate with any pre-licensing inspection by the department of the applicant's place of business.

(i) Issuance of license. In accordance with §229.281 of this title (relating to Processing License/Permit Applications Relating to Food and Drug Operations), the department may license a wholesale distributor of prescription drugs who meets the requirements of these sections, and pays all license fees in compliance with §229.427 of this title (relating to Licensure Fees).

(j) Transfer of license. Licenses shall not be transferable from one person to another or from one place of business to another.

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(k) License term. Unless the license is amended as provided in subsection (m) of this section or suspended or revoked as provided in §229.428 of this title (relating to Refusal, Cancellation, Suspension, or Revocation of a License), the license is valid for two years.

(l) Amendment of license. A license that is amended, including a change of name, ownership, or a notification of a change in the location of a licensed place of business will require submission of an application as outlined in §229.425 of this title (relating to Licensing Procedures) and submission of fees as outlined in §229.427 of this title.

(m) Renewal of license.

(1) The license application as outlined in §229.425 of this title and nonrefundable licensing fees as outlined in §229.427 of this title for each place of business shall be submitted to the department prior to the expiration date of the current license. A person who files a renewal application after the expiration date must pay an additional \$100 as a delinquency fee.

(2) A licensee who fails to submit a renewal application prior to the current licensure expiration date and continues operations may be subject to the enforcement and penalty provisions in §229.432 of this title (relating to Enforcement and Penalties), and/or the refusal, cancellation, suspension and revocation provisions in §229.428 of this title.

(3) A renewal license shall only be issued when all past due license fees and delinquency fees are paid.

§229.425. Licensing Procedures.

(a) License application forms. License application forms may be obtained from the department, 1100 West 49th Street, Austin, Texas, 78756, or online at <http://www.dshs.state.tx.us/license.shtm>.

(b) Contents of license application. The application for licensure as a wholesale distributor of prescription drugs shall be signed and verified, submitted on a license application form furnished by the department, and contain the following information:

- (1) all trade or business names under which the business is conducted;
- (2) the address and telephone number of each place of business that is licensed;
- (3) the type of business and the name, residence address, and valid driver's license number of:

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

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

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

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

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

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

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

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

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

(6) the name, date of birth, residence address, telephone number, and any information necessary to complete a criminal history record check on a designated representative of each place of business;

(7) the state of incorporation, if the business is a corporation;

(8) a list of all licenses and permits issued to the applicant by any other state under which the applicant is permitted to purchase or possess prescription drugs;

(9) the name of the manager for each place of business;

(10) a list of categories which must be marked and adhered to in the determination and paying of the fee; and

(11) a statement verified by the applicant's signature that acknowledges the applicant has read, understood, and agrees to abide by the provisions of these sections and those of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(c) Designated representatives and managers.

(1) For each person who is a designated representative and/or a manager of each place of business, the applicant shall provide the following to the department:

(A) the person's place(s) of residence for the past seven years;

(B) the person's date and place of birth;  
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(C) the person's occupations, positions of employment, and offices held during the past seven years;

(D) the business name and address of any business, corporation, or other organization in which the person held an office under paragraph (3) of subsection (b) of this section or in which the person conducted an occupation or held a position of employment;

(E) a statement of whether during the preceding seven years the person was the subject of a proceeding to revoke a license and the nature and disposition of the proceeding;

(F) a statement of whether during the preceding seven years the person has been enjoined, either temporarily or permanently, by a court from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, including the details concerning the event;

(G) a written description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were named as a party;

(H) a description of any felony offense for which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere;

(I) a description of any criminal conviction of the person under appeal, a copy of the notice of appeal for that criminal offense, and a copy of the final written order of an appeal not later than the 15th day after the date of the appeal's disposition; and

(J) a photograph of the person taken not earlier than 30 days before the date the application was submitted.

(2) The information submitted under paragraph (1) of this subsection must be attested to under oath.

(d) Criminal history. The department will obtain an applicant's criminal history record information and may forward the fingerprints to the Federal Bureau of Investigation for a federal criminal history check.

(e) Renewal license application. The renewal application for licensure as a wholesale distributor of prescription drugs shall be made on a license application form furnished by the department.

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(f) Texas Online. Applicants may submit initial and renewal license applications under these sections electronically by the Internet through Texas Online at [www.texasonline.state.tx.us](http://www.texasonline.state.tx.us). The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online.

§229.426. Report of Changes.

(a) Change in the content of a license application. The license holder shall notify the department in writing within ten days of any change which would render the information contained in the application for the license, reported pursuant to §229.425 of this title (relating to Licensing Procedures), no longer accurate. Failure to inform the department no later than ten days of a change in the information required in the application for a license may result in a suspension or revocation of the license.

(b) Change in location of place of business. Not fewer than 30 days in advance of the change, the licensee shall notify the department in writing of the licensee's intent to change the location of a licensed place of business. The notice shall include the address of the new location, and the name and residence address of the individual in charge of the business at the new location. Not more than 10 days after the completion of the change of location, the licensee shall notify the department in writing to confirm the completion of the change of location, and provide verification of the information previously provided or correct and confirm any information that has changed since providing the notice of intent. The notice and confirmation required by this subsection will be deemed adequate if the licensee sends the notices by certified mail, return receipt requested, to the department at 1100 West 49th Street, Austin, Texas 78756, or submits them electronically through the Texas Online Internet website.

§229.427. Licensure Fees.

(a) License fee. Except as provided by §229.423 of this title (relating to Exemptions), no person may operate or conduct business as a wholesale distributor of prescription drugs without first obtaining a license from the department. All applicants for an initial wholesale distributor of prescription drugs license or a renewal license shall pay a licensing fee unless otherwise exempt as provided by subsection (c) of this section. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due license fees and delinquency fees are paid.

(1) In-state wholesale distributors of prescription drugs who are not manufacturers shall pay a two-year license fee based on the gross annual sales of all drugs.

(A) For a wholesale distributor of only compressed medical gases with gross annual drug sales of \$0 - \$20,000, the fees are:

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(i) \$675 for a two-year license;

(ii) \$675 for a two-year license that is amended due to a change of ownership; and

(iii) \$337 for a license that is amended during the current licensure period due to minor changes.

(B) For a wholesale distributor with gross annual drug sales of \$0 - \$199,999.99, the fees are:

(i) \$1,080 for a two-year license;

(ii) \$1,080 for a two-year license that is amended due to a change of ownership; and

(iii) \$540 for a license that is amended during the current licensure period due to minor changes.

fees are:

(C) For a wholesale distributor with gross annual drug sales of \$200,000 - \$19,999,999.99, the

(i) \$1,755 for a two-year license;

(ii) \$1,755 for a two-year license that is amended due to a change of ownership; and

changes.

(iii) \$877 for a license that is amended during the current licensure period due to minor

million, the fees are:

(D) For a wholesale distributor with gross annual drug sales greater than or equal to \$20

(i) \$2,295 for a two-year license;

(ii) \$2,295 for a two-year license that is amended due to a change of ownership; and

minor changes.

(iii) \$1,147 for a license that is amended during the current licensure period due to

(2) In-state wholesale distributors of only compressed medical gases who are not manufacturers and who also are required to be licensed as a device distributor under §229.439(a)

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of this title (relating to Licensure Fees) or as a wholesale food distributor under §229.182(a)(3) of this title (relating to Licensing/Registration Fee and Procedures) shall pay a combined two-year license fee for each place of business. License fees are based on the combined gross annual sales of these regulated products (foods, drugs, and/or devices).

are:

(A) For a wholesale distributor with combined gross annual sales of \$0 - \$199,999.99, the fees

(i) \$540 for a two-year license;

(ii) \$540 for a two-year license that is amended due to a change of ownership; and

changes.

(iii) \$270 for a license that is amended during the current licensure period due to minor

the fees are:

(B) For a wholesale distributor with combined gross annual sales of \$200,000 - \$499,999.99,

(i) \$810 for a two-year license;

(ii) \$810 for a two-year license that is amended due to a change of ownership; and

changes.

(iii) \$405 for a license that is amended during the current licensure period due to minor

the fees are:

(C) For a wholesale distributor with combined gross annual sales of \$500,000 - \$999,999.99,

(i) \$1,080 for a two-year license;

(ii) \$1,080 for a two-year license that is amended due to a change of ownership; and

(iii) \$540 for a license that is amended during the current licensure period due to minor changes.

(D) For a wholesale distributor with combined gross annual sales of \$1 million - \$9,999,999.99, the fees are:

(i) \$1,350 for a two-year license;

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(ii) \$1,350 for a two-year license that is amended due to a change of ownership; and

(iii) \$675 for a license that is amended during the current licensure period due to minor changes.

(E) For a wholesale distributor with combined gross annual sales greater than or equal to \$10 million, the fees are:

(i) \$2,025 for a two-year license;

(ii) \$2,025 for a two-year license that is amended due to a change of ownership; and

(iii) \$1,012 for a license that is amended during the current licensure period due to minor changes.

(3) In-state wholesale distributors of prescription drugs who are manufacturers shall pay a two-year license fee based on the gross annual sales of all drugs.

(A) For a wholesale distributor with gross annual drug sales of \$0 - \$199,999.99, the fees are:

(i) \$1,080 for a two-year license;

(ii) \$1,080 for a two-year license that is amended due to a change of ownership; and

(iii) \$540 for a license that is amended during the current licensure period due to minor changes.

(B) For a wholesale distributor with gross annual drug sales of \$200,000 - \$19,999,999.99, the fees are:

(i) \$1,755 for a two-year license;

(ii) \$1,755 for a two-year license that is amended due to a change of ownership; and

(iii) \$877 for a license that is amended during the current licensure period due to minor changes.

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(C) For a wholesale distributor with gross annual drug sales greater than or equal to \$20 million, the fees are:

(i) \$2,295 for a two-year license;

(ii) \$2,295 for a two-year license that is amended due to a change of ownership; and

(iii) \$1,147 for a license that is amended during the current licensure period due to minor changes.

(4) Out-of-state wholesale distributors of prescription drugs shall pay a two-year license fee based on all gross annual sales of drugs delivered into Texas.

(A) For each wholesale distributor with gross annual drug sales of \$0 – \$19,999,999, the fees are:

(i) \$1,350 for a two-year license;

(ii) \$1,350 for a two-year license that is amended due to a change of ownership; and

(iii) \$675 for a license that is amended during the current licensure period due to minor changes.

(B) For each wholesale distributor with gross annual drug sales of greater than or equal to \$20 million, the fees are:

(i) \$2,025 for a two-year license;

(ii) \$2,025 for a two-year license that is amended due to a change of ownership; and

(iii) \$1,012 for a license that is amended during the current licensure period due to minor changes.

(b) Proration of license fees. A person that has more than one place of business may request a one-time proration of the license fees when applying for a license for each new place of business. Upon approval by the department, the license for the new place of business will have a renewal date that is the same as the firm's other licensed places of business.

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(c) Exemption from license fees. A person is exempt from the license fees required by this section if the person is a charitable organization, as described in the Internal Revenue Code of 1986, §501(c)(3), or a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

§229.428. Refusal, Cancellation, Suspension or Revocation of License.

(a) The commissioner may refuse an application for a wholesale distributor of prescription drugs license or may suspend or revoke such a license if the applicant or licensee:

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

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

(3) is an association, partnership, or corporation and the managing officer and/or any officer or director of a corporation has been convicted of a felony or misdemeanor involving the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) has violated any of the provisions of the Texas, Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act) or these sections;

(5) has violated the Health and Safety Code, §431.021(1)(3), concerning the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(6) has violated the Texas Controlled Substances Act, Health and Safety Code, Chapter 481, or the Texas Dangerous Drug Act, Health and Safety Code, Chapter 483;

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

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

(9) has failed to pay a license fee or a renewal fee for a license; or

(10) has obtained or attempted to obtain a license by fraud or deception.

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(b) The department may, after providing opportunity for hearing, refuse to license a wholesale distributor of prescription drugs, or may suspend or revoke a license for violations of the requirements in these sections or for any of the reasons described in the Act.

(c) Any hearings for the refusal, suspension, or revocation of a license are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(d) If the department suspends a license, the suspension shall remain in effect until the department determines that the reason for the suspension no longer exists. If the suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in §229.425 of this title (relating to Licensing Procedures); however,

the department may choose not to renew the license until the department determines that the reason for suspension no longer exists.

(e) If the department revokes or does not renew a license, a person may reapply for a license by complying with the requirements and procedures in §229.425 of this title at the time of reapplication. The department may refuse to issue a license if the reason for revocation or non-renewal continues to exist.

(f) A license issued under these sections shall be returned to the department if the person's place of business:

(1) ceases business or otherwise ceases operation on a permanent basis;

(2) relocates; or

(3) changes name or ownership. For a corporation, an ownership change is deemed to have occurred, resulting in the necessity to return the license to the department, when 5.0% or more of the share of stock of a corporation is transferred from one person to another.

### **§229.429. Minimum Standards for Licensure.**

(a) General requirements. All persons engaged in the wholesale distribution of prescription drugs must comply with the applicable minimum standards in this section, in addition to the statutory requirements contained in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act) and those requirements in §229.420 of this title (relating to Applicable Laws and Regulations). For the purpose of this section, the policies described in the United States Food and Drug Administration's (FDA's) Compliance Policy Guides as they apply to prescription drugs shall be the policies of the department.

(b) Federal establishment registration and drug listing. All persons who operate as prescription drug manufacturers in Texas shall meet the requirements in 21 Code of Federal Regulations (CFR), Part 207, titled "Registration of Producers of Drugs and Listing of Drugs in

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Commercial Distribution." New prescription drugs offered for sale by wholesale distributors shall have met, if applicable, the requirements of 21 CFR, Part 314, titled "Applications for FDA Approval to Market a New Drug."

(c) Good manufacturing practices. Manufacturers of prescription drug products shall be in compliance with the applicable requirements in 21 CFR, Part 210, titled "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; 21 CFR, Part 211, titled "Current Good Manufacturing Practice for Finished Pharmaceuticals; General"; 21 CFR, Part 225, titled "Current Good Manufacturing Practice for Medicated Feeds"; and 21 CFR, Part 226, titled "Current Good Manufacturing Practice for Type A Medicated Articles." The regulations in these parts govern the methods used in, and the facilities or controls used for, the manufacture, processing, packing, or holding of a drug to assure that each drug meets the requirements of the Federal Act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(d) Buildings and facilities.

(1) All manufacturing, processing, packing, or holding of drugs by prescription drug manufacturers shall take place in buildings and facilities described in subsection (c) of this section.

(2) No manufacturing, processing, packing, or holding of prescription drugs shall be conducted in any personal residence.

(3) No sale of prescription drugs shall be conducted in any flea market.

(4) Any place of business used by a wholesale distributor of prescription drugs who is not a manufacturer to store, warehouse, hold, offer, transport, or display drugs shall:

(A) be in compliance with the requirements adopted in §229.420(a)(14) of this title;

(B) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(C) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, and space;

(D) be maintained in a clean and orderly condition;

(E) be free from infestation by insects, rodents, birds, or vermin of any kind; and

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(F) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated.

(e) Storage of prescription drugs. All prescription drugs stored by wholesale distributors shall be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs.

(f) Minimum restrictions on transactions.

(1) Returns. A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse in accordance with the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. The returns or exchanges received by the wholesale distributor as provided by this subsection are not subject to the pedigree requirement under §431.412 of the Act. In connection with the returned goods process, a wholesale distributor shall establish appropriate business practices and exercise due diligence designed to prevent the entry of adulterated or counterfeit drugs into the distribution channel.

(2) Distributions. A manufacturer or wholesale distributor may distribute prescription drugs only to a person licensed under this subchapter, or the appropriate state licensing authorities, if an out-of-state wholesaler or retailer, or authorized by federal law to receive the drug. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor must verify that the person is legally authorized by the department or the appropriate state licensing authority to receive the prescription drugs or authorized by federal law to receive the drugs.

(3) Premises. Prescription drugs distributed by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license, except as listed in paragraph (4) of this subsection. A manufacturer or wholesale distributor may distribute prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(A) the identity and authorization of the recipient is properly established; and

(B) delivery is made only to meet the immediate needs of a particular patient of the authorized person.

(4) Delivery to hospital pharmacies. Prescription drugs may be distributed to a hospital pharmacy receiving area if a pharmacist or an authorized receiving person signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually

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received shall be reported to the delivering manufacturer or wholesale distributor not later than the next business day after the date of delivery to the pharmacy receiving area.

(g) Prescription drug labeling. Prescription drugs sold by wholesale distributors shall meet the labeling requirements of the Act and those adopted in §229.420(a) of this title (relating to Applicable Laws and Regulations).

(h) Prescription drugs that are combination products. Any prescription drug that is a combination product as described in §229.424(c) of this title (relating to Licensure Requirements) is also subject to the applicable requirements in subchapter X of this chapter (relating to Licensing of Device Distributors and Manufacturers).

**(i) Prescription drugs that are also cosmetics. Any prescription drug that is also a cosmetic or component thereof is also subject to the applicable requirements of subchapter D of this chapter (relating to Regulation of Cosmetics).**

**(j) Nonprescription drugs. Nonprescription drugs offered for sale by wholesale distributors of prescription drugs shall be in compliance with the applicable requirements of subchapter O of this chapter (relating to Licensing of Wholesale Distributors of Nonprescription Drugs).**

**§229.430. Enforcement and Penalties.**

(a) Inspection.

(1) To enforce these sections or the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act), the commissioner, an authorized agent, or a health authority may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

(A) enter at reasonable times a place of business, including a factory or warehouse, in which a prescription drug is manufactured, packed, or held for introduction into commerce or held after the introduction;

(B) enter a vehicle being used to transport or hold a prescription drug in commerce; or

(C) inspect at reasonable times, within reasonable limits, and in a reasonable manner, the place of business or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of these sections or the Act.

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

(A) is adulterated or misbranded;

(B) may not be manufactured, introduced into commerce, sold, or offered for sale under the Act; or

(C) is otherwise in violation of these sections or the Act.

(3) An inspection under paragraph (2) of this subsection may not extend to:

(A) financial data;

(B) sales data other than shipment data;

(C) pricing data;

(D) personnel data other than data relating to the qualifications of technical and professional personnel performing functions under the Act;

(E) research data other than data:

(i) relating to new drugs and antibiotic drugs; and

(ii) subject to reporting and inspection under regulations issued under §505(i) or (j) of the Federal Act; or

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

(4) An inspection under paragraph (2) of this subsection shall be started and completed with reasonable promptness.

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

(c) Access to records.

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(1) A person who is required to maintain records referenced in these sections or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act) or Chapter V of the Federal Food, Drug, and Cosmetic Act (Federal Act) or a person who is in charge or custody of those records shall, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times access to and to copy and verify the records.

(2) A person, including a carrier engaged in commerce, or other person receiving a prescription drug in commerce or holding a prescription drug received in commerce shall, at the request of an authorized agent, permit the authorized agent at all reasonable times to have access to and to copy and verify all records showing:

(A) the movement in commerce of any prescription drug;

(B) the holding of any prescription drug after movement in commerce; and

(C) the quantity, shipper, and consignee of any prescription drug.

(d) Retention of records. Records required by these sections shall be maintained at the place of business or other location that is reasonably accessible for a period of at least three years following disposition of the prescription drug unless a greater period of time is required by laws and regulations adopted in §229.420 of this title (relating to Applicable Laws and Regulations).

(e) Adulterated or misbranded prescription drug. If the department identifies an adulterated or misbranded prescription drug, the department may impose the applicable enforcement provisions of subchapter C of the Act including, but not limited to: detention, emergency order, recall, condemnation, destruction, injunction, civil penalties, criminal penalties, and/or administrative penalties. Administrative and civil penalties will be assessed using the Severity Levels contained in §229.251 of this title (relating to Minimum Standards for Licensure).

(f) Order to cease distribution.

(1) The commissioner shall issue an order requiring a person, including a manufacturer, distributor, or retailer of a prescription drug, to immediately cease distribution of the drug if the commissioner determines there is a reasonable probability that:

(A) a wholesale distributor has:

(i) violated these sections or the Act;

(ii) falsified a pedigree; or

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(iii) sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use that could cause serious adverse health consequences or death; and

(B) other procedures would result in unreasonable delay.

(2) An order under this subsection must provide the person subject to the order with an opportunity for an informal hearing on the actions required by the order to be held not later than the 10th day after the date of issuance of the order.

(3) If, after providing an opportunity for a hearing, the commissioner determines that inadequate grounds exist to support the actions required by the order, the commissioner shall vacate the order.