TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DRUGS AND MEDICAL DEVICES GROUP WEB SITE:
http://www.dshs.state.tx.us/dmd/

LICENSING OF WHOLESALE DISTRIBUTORS OF NON PRESCRIPTION DRUGS— INCLUDING GOOD MANUFACTURING PRACTICES
(25 Texas Administrative Code, §§229.241 – 229.252)

§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;

(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;

(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;

(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.

§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.

(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).

(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 – Including Good Manufacturing Practices).

(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

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.

(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 §229.252 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;

(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 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.

(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:

(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.

(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 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.

(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 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.

(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 tile (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

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

Revised 02/01/07