TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 229 FOOD AND DRUG
SUBCHAPTER O LICENSING OF WHOLESALE DISTRIBUTORS OF NONPRESCRIPTION DRUGS--INCLUDING GOOD MANUFACTURING PRACTICES

§229.241. Purpose.

This subchapter provides 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 (USC) §301, 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, Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code, 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, 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 Drug Products Intended for Oral Ingestion that Contain Alcohol, as amended;

(26) 21 CFR 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 Human Use, as amended;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(46) 21 CFR Part 369, Interpretive Statements Re Warnings on Drugs and Devices for Over-the-Counter Sale, as amended;

(47) 21 CFR Part 700, General, as amended;

(48) 21 CFR Part 701, Cosmetic Labeling, as amended; and

(49) 21 CFR Part 740, Cosmetic Product Warning Statements, as amended.

(b) Electronic copies of these laws and regulations are available online at www.dshs.texas.gov.

(c) Nothing in this subchapter relieves 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, have the following meanings, unless the context clearly indicates otherwise.

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

(2) Adulterated drug--Has the meaning specified in the Act at §431.111.

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

(4) Broker--A person engaged in offering or contracting for wholesale distribution sale or transfer of a nonprescription drug into, within, or out of Texas and who does not take title to or physical possession of the nonprescription drug.

(5) 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.

(6) Commissioner--Commissioner of the Texas Department of State Health Services.

(7) Component--Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

(8) 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.

(9) Department--The Texas Department of State Health Services.

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

(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 humans or other animals; or

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

(11) 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 humans or other animals; articles, other than food, intended to affect the structure or any function of the body of humans 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), 21 USC §343, and for which the claim is approved by the United States Food and Drug Administration (FDA) is not a drug solely because the label or labeling contains such a claim.

(12) Federal Act--Federal Food, Drug, and Cosmetic Act, 21 USC §301, et seq., as amended.

(13) 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.

(14) Inactive ingredient--Any component other than an active ingredient, including any excipient, flavor, fragrance, and color.

(15) 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.

(16) 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.

(17) Misbranded drug--Has the meaning specified in the Act at §431.112.

(18) Nonprescription drug--Any drug that is not a prescription drug, including the terms Over-the-Counter Drug and Non-legend Drug.

(19) Nonprescription drug product--A finished dosage form, for example, tablet, capsule, solution, etc., containing an active nonprescription ingredient. 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 Subchapter D of this chapter (relating to Regulation of Cosmetics) and Subchapter X of this chapter (relating to Licensing of Device Distributors and Manufacturers).

(20) Over-the-Counter (OTC) drugs--Drugs that are safe and effective for use by the general public without seeking treatment by a health professional.

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

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

(23) 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 at §503(b).

(24) Wholesale distribution--Distribution to a person other than a consumer or patient, including distribution to any person by a manufacturer, repackager, own label distributor, broker, jobber, warehouse, or wholesaler. This term does not include:

(A) intracompany sales of nonprescription drugs, which means transactions or transfers of nonprescription drugs between a division, subsidiary, parent, or affiliated or related company under common ownership and control or any transaction or transfer between co-license holders of a co-licensed product;

(B) the distribution of nonprescription drug samples by a representative of a manufacturer or wholesale drug distributor;

(C) the delivery of, or offer to deliver, a nonprescription drug by a common carrier solely in the common carrier's usual course of business of transporting nonprescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the nonprescription drug; and

(D) the sale or transfer from a purchaser, other than a consumer, seller, or warehouser, of expired, damaged, returned, or recalled nonprescription drugs to the original manufacturer or to a reverse logistics provider.

§229.244. Sale of Nonprescription Drugs.

Any reference in this subchapter to the sale of nonprescription drugs includes:

(1) manufacturing, packaging, exposing, offering, possessing, or holding any nonprescription drug for sale;

(2) selling, dispensing, or providing any nonprescription drug; and

(3) supplying or applying 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 subchapter (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 this subchapter or under the Act.

§229.246. Licensure Requirements.

(a) General. Except as provided by §229.245 of this subchapter (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 subchapter, 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 within 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, the wholesale distributor must obtain a license as described in this section.

(d) Proof of licensure. The license holder must show proof of licensure in a format readily available at each place of business.

(e) New place of business. Each person acquiring or establishing a place of business for wholesale distribution of nonprescription drugs after the effective date of this subchapter must obtain a license before beginning operation.

(f) Two or more places of business. A wholesale distributor of nonprescription drugs must obtain a license for each place of business.

(g) Pre-licensing inspection. The applicant must 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 this subchapter for applicants located out-of-state.

(h) Issuance of license. In accordance with §229.281 of this chapter (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 in this subchapter and pays all license fees under §229.249 of this subchapter (relating to Licensure Fees).

(i) Transfer of license. Licenses are not transferable.

(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 subchapter (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 or a notification of a change in the location of a licensed place of business requires submission of an application as outlined in §229.247 of this subchapter (relating to Licensing Procedures) and submission of fees as outlined in §229.249 of this subchapter.

(l) Renewal of license.

(1) The license application as outlined in §229.247 of this subchapter and nonrefundable licensing fees as outlined in §229.249 of this subchapter for each place of business must be submitted to the department before the expiration date of the current license.

(2) A person who files a renewal application after the expiration date must pay an additional $100 delinquency fee.

(3) A person who fails to submit a renewal application before the current license expires and continues operations is subject to enforcement and penalty provisions in §229.252 of this subchapter (relating to Enforcement and Penalties), and the refusal, cancellation, suspension, and revocation provisions in §229.250 of this subchapter.

(4) A renewal license must only be issued when all past due administrative penalties, license fees, and delinquency fees are paid.

§229.247. Licensing Procedures.

(a) License application forms. License application forms may be obtained from the Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas, 78756, or online at www.dshs.texas.gov.

(b) Contents of license application. The application for licensure as a wholesale distributor of nonprescription drugs must 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 to be 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 and valid driver license number for each individual in an actual administrative capacity which, in the case of proprietorship, must 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;

(6) a list of categories which must be marked and adhered to in the determination and payment of the fee as described in §229.249 of this subchapter (relating to Licensure Fees); and

(7) a statement verified by the applicant's signature acknowledging the applicant read, understood, and agrees to abide by the provisions of this subchapter and those of the Act.

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

§229.248. Report of Changes.

(a) Change in the content of a license application. The license holder must notify the department of any change in the information on the license application in writing within 10 days of the change. Failure to inform the department within 10 days of a change in the information required in the application for a license may result in an enforcement action, including suspension or revocation of the license.

(b) Change in location of place of business. The license holder must notify the department at least 30 days in advance of an intended change of address of the licensed place of business. The notice must include the address of the new location and the name of the individual in charge of the business at the new location. Within 10 days of beginning operations at the new location, the license holder must notify the department in writing to confirm the move and provide verification or correction of the information provided on the notice of intent. The license holder must simultaneously return the original license to the department. The notice and confirmation required by this subsection will be deemed adequate if the license holder submits the notices by certified mail, return receipt requested, to the Texas Department of State Health Services at 1100 West 49th Street, Austin, Texas 78756, or submits notices electronically through www.texas.gov.

§229.249. Licensure Fees.

(a) License fee. Except as provided by §229.245 of this subchapter (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 must 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 administrative penalties, license fees, and delinquency fees are paid.

(1) In-state wholesale distributors of nonprescription drugs who are not manufacturers must 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 issued due to a change of ownership; and

(iii) $520 for a license issued 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 issued due to a change of ownership; and

(iii) $845 for a license issued 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 issued due to a change of ownership; and

(iii) $1,105 for a license issued 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 chapter (relating to Licensure Fees) or as a wholesale food distributor under §229.182(a)(3) of this chapter (relating to Licensing/Registration Fee and Procedures) must 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 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 issued due to a change of ownership; and

(iii) $260 for a license 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 issued due to a change of ownership; and

(iii) $390 for a license 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 issued due to a change of ownership; and

(iii) $520 for a license 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 issued due to a change of ownership; and

(iii) $650 for a license 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 issued due to a change of ownership; and

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

(3) In-state wholesale distributors of nonprescription drugs who are manufacturers must 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 issued due to a change of ownership; and

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

(B) For a wholesale distributor with gross annual nonprescription drug sales of $200,000 - $1,999,999.99, the fees are:

(i) $1,235 for a two-year license;

(ii) $1,235 for a two-year license issued due to a change of ownership; and

(iii) $620 for a license amended during the current licensure period due to minor changes.

(C) For a wholesale distributor with gross annual nonprescription drug sales of $2 million to $9,999,999.99, the fees are:

(i) $1,560 for a two-year license;

(ii) $1,560 for a two-year license issued due to a change of ownership; and

(iii) $780 for a license amended during the current licensure period due to minor changes.

(D) For a wholesale distributor with gross annual nonprescription drug sales of $10 million to $19,999,999.99, the fees are:

(i) $1,885 for a two-year license;

(ii) $1,885 for a two-year license issued due to a change of ownership; and

(iii) $940 for a license amended during the current licensure period due to minor changes.

(E) 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 issued due to a change of ownership; and

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

(4) Out-of-state wholesale distributors of nonprescription drugs must 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 - $19,999,999.99, the fees are:

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

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

(iii) $650 for a license 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 issued due to a change of ownership; and

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

(b) Proration of license fees. A person having 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 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, 26 USC §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 department may refuse an application for a wholesale distributor of nonprescription drugs license or may suspend or revoke such a license if the applicant or license holder:

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

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

(3) is an association, partnership, or corporation and the managing officer 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, Texas Health and Safety Code Chapter 431 (Act), or this subchapter.

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

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

(8) has failed to complete a license application or submits an application containing false, misleading, or incorrect information, or 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 this subchapter 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 must remain in effect until the department determines the reason for the suspension no longer exists. If the suspension overlaps a renewal date, the suspended license holder must comply with the renewal procedures in §229.247 of this subchapter (relating to Licensing Procedures); however, the department may choose not to renew the license until the department determines 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 subchapter 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 this subchapter must 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, requiring return of the license to the department, when 5.0 percent 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.

(1) 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 Act and in §229.242 of this subchapter (relating to Applicable Laws and Regulations).

(2) For the purpose of this section, the policies that apply to nonprescription drugs as described in the United States Food and Drug Administration's (FDA) Compliance Policy Guides are the policies of the department.

(3) Nonprescription drug wholesalers must not purchase or receive drugs in this state other than from drug distributors licensed by the department.

(b) Federal establishment registration and drug listing.

(1) All persons who operate as nonprescription drug manufacturers in Texas must meet the requirements in 21 Code of Federal Regulations (CFR) Part 207, Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code.

(2) New nonprescription drugs offered for sale by wholesale distributors must have met, if applicable, the requirements of 21 CFR Part 314, Applications for FDA Approval to Market a New Drug.

(c) Good manufacturing practices. Manufacturers of nonprescription drug products must comply with the applicable requirements in:

(1) 21 CFR Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, as amended;

(2) 21 CFR Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals, as amended;

(3) 21 CFR Part 225, Current Good Manufacturing Practice for Medicated Feeds, as amended

(4) 21 CFR Part 226, Current Good Manufacturing Practice for Type A Medicated Articles, as amended; and

(5) the regulations in this subsection governing the methods used in, and the facilities or controls used for, the manufacture, processing, packing, or holding of a drug to ensure each drug meets the requirements of the Federal Food, Drug, and

Cosmetic Act, 21 USC §301, et seq., as amended, (Federal Act) as to safety, and has the identity and strength meeting the quality and purity characteristics it purports or is represented to possess.

(d) Buildings and facilities.

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

(2) Manufacturing, processing, packing, or holding of nonprescription drugs must not be conducted in any personal residence.

(3) Sale of nonprescription drugs must not 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 must:

(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 and in good repair, including the walls, ceilings, windows, doors, and floors of the premises;

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

(E) utilize a quarantine area for storage of drugs that are outdated, damaged, deteriorated, returned, recalled, misbranded, or adulterated, that is clearly designated and separated from other sections where drugs are stored so drugs in this subchapter are not confused with usable drugs.

(e) Storage of nonprescription drugs. All nonprescription drugs stored by wholesale distributors must be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs and the standards set forth in the latest edition of the United States Pharmacopeia/National Formulary (USP/NF). If no storage requirements are established for a nonprescription drug, the nonprescription drug may be held at controlled room temperature, as defined in the USP/NF, to help ensure that its identity, strength, quality, and purity are not adversely affected. Prior to storage in inventory, a wholesale distributor must:

(1) upon receipt, visually examine each outside shipping container for identity and to prevent the acceptance of contaminated drugs otherwise unfit for distribution; and

(2) carefully inspect each outgoing shipment for identity of the drug and to

prevent delivery of drugs that have been damaged in storage, including drugs held under improper conditions.

(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 must be established and followed and include:

(1) a procedure for identifying and retrieving nonprescription drug products 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 must meet the labeling requirements of the Act and 21 CFR Part 201, 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 this chapter (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 this chapter (relating to Regulation of Cosmetics).

§229.252. Enforcement and Penalties.

(a) Inspection. To enforce this subchapter or the 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 this subchapter or the Act.

(b) Receipt for samples. An authorized agent or health authority who inspects 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, must give 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 this subchapter or under the Act, or Federal Food, Drug, and Cosmetic Act (Federal Act), Chapter V, or a person who is in charge or custody of those records, must, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times access to records for verification and copying.

(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 must, 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 this subchapter must 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 §229.242 of this subchapter (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 detention, emergency order, recall, and administrative penalties. Administrative penalties will be assessed using the Severity Levels contained in §229.261 of this chapter (relating to Assessment of Administrative Penalties). The department may request the attorney general or local law enforcement institute an action for criminal penalties, collection of civil penalties, condemnation, destruction, and injunction under the Act.