



LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

12091 Bricksome Avenue, Suite B Baton Rouge, LA 70816
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INSTRUCTIONS APPLICATION FOR LICENSE WHOLESALE DISTRIBUTOR OF LEGEND DRUGS OR DEVICES

An APPLICATION form must be submitted to obtain a wholesale distributor license to sell and/or ship legend drugs or devices wholesale in and/or into the State of Louisiana as provided by LA R.S. 37:3461 through R.S. 37:3482 and as amended.

The license issued shall be valid only for the physical location for which it is issued. Licenses are not transferable for location change or change of ownership of the business or physical distribution location. Changes in information for a license must be submitted in writing within 60 days after such changes become effective. Licenses expire on December 31st of each calendar year. New licenses issued by the Board shall expire on December 31 of the calendar year issued.

The application form must be fully completed (please print or type), signed by an authorized representative of the applicant, and submitted to the Board at the address above, along with the appropriate fee(s) (made payable to the *Louisiana Board of Wholesale Drug Distributors*) and all required documentation.

INSTRUCTIONS:

- 1) Indicate the type of application being made.
 - a) Initial License - for entities that have never been licensed in Louisiana.
 - i) Inspection - for in-state facilities only - entities located in Louisiana - applying for initial license (or location changes)
 - b) Location Change - for current licensees whose business and/or distribution facility has moved to a new location. The applicant is applying for a new license for the new facility location. Provide the effective date of the change and the current Louisiana license number held.
 - c) Change of Ownership - for current licensees when ownership of the licensee has changed by sale, merger, acquisition, trade, transfer etc. of stocks and/or assets. The application is being made for a new license under the new ownership. Provide the effective date of the change and the current Louisiana license number held.
 - i) A copy of the final transaction documentation for the acquisition, merger, sell, trade, transfer, etc. (ie.- a certificate of acquisition-merger-trade-transfer, bill of sale, stock certificate, incorporation amendment, etc.) which effected the change in ownership must be submitted with the application. *Please note that an agreement or contract is not acceptable.*
 - d) Reinstatement and (late) Renewal - for licensees whose license had expired, was suspended, or revoked (both fees must be paid).
- 2) Do not write in the shaded sections - FOR BOARD USE ONLY.
- 3) SECTION I - Indicate the name of the company making application (applicant).
 - a) Indicate any "doing business as" (dba) or trade names used by the applicant. Please note that a separate license is required for each division, subdivision, subsidiary, or affiliate company owned by the same business entity or parent company when wholesaler/ distributor operations are conducted independently by the division, subdivision, subsidiary, or affiliate company and/or the division, subdivision, subsidiary, or affiliate company is independently incorporated.
- 4) SECTION II - Indicated the address of the primary distribution location from which product is shipped.
 - a) Check the appropriate description of the distribution facility being used - Applicant's Own Facility or 3PL.
 - b) Enter the physical address for the distribution center location being utilized.
 - c) Check to indicate if the applicant uses both its own facility and also uses 3PL(s) for distribution. Attach a list of the 3PL(s) and their distribution facility address(s) being used.
 - d) If a third party logistic (3PL) provider [as defined in item 9.a)vii) below] is used, indicate the name of the 3PL company.
 - i) Check to indicate if the 3PL named in this section is the only 3PL used for distribution. OR
 - ii) Check to indicate if there is more than one 3PL [as defined in item 9.a)vii) below] used for distribution of product. Attach a list of the additional 3PLs used along with the 3PLs distribution addresses to the application.
- 5) SECTION III - Indicate the contact person for the applicant's distribution facility or the applicant's contact person for management of the legend drug or device product owned by the applicant as distributed by a 3PL provider; include the contact person's email address, telephone number, and fax number.
- 6) SECTION IV - Indicate the applicant's mailing address, city, state, and zip code for receipt of license/ regulatory information.
 - a) Indicate the name of the contact person for licensing and regulatory affairs; include the contact person's email address, telephone number, and fax number.
- 7) SECTION V - Indicate the contact person for application/ regulatory/ licensing issues; include the contact person's email address, telephone number, and fax number.
- 8) SECTION VI - Indicate the address of the business location for the applicant.
 - a) Check to indicate if legend drugs and/or devices are distributed from the business addressed provided (if the business address is different from the distribution address provided in Section II). **MAKE NOTE: ALL LOCATIONS THAT PHYSICALLY DISTRIBUTE PRODUCT MUST BE SEPARATELY LICENSED.**

- 9) SECTION VII - Indicate the name of the person to be designated by the applicant as the applicant's Designated Responsible Party responsible for operations at the applying facility; include the Designated Responsible Party's email address, telephone number, and fax number.
- 10) SECTION VIII -
- a) Check to indicate all that apply for the type of business conducted by the applicant:
 - i) Wholesaler - any person having ownership and engaged in the selling of legend drugs or devices in or into Louisiana.
 - ii) Distributor - any person engaged in the physical distribution of legend drugs or devices in or into Louisiana.
 - iii) Manufacturer - any person who manufactures legend drugs and includes a labeler or primary distributor; any person who prepares legend drugs in dosage form by mixing, compounding, encapsulating, entableting, or by other process; or any person who manufactures, assembles, processes, or modifies legend devices.
 - iv) Re-packager - any person who repackages or engages in repackaging of legend drug or device product.
 - v) Broker - a person participating in wholesale drug or device distribution that buys or sells the drug or device but does not take physical possession such that it is sold to the broker and shipped to a third party.
Agent - a person authorized by another person, called the principal, to act for him or on his behalf in wholesale drug or device distribution and who may or may not take physical possession such that the drug or device is sold to the agent and may be shipped to a third party.
 - vi) Freight Forwarder - a person participating in wholesale drug or device distribution that acts as the agent for the distribution of a drug or device and does or does not take physical possession such that it is sold to the broker and shipped to a third party.
 - vii) Third Party Logistic (3PL) Provider - a person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, but does not take title to the legend drug or device or have responsibility to direct the sale or disposition of the legend drug or device.
 - viii) Jobber - a person who purchases drugs or devices usually in bulk to sell to another person in the wholesale drug/device distribution industry.
Private Labeler - a person that packages and/or manufactures and packages a drug or device that bears the name of the distributor along with the distributor's national drug code number and lot number.
 - ix) Nuclear Pharmacy - a person that compounds radioactive materials for use in nuclear medicine procedures.
 - x) Ship Chandlers - a person that provides legend drugs or devices to seafaring ships.
 - xi) Reverse Distributors - a person that receives legend drugs or devices for the purpose of arranging the return and/or the destruction of the legend drugs or devices.
 - xii) Retail Pharmacy Warehouse - a person that acts as a central warehouse and performs intracompany sales or transfers to retail pharmacies under common ownership.
 - b) Check to indicate the type of ownership of applicant.
 - c) Indicate the state in which the applicant is incorporated (or of formation).
 - d) A separate license is required for each facility or physical location directly or indirectly owned or operated by the same business entity or for a parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies when wholesaler/distributor operation are conducted at more than one independently incorporated division, subdivision, subsidiary, or affiliate company location and there exists joint ownership and control among all the entities.
- 11) SECTION IX -
- a) Check to indicate all manners of distribution that apply.
 - b) Check to indicate all types of product being distributed.
- 12) SECTION X - Provide a list of any owners of the applicant company/corporation that possess greater than 10% interest in the company/corporation and percentage of ownership.
- 13) SECTION XI - Provide a list of the company/ corporate officer and directors.
- 14) SECTION XII - Out-of-State Facilities must provide a copy of their current state wholesaler/ distributor (or manufacturer, if applicable) license as issued by the regulatory agency in the state in which the applicant facility is located.
- a) Check to indicate if the state in which the applicant is located does not require the applicant to license and the applicant utilizes a 3PL for distribution. The applicant must submit a copy of correspondence from the licensing agency of the state in which the applicant is located which states that no license is required along with a copy of the 3PL provider's license issued by the state in which the 3PL is located.
 - b) Check to indicate if the legend device only distributor's state in which it is located does not require the applicant to license. The applicant must submit a copy of correspondence from the licensing agency of the state in which it is located stating that no license is required. If the applicant is a manufacturer, submit a copy of an FDA establishment registration.
- 15) SECTION XIII - The applicant must submit a list of every state or territory where the applicant holds a current license as a wholesale legend drug or device distributor. (No license copies are required except as required in Section XI, when applicable).
- 16) SECTION XIV - If the applicant is distributing controlled substances, the applicant must provide
- a) Its federal DEA number and
 - b) A Louisiana Controlled Dangerous Substance (CDS) registration number (as issued through the LA Board of Pharmacy, CDS Program).
- 17) SECTION XV, Disciplinary Actions - Complete all questions regarding disciplinary action taken against the applicant facility. If any question is answered "yes", attach to the application an explanation and any pertinent documentation regarding the action taken.
- 18) SECTION XVI, Application Certification - After completion of the form, an authorized representative of the applicant must read the certification and sign and date the application in acceptance.

APPLICATION CHECKLIST

Application for Licensure as a Wholesale Distributor of Legend Drugs or Devices

- Completed and signed Application for License form – Wholesale Distributor of Legend Drugs or Devices. All items must be completed. Enter “NA” if an item does not apply to your company. The application must be signed and dated.
 - If Change of Ownership – attach a copy of the final transaction document for the sell, merger, acquisition, trade, transfer, (etc.) which effected the change in ownership; acceptable documents include a certificate of acquisition, certificate of merger, certificate of trade, certificate of transfer, bill of sale, stock certificate, (etc.) ; *Note that a purchase agreement or contract is not acceptable.*
 - If applicable, a list of additional third party logistic (3PL) service providers if more than one 3PL is utilized.
 - If made on separate sheet, list of any owners and list of officer and directors.
- Out of State applicants, a copy of wholesaler/ distributor (or manufacturer, if applicable) license from the regulatory agency as issued by the state in which the applicant facility is located
 - If no license is required in the state in which the applicant is located:
 - A copy of correspondence from the regulatory agency of the state in which the applicant is located stating such.
 - Copy of 3PL, if applicable, wholesaler/ distributor license from the regulatory agency as issued to the 3PL by the state in which the 3PL is located.
 - Legend device manufacturers, a copy of an FDA establishment registration.
- If made on separate sheet, list of every state or territory where the applicant facility holds a current license for wholesale drug or device distribution.
- Explanation and any pertinent documentation related to disciplinary action if “yes” is answered to any question on the application form
- Payment of appropriate License Fee(s) made payable to the *Louisiana Board of Wholesale Drug Distributors*