



LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

12091 Bricksome Avenue, Suite B Baton Rouge, LA 70816
 (225) 295-8567 Fax (225) 295-8568 admin@Lsbwdd.org www.Lsbwdd.org

**APPLICATION for LICENSURE
 DISTRIBUTOR of LEGEND DRUGS or DEVICES**

NOTES:

New licenses issued by the Board shall expire on December 31 of the calendar year issued.

DO NOT WRITE IN SHADED AREAS - Board Use Only.

To reinstate a Louisiana license that has been cancelled, expired, suspended, or revoked, contact the Board office to request a reinstatement form.

Type of Application - Check All Appropriate Boxes:

- INITIAL LICENSE**
- Location Change:** Effective Date: _____; Current License No. _____ **CANCEL**
- Change of Ownership:** Effective Date: _____; Current License No. _____ **CANCEL**
 - A copy of the final transaction documents for the sell, merger, acquisition, trade, transfer, etc. which effected the change in ownership is attached.

License Sub-Types (see bottom of page 4 for descriptions) - Check All Appropriate Boxes:

- Standard Distributor**
- Wholesale Distributor**
- Third Party Logistics Provider (3PLP) Distributor**

Fee Schedule - Check the appropriate box as determined by the # of license sub-types check in the above section; pay amount noted for the selection:

- One License Sub-Type checked above - Fee:** \$400
- Two License Sub-Types checked above - Fee:** \$425
- Three License Sub-Types checked above - Fee:** \$450
- In-State Facilities Only: Facility Inspection for initial and location change - Fee:** \$100

APPL# _____	Approved _____	License No. _____	Date _____	IS
				OOS

Applicant Company Name: _____
d/b/a or trade name (if applicable): _____

Primary Distribution Location from which product is shipped:

Distribution Center Address: _____

Distribution City, State, Zip Code: _____

If 3PL used- c/o (Name of 3PL Service Provider): _____ [LA Lic#: _____]

Check here if additional 3PLs are also used for distribution; attach a list of additional 3PLs with distribution addresses.

Type of Business Conducted: (Mark all that apply) Sales Facilitates Delivery (physically distributes)

Standard Distributor: Sub-categories (Mark all that apply): *(Does not apply if "Standard Distributor" license sub-type is not marked above.)*

- Not Applicable
- Manufacturer/ Virtual Re-packager Broker/Agent Freight Forwarder Jobber/Private Labeler Nuclear Pharmacy
- Ship Chandlers Reverse Distributor Retail Pharmacy Warehouse Pharmacy Compounder/503b

Type of Business: Individual (Proprietorship) Partnership LP Corporation LLC

Type of Ownership: Individuals Corporately Owned Publicly Traded Privately Held
 Non-Profit (Charitable)

- INDIVIDUAL(S) - List the name(s) and the percent of ownership held for each individual person possessing greater than 10% interest in the applicant. Information Attached on Separate Sheet

Name	% of Ownership	Name	% of Ownership

FACILITIES LOCATED IN LOUISIANA ONLY:

- Completed CRIMINAL HISTORY RECORDS CHECK authorization form (201502C), State Police criminal history records processing forms (available on Board's website), provide fingerprints as obtained from local law enforcement, and fees payment for each individual owner possessing greater than 10% interest in the applicant company is enclosed with this application.

- CORPORATELY OWNED - List the name(s) of parent company(s). Information Attached on Separate Sheet

Company Name

- PUBLICLY TRADED - Provide the trading symbol - _____
- PRIVATELY HELD - List the name(s) of financial, investment, trust, etc entity(s). Information Attached on Separate Sheet

Company Name

State of Incorporation (or Formation): _____

Manner of Distribution: (Mark all items that apply.)

- Legend drugs or devices are sold and/or shipped directly to dispensing/administering parties (i.e. - pharmacies, hospitals, physician offices, maritime ships, etc.)
- Legend drugs or devices are sold and/or shipped to distributors

Type of Product Distributed: (Mark all items that apply.)

- Legend Drugs
- Legend Drugs (CS)¹ (Controlled Substances)
- Legend Devices
- Medical Gases

¹ DEA and Louisiana state registration is required to distribute controlled substances in/into the state. Changes in types of product being distributed must be reported to the Board office via letter, fax, or email.

OUT-OF-STATE FACILITIES only:

NA- Applicant Facility Located In Louisiana

Current home state distributor (or manufacturer, if applicable) license as issued by the state in which the applicant facility is located; attach copy of license.

License Number: _____ **Expiration Date:** _____

- Check here if the state in which the applicant is located does not require distributor (or manufacturer, if applicable) licensing and a 3PL is used for distribution; must submit a copy of correspondence from the licensing agency of the state in which the applicant is located indicating that no license is required along with a copy of the 3PL license from the state in which the 3PL is located.
- Check here if the applicant is a legend device only distributor whose licensing agency of the state in which it is located does not require licensing; must submit a copy of correspondence from the licensing agency of the state in which the applicant is located indicating that no license is required. If the applicant is a manufacturer, submit a copy of an FDA establishment registration.

Federal DEA Number: _____ Not Applicable

Louisiana State Controlled Substance Number: _____ Not Applicable
(As issued by the Louisiana Board of Pharmacy, CDS Program, if applicable)

Company/Corporate Officers and Board of Directors:

- Officers - List the name(s) and title(s) of the officers. Information Attached on Separate Sheet

Name	Title	Name	Title

- **Directors** – List the name(s) of the members of the Board of Directors (if applicable).

Not applicable

Information attached on Separate Sheet

Name	Name	Name	Name

Provide a list of every state or territory, other than Louisiana, where the applicant holds a current license as a drug or device distributor.

Not licensed in any other states

Information Attached on Separate Sheet

State	State	State	State	State	State

Facility Contact Person: _____

E-Mail Address: _____

Telephone Number: _____ **Fax Number:** _____

Regulatory Contact is same as Facility Contact Person

Regulatory Contact Person: _____

E-Mail Address: _____

Telephone Number: _____ **Fax Number:** _____

Designated Responsible Party: _____

E-Mail Address: _____

Telephone Number: _____ **Fax Number:** _____

Completed DRP QUALIFICATION REVIEW FORM for the individual noted in this section is enclosed with application.

Rvw/ Appvd

Same as Distribution Address

Mailing Address for license/ regulatory: _____

Mailing City, State, Zip Code: _____

Same as Distribution Address OR Same as Mailing Address

Business Location Address: _____

Business City, State, Zip Code: _____

Check here if this address is different from the Primary Distribution Address above AND legend drugs/ devices are physically distributed from this location also.

LA License # _____ NOTE: ALL LOCATIONS THAT PHYSICALLY DISTRIBUTE PRODUCT MUST BE SEPARATELY LICENSED.

Disciplinary Actions: (For applying facility location)

Has the applicant ever been denied a license, certificate, registration, or permit for distribution of legend drugs (including controlled substances) or devices? No Yes

Has any license, certificate, registration, or permit for distribution of legend drugs (including controlled substances) or devices ever held by you or the applicant been sanctioned, fined, revoked, suspended, placed on probation and/or otherwise been the subject of disciplinary review or investigation in another state? No Yes

Is there any investigative or disciplinary action pending against any license, certificate, registration, or permit for distribution of legend drugs (including controlled substances) or devices held by the applicant in another state? No Yes

Has any owner, officer, director, designated responsible party, or other person in charge of drug distribution for the applicant ever been convicted of or plead guilty to or plead nolo contendere to a felony or misdemeanor, other than a traffic violation, under any federal, state, or local laws, rules or ordinances? No Yes

If the answer to any of the above questions is "Yes", please attach an explanation and any pertinent documentation related to the matter.

Application Certification: I hereby certify, (1) I, the undersigned, am a representative of the applicant authorized to execute on their behalf such documents as this; (2) by my signature below, the applicant (a) will operate the facility in a manner prescribed by federal, state, and local laws and all rules promulgated by the Board, (b) assumes all responsibility for acts and/or omissions committed by any personnel employed by it, and (c) make certain personnel employed by the applicant have the appropriate education, training, and experience to assume responsibility for handling, distribution, and storage of legend drugs or devices; and (3) to the best of my knowledge and belief, the information provided in this application is true and correct in all respects. Authorization is hereby given to the Louisiana Board of Drug and Device Distributors or their agent to investigate the information contained in this application. It is understood that information provided in this application may be provided to other federal, state, or local government or enforcement agencies.

Name of Authorized Representative (print or type)

Title of Authorized Representative

Signature of Authorized Representative

Date

DISTRIBUTORS OF LEGEND DRUGS OR DEVICES

Sub-Types:

STANDARD DISTRIBUTOR

Description: Any person (entity) that sales or facilitates the delivery of legend drugs or legend devices to persons other than the consumer or patient; including, but not limited to, manufacturers, repackagers, own-label distributors, jobbers, retail pharmacy warehouses, pharmacies, brokers, agents, freight forwarders, ship chandlers, reverse distributors, compounders/503b, and nuclear pharmacies.

WHOLESALE DISTRIBUTOR

Description: Any person (entity) that sales or facilitates the delivery of drug product to persons other than the consumer or patient excluding, but not limited to, manufacturers, repackagers, third-party logistic providers, distributors of devices, medical gases, intravenous drugs for replenishment or irrigation, blood or blood components; radioactive drugs or biologicals, imaging drugs, homeopathic drugs, and compounded drugs.

THIRD-PARTY LOGISTICS PROVIDER

Description: Any person (entity) that provides or coordinates warehousing, facilitates the delivery of, or other logistic services for a legend drug or legend device interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.

Designated Responsible Party (DRP) Qualification Review

Check the appropriate DRP Applicant type:

DRP Applicant for a NEW license application

Name of Applicant Company: _____ App# _____

DRP Applicant Change for a current Louisiana licensee: License Info Change Request Renewal

Name of LA Licensee: _____ License No. _____

Name of DRP Appointee: (As marked on licensure application form for new applicants or the name of the new DRP applicant for current licensees.)

DRP Date of Birth: _____

Address of the Facility location where the DRP applicant is physically present during regular business hours:

Address City State Zip

Date DRP applicant Hired: _____

Resume Attached (If < 2 yrs)

If the DRP applicant has been employed by the above named applicant/licensee for less than two years, attach a summary of the DRP applicant's employment history for at least two-years of full-time employment with either a pharmacy, legend drug or device distributor, or medical gas distributor in a capacity related to the dispensing, distribution, and recordkeeping of legend drugs or devices; or other similar qualifications for acceptance by the Board.

Current Position Held by DRP Applicant: _____

Is the DRP applicant:

Employed in a full-time position Yes No

Actively involved in or aware of the daily legend drug/device distribution operations of the applying/licensed facility Yes No

Works in a capacity related to the distribution or dispensing, and recordkeeping of legend drugs or devices Yes No

Description of DRP Applicant's Current Daily Duties (use separate sheet if additional room is needed): See Attached

Name of Authorized Representative (print or type)

Title of Authorized Representative

Signature of Authorized Representative

Date

APPLICANT/LICENSEE FACILITIES LOCATED IN LOUISIANA ONLY:

Completed CRIMINAL HISTORY RECORDS CHECK Board authorization form, State Police authorization and disclosure forms (available on Board's website), provide fingerprints as obtained from local law enforcement, and fees payment for the above DRP applicant IS ENCLOSED with this DRP qualification review.

Not Applicable- if applying/licensed facility is physically located outside Louisiana.

BOARD OFFICE USE ONLY:

Date Reviewed:	Reviewed By:	<input type="checkbox"/> Acceptable <input type="checkbox"/> Not Acceptable	Notes:
		CHRCk Rqrd: <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> APPROVED By: _____ Date: _____



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CRIMINAL HISTORY RECORDS CHECK

A CRIMINAL HISTORY RECORD is information collected by state and federal criminal justice agencies on persons consisting of identifiable description and notations of arrests, detentions, indictments, bills of information, or any formal criminal charges and any disposition arising there from. A criminal history record search in accordance with La. R.S. 37:3477 and LAC 46:XXXIV.305.B is required by the Board for all new applicants physically located in Louisiana to include the designated responsible party and any individual owners who owns greater than 10% interest in the applicant company; and for those licensees of previously issued licenses if a new DRP is appointed or if ownership interest of more than 10% has been transferred to a new owner. Conviction of a felony violation of federal or state law may be grounds for denial of or disciplinary action against a license as a distributor of legend drugs or devices.

APPLICATION FOR CRIMINAL HISTORY RECORDS SEARCH

Each qualified person must:

- Sign the Board’s authorization statement below;
- Complete and sign the LA State Police, Bureau of Criminal Identification and Information disclosure authorization form (Form DPSSP 6696) [available on Board’s website];
- Complete LSP, BCII, Applicant Processing-Disclosure form (LSPAPP3/R09.10) [available on Board’s website], and
- Obtain fingerprints through your local law enforcement office (Form FD-258).

Submit to the Board office (with the license application for new applicants or the DRP qualification review form for new DRP for current licensees) both authorization forms, the processing-disclosure form, and fingerprint card for each qualifying person along with separate payment of processing fees totaling **\$38 (effective 01/01/2019 FBI fee increase new processing fees totaling \$39.25)** for each made out to the LOUISIANA DEPARTMENT OF PUBLIC SAFETY via cashier’s check, business check with pre-printed business name, or money order.

AUTHORIZATION FOR CRIMINAL HISTORY RECORDS SEARCH

By signing and dating this notice, the undersigned individual hereby authorizes the Louisiana Board of Drug and Device Distributors to provide my fingerprint card to the Louisiana Bureau of Criminal Identification and Information of the office of state police within the Louisiana Department of Public Safety for submission to the Federal Bureau of Investigation for the generation of a criminal history records report.

_____ DRP and/or Owner

Print Individual’s Name

Signature _____ Date _____

New Applicant- Name: _____ App# _____

Current Licensee Name: _____ LA Lic No. _____ Info Change Renewal

BOARD OFFICE USE ONLY:

Date App or DRP Rvw Form Rcvd:	<input type="checkbox"/> Payment Chk/ Enclosed MO#:	ID:	DATE SENT TO LSP:
Required forms attached and complete: <input type="checkbox"/> LSP Disclsr Authrzttn <input type="checkbox"/> CrmnlHist Determinatn <input type="checkbox"/> Fingerprint Cd			DATE RPT RCVD FROM LSP: