LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS
12091 Bricksome Avenue, Suite B Baton Rouge, LA 70816
(225) 295-8567 Fax (225) 295-8568 admin@drugboard.LA.gov www.drugboard.LA.gov

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 LOUISINA ONLY:

☐ CRIMINAL HISTORY RECORDS (Background) CHECK required for any individual owner(s) possessing greater than 10% interest in applicant company. Louisiana State Police application for CHRck is by an online application platform; a submission link to the CHRck electronic application is available on Board's website - *Application* page.

- 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:

☐ CRIMINAL HISTORY RECORDS (Background) CHECK (CHRck) is required for the individual person appointed as DRP at applicant facilities located in Louisiana. Louisiana State Police application for CHRck is by an online application platform. A submission link to the CHRck electronic application is available on Board's website - Application page.

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

BOARD OFFICE USE ONLY:

Date Reviewed:	Reviewed By:	☐ Acceptable ☐ Not Acceptable	Notes:	
		CHRCk Rqrd: ☐ Yes ☐ No	☐ APPROVED By:	Date:

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NOTICE

The Louisiana State Police, Bureau of Criminal Identification and Information, has changed the process for submission of applications for criminal history records (background) checks (CHRck) to an electronic fingerprint-based application service- IdentoGO. LSP is no longer accepting paper applications. Results of CHRck applications electronically submitted can be available to this agency within 48-72 hours after your enrollment appointment.

CRIMINAL HISTORY RECORDS (Background) CHECKS
Applicant/Licensed facilities physically located in Louisiana:

A criminal history records (background) check is required for any individual person(s) who own greater than 10% interest in the applicant/licensee company and the designated responsible party (DRP) individual.
A link to the online-fingerprint application service is available on the Board's website at www.drugboard.La.gov on the Application, Renewal, *and* License Info Change *page links.*

INSTRUCTIONS:

- On the Board's website, www.drugboard.LA.gov, lower part of the selected link page (Application, Renewal, or License Info Change), click the red "GET STARTED" button,
- Select the state IN WHICH the applicant/licensee facility IS PHYSICALLY LOCATED from the list provided.
- If CHRck is required, continue by completing the authorization form for CHRck provided and "Submit Form".
- The electronic application vendor utilized by LSP, IdentoGO's application website will open.
- Complete IdentoGO application and schedule appointment.