LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS
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INSTRUCTIONS FOR APPLICATION FOR LICENSE AS A DISTRIBUTOR OF LEGEND DRUGS OR LEGEND DEVICES

An APPLICATION form must be submitted to obtain a distributor license to sale or facilitate delivery of legend drugs or devices in or into the State of Louisiana to entities other than the consumer/patient as provided by LA R.S. 37:3461 through R.S. 37:3482 (as amended).

The distributor license issued shall be valid only for the physical location for which it is issued (or business location when a 3PLP is utilized for facilitation of delivery of drugs/devices). Licenses are not transferable for location change or change of ownership of the business or physical distribution location. Any licensee changing their physical location is required to submit an application for location change at least 30 days prior to such location change. 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.***

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 distribution 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.

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 Drug and Device 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.
   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.*

   NOTE: To reinstate and (late) renew a Louisiana license that has been cancelled, expired, suspended, or revoked – contact the Board office to request a license reinstatement/renewal form.
2) Indicate the appropriate distributor license sub-type(s); mark all that apply.
   a) Standard Distributor- 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 warehouse, pharmacies, brokers, agents, freight forwarders, ship chandlers, reverse distributors, compounders (503b), and nuclear pharmacies.
   b) Wholesale Distributor- any person/entity that sales or facilitates the delivery of drug product (as defined by federal government) to persons other than the consumer/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.
   c) Third-party Logistics Providers (3PLPs)- any person/entity that provides or coordinates warehousing, facilitates the delivery of, or other logistic services for a legend drug or legend device in interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of the drug or device but does not take ownership of the drug or device nor have responsibility to direct the sale or disposition of the drug or device.
3) Indicate the appropriate license fee due based on the number of license sub-types marked in item 2) above.
   a) One license sub-type checked- Fee: $400;
   b) Two license sub-types checked- Fee $425;
   c) Three license sub-types checked- Fee $450.
   d) Inspection – for in-state facilities only – entities located in Louisiana – applying for initial license (or location changes)- Fee: $100.
4) Do not write in the shaded sections – FOR BOARD USE ONLY.

5) 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 r/ 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.
6) Enter the physical address of the primary distribution location from which legend drugs/devices are shipped.
   a) If a third party logistic provider (3PLP) [as defined in item 6.d) below] is used, indicate the name of the 3PLP company.
      i) Check to indicate:
         (1) If the applicant also utilizes 3PLPs or utilizes more than one (primary) 3PLPs [as defined in item 6.d) below] for distribution.
      ii) Attach a list of the additional 3PLPs used along with the 3PLPs' distribution addresses to the application.
7) Indicate all that apply for the type of business conducted by the applicant:
   a) Sales – any person having ownership and engages in the sale of legend drugs or devices in or into Louisiana.
   b) Facilitates Delivery – any person engaged in the physical distribution of legend drugs or devices in or into Louisiana.
8) Indicate all that apply for sub-type standard distributor the sub-category(s) of the applicant:
   a) Manufacturer – any person who manufacturers 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 manufacturers, assembles, processes, or modifies legend devices.
      i) Virtual manufacturer- any person who owns a legend drug or legend device and contracts out physical manufacturing of the drug or device.
   b) Re-packager – any person who repackages or engages in repackaging of legend drug or device product.
   c) Broker – a person participating in 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 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.
   d) Freight Forwarder – a person participating in 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.
   e) Jobber – a person who purchases drugs or devices usually in bulk to sell to another person in the 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.
   f) Nuclear Pharmacy – a person that compounds radioactive materials for use in nuclear medicine procedures.
   g) Ship Chandlers – a person that provides legend drugs or devices to seafaring ships.
   h) 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.
   i) Retail Pharmacy Warehouse – a person that acts as a central warehouse and performs intra-company sales or transfers to retail pharmacies under common ownership.
   j) Pharmacy – any person licensed as a dispensing pharmacy by a state board of pharmacy.
   k) Compounder – a person that produces a drug by combining ingredients.
9) Indicate the type of business of applicant.
10) Indicate the type of ownership of applicant.
   a) Provide the name(s) or a list of owners of the applicant company/corporation.
      i) If the applicant is owned by individual person(s) that possess greater than 10% interest in the company/corporation, provide a list of names and percentage of ownership.
         (1) *For applicants whose facility in located in Louisiana ONLY*, a criminal history records check must be performed for each individual owner listed that possesses greater than 10% interest in the applicant company; a completed CRIMINAL HISTORY RECORDS CHECK authorization form (201603C) and State Police criminal history records processing forms (available on Board's website) and fee payment must be submitted with the license application form.
      ii) If the applicant is "Corporately Owned", provide the name(s) of Parent company(s);
      iii) If the applicant is "Publicly Traded", provide the trading symbol;
      iv) If the applicant is "Privately Held", provide the name(s) of financial, investment, trust (etc.) entities.
11) Indicate the state in which the applicant is incorporated (registration or formation).
12) Indicate all manners of distribution that apply.
13) Indicate all types of product being distributed.
14) Out-of-State Facilities must provide a copy of their current state 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 <u>and</u> the applicant utilizes a 3PLP 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 3PLP provider's license issued by the state in which the 3PLP is located.
   b) Check to indicate if the legend device <u>only</u> 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) If the applicant is distributing controlled substances, the applicant must provide
   a) Federal DEA number and
   b) Louisiana Controlled Dangerous Substance (CDS) registration number (as issued through the LA Board of Pharmacy, CDS Program).

16) Provide a list of the company/ corporate officer; include names and titles. Provide a list of the members of the Board of Directors (if applicable). If the applicant is an LLC with no executive officers, please provide a list of the LLC members.
17) Provide a list of every state or territory where the applicant holds a current license as a legend drug or device distributor. (No license copies are required except as provided for in number 14) above, when applicable).
    a) If not licensed in any other states, mark appropriately.
18) 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 3PLP provider; include the facility contact person's email address, telephone number, and fax number.
19) Indicate the contact person for application/ regulatory/ licensing issues; include the regulatory contact person's email address, telephone number, and fax number; "Regulatory Contact is same as Facility Contact Person" may be selected if it applies.
20) Indicate the name of the person to be designated by the applicant as the applicant's Designated Responsible Party (DRP) responsible for operations at the applying facility; include the Designated Responsible Party's email address, telephone number, and fax number.
    a) DRP qualifications must be provided for review; a completed DRP QUALIFICATION REVIEW FORM for the individual appointed in this section as the DRP for the applicant must be submitted with the application form. *For applicants whose facility in located in Louisiana ONLY*- a criminal history records check must be performed for the DRP appointee; a completed CRIMINAL HISTORY RECORDS CHECK Board authorization form and State Police criminal history records processing forms (two forms available on Board's website) and fee payment must be submitted to the Board with the license application form.
21) Indicate the applicant's mailing address, city, state, and zip code for receipt of license/ regulatory information.
22) Indicate the address of the business location for the applicant.
    a) Check to indicate if the business address is different from the distribution address provided in previous section and legend drugs and/or devices are distributed from the business addressed provided; provide the Louisiana license number for business address, when applicable. NOTE: ALL LOCATIONS THAT PHYSICALLY DISTRIBUTE PRODUCT MUST BE SEPARATELY LICENSED.
23) 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.
24) 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 Distributor of Legend Drugs or Devices

- ☐ Completed and signed Application for License form – 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 providers (3PLPs) if more than one 3PLP is utilized.
- ☐ *For applicant facilities located in Louisiana only* with individual ownership - a completed CRIMINAL HISTORY RECORDS CHECK authorization form, State Police criminal history processing forms (available on Board's website), and fee payment for each individual owner possessing greater than 10% interest in the applicant company.
- ☐ 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 (or for devices FDA registration, when applicable)
  - ● 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 3PLP, if applicable, r/ distributor license from the regulatory agency as issued to the 3PLP by the state in which the 3PLP is located.
    - ☐ Legend device manufacturers, a copy of an FDA establishment registration.
- ☐ If made on separate sheet, list of officer and directors.
- ☐ If made on separate sheet, list of every state or territory where the applicant facility holds a current license for drug or device distribution.
- ☐ DRP QUALIFICATION REVIEW FORM for the individual designated as the DRP – *for applicant facilities located in Louisiana only* this includes a completed CRIMINAL HISTORY RECORDS CHECK authorization form and State Police criminal history processing forms (available on Board's website) and fees payment.
- ☐ Explanation and any pertinent documentation related to disciplinary action if "yes" is answered to any of the disciplinary action questions on the application form
- ☐ Application certification by signature of an authorized representative of the applicant.
- ☐ Payment of appropriate License Fee(s) made payable to the *Louisiana Board of Drug and Device Distributors*

Applicants with facility located in Louisiana are required to have an inspection performed before license is issued. An additional $100 inspection fee must be paid with the application. Before an inspection will be scheduled, the following items must be provided to the Board office:

1. Proof of monitored alarm system;
2. Copy of or description of the perpetual inventory system for recording all transactions for drugs, devices, and/or medical gases;
3. Proof of a temperature monitoring system [copy of current log sheet];
4. Copy of established policies and procedures [a guideline (outline) of minimum required items to cover is available on the Board's website]; and
5. Lists of employees with access to product and of employees with access into the building after hours.

Once these items are received, the Board's inspector will contact you to schedule a date to perform the inspection.