State of Louisiana

Department of Health
Office of Public Health

Basic Requirements for a Drug Storage Warehouse/Distributor

This plans review packet is to provide you with the information needed to apply for a Permit to Operate a drug distribution operation. The following can be printed from our website (ldh.la.gov/fdu)—they are attached for your convenience:

Please find the following attached to this document **(items in bold need to be submitted for review)**:

1. **FD-1B: Plans Review Questionnaire For Food And Drug Establishments**
   - Note that this document requests a **set of plans and specifications for the facility** and these should also be provided to your inspector for review.

2. **FD-1E: Utility No Objection Notice**
   - Provide this form to the local health unit for approval of sewage disposal and water supply.

3. **FD-9(N): Application for Registration *(if applicable—if you are distributing products under your own label or that are otherwise unregistered)***
   - **Label Proofs must be submitted for review via email, by fax or by mail** *before your establishment will be issued a Permit-To-Operate.* The fees and application for the registration will be collected when a Permit to Operate is issued; *do not* send in fees prior to approval of the label(s). **Verification of FDA pre-market approval is required before products will be registered.**

4. Title 51 Public Health – Sanitary Code, Part VI. Manufacturing, Processing, Packing and Holding of Foods, Drugs and Cosmetics, Chapter 1. General Regulations; and Chapter 17. Drug Distributors, Drug Wholesalers, and Drug Storage Warehouses.

   - Applicable sections from the FDA U.S. Food and Drug Administration: Code of Federal Regulations 21 CFR for all parts of this plans review packet may be found and printed from the FDA Website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

Carefully review the drug distribution regulations. Also please note that, depending on the specific nature of your operation, you may need a license or permit from the Louisiana State Board of Wholesale Drug Distributors or the Louisiana Board of Pharmacy. Contact information for these entities may be found here: http://ldh.la.gov/index.cfm/page/1317.

A Temporary Permit to Operate will be issued after the plans have been reviewed and approved and a pre-operational inspection demonstrates the facility is in compliance with our requirements. If a registration is required, all labels must be deemed acceptable for registration before a Permit-to-Operate will be issued. Appropriate fees for both the permit and product registration will need to be collected at the time the applications are completed.

If you wish to discuss any of the basic requirements, or some specific aspect of your proposed drug distribution operation with an officer or employee of this agency, please don't hesitate to contact this office.