State of Louisiana

Department of Health
Office of Public Health

Basic Requirements for a Drug Manufacturer

This plans review packet is to provide you with the information needed to apply for a Permit to Operate a drug manufacturing and distributing establishment. 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. Guidelines for Prospective Drug Manufacturers.

2. **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.

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

4. **FD-9(N): Application for Registration**
   - **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.**

5. Title 51 Public Health – Sanitary Code, Part VI. Manufacturing, Processing, Packing and Holding of Foods, Drugs and Cosmetics. Chapter 1. General Regulations; and Chapter 15. Current Good Manufacturing Practices in the Manufacture of Drugs.

   - 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

6. Section 510 of the Federal Food, Drug, and Cosmetic Act requires manufacturers, repackers, and relabellers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and human biological products to register their establishment(s) and submit a listing of every product in commercial distribution with the FDA. This information helps FDA maintain a catalog of all human and veterinary drugs and biologics in commercial distribution in the United States. **You will be required to provide verification of federal registration at the time of permitting.**
   - Electronic drug registration and listing instructions can be found here: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm

Carefully review the Basic Requirements For Prospective Drug Manufacturers. Please submit a set of plans and specifications to this office for compliance review including all items indicated in the plans review questionnaire document.

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. 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 manufacturing or processing operation with an officer or employee of this agency, please don't hesitate to contact this office.