State of Louisiana

Department of Health and Hospitals
Center for Environmental Health Services

Basic Requirements for a Distillery/Winery/Brewery/Liquor Manufacturer

This plans review packet is to provide you with the information needed to apply for a Permit to Operate a food manufacturing and distributing establishment. The following can be printed from our website (www.dhh.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 Food Manufacturers: Basic Requirements For Prospective Food Manufacturers, Processors, Packers and Repackers.

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, water supply and sizing of grease trap.

4. You do not need to register alcoholic beverages with this office but you will need to register with the Office of Alcohol and Tobacco Control of the Louisiana Department of Revenue. Call 225-925-4041 for additional information on this process.

5. Title 51 Public Health – Sanitary Code, Part VI. Manufacturing, Processing, Packing and Holding of Foods, Drugs and Cosmetics. Chapter 1. General Regulations; Chapter 3. Current Good Manufacturing Practices in Manufacturing, Processing, Packing or Holding Human Food; and Chapter 7. Food Storage Warehouse and Food Salvage Operations.
   - **Have your firm's process plan (s) and recall plan available for review at the time of inspection.**

   - 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. US FDA [Food and Drug Administration] requires that all food manufacturing facilities register in accordance with The Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Registrations can be submitted online at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm. Registration of the firm may take place once a Permit to Operate is issued.

Please be aware that manufacturing distilled spirits may have other requirements that need to be fulfilled with regard to liquor manufacturing. The items listed above will ensure that your firm meets Department of Health and Hospitals requirements, but you will also need to ensure that you have submitted your labels for review and approval to TTB (The Tax and Trade Bureau of the U.S. Department of the Treasury) if your products are greater than 6% ABV (alcohol-by-volume). Additionally, you will need to apply for the relevant in-state manufacturer's license through the Louisiana Department of Revenue's Office of Alcohol and Tobacco Control (ATC). You may reach the ATC at 225-925-4041 or Emily.Cassidy@atc.la.gov.

If you are brewing beer products, there are several other items to note prior to seeking or submitting paperwork:

- In accordance with TTB Ruling 2013-1, if you are distributing a malt beverage, as defined in the Federal Alcohol Administration Act, in intrastate commerce (*within* Louisiana) only, you are not required to obtain a Certificate of Label Approval or a Certificate of Label Exemption for that product. However, all products must bear the marking, branding, and labelling information required by 27 CFR 25 Subpart J and the alcohol health warning statement required by 27 CFR 16.21. Therefore, if you are intending to register and sell a malt beverage in intrastate commerce only, you will need to submit label artwork in lieu of a COLA/COLE and a statement on your firm's letterhead that this product is only intended for intrastate distribution.

- In accordance with TTB Ruling 2008-3, a beer may be produced using malt substitutes or without hops and still be considered legally a "beer" under the Internal Revenue Code, but it would not be considered a "malt beverage" under the Federal Alcohol Administration Act. This means that primary regulatory authority over the labelling would revert to the Food and Drug Administration. With the exception of the mandatory health warning, referenced

above in 27 CFR 16.21, the product would need to adhere to the labelling requirements from the Food, Drug, and Cosmetic Act, Fair Packaging and Labelling Act, and associated regulations. As a result, such products will also not have a certificate of label approval issued by the TTB; when submitting a registration for such items, include the label artwork in lieu of a COLA.

Carefully review the Basic Requirements For Prospective Food Manufacturers, Processors, Packers And Repackers. 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 food manufacturing or processing operation with an officer or employee of this agency, please don’t hesitate to contact this office.