Basic Requirements for a Basic Food 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. 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).

   - 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


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.