State of Louisiana

Department of Health
Office of Public Health

Basic Requirements for a Cosmetics Manufacturer/Distributor

This plans review packet is to provide you with the information needed to apply for a Permit to Operate a cosmetics manufacturing and/or 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. Basic Guidelines for Prospective Cosmetics Manufacturers (not applicable to distributors).

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-9(N): Application for Registration *(if applicable—needed only if you are manufacturing products for distribution or are distributing products under your own label)***
   - **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).

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

5. Title 51 Public Health – Sanitary Code, Part VI. Manufacturing, Processing, Packing and Holding of Foods, Drugs and Cosmetics. Chapter 1. General Regulations.
   - 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] has a Voluntary Cosmetic Registration Program (VRCP).
   - The Voluntary Cosmetic Registration Program (VCRP) is an FDA post-market reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States. There are two parts to the VCRP; you may participate in both parts of the program or only one part. No fees are required to participate in this voluntary program. Please visit the following website for more information: https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program

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