State of Louisiana

Department of Health
Office of Public Health

Basic Requirements for a Blood Products Manufacturer

This plans review packet is to provide you with the information needed to apply for a Permit to Operate. 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. 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

4. 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.**
    - Form FDA-2830, Blood Establishment Registration and Product Listing, is used for submission of registration and product listing information to the FDA. The form may be downloaded from FDA's website to complete and submit by mail. The information may also be submitted electronically. Visit this link for further information: https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing

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