

Guidelines for Obtaining Exemption Letter

PURCHASE OF LEGEND DRUGS FOR LAWFUL RESEARCH, TEACHING, OR TESTING

Submit correspondence to the department explaining the conditions of the lawful research, teaching, or testing, along with a statement signed by the individual who will be responsible for the prescription drugs that the drugs will be secured, access will be restricted to authorized individuals, and that the prescription drugs are not for resale. Please use official stationery with the company or institutional name and address. Provide the exact physical address / location where the drugs will be used / kept if different from the address on the letterhead.

If applicable, this correspondence should also identify:

- a. The name in which purchases will be made
- b. The specific prescription drug(s) required for the activity
- c. The quantity which will ordinarily be purchased
- d. The frequency of the purchases
- e. The name and state permit or license number of suppliers of the prescription drugs

Submit your request to:

Florida Department of Health
Board of Pharmacy, Drugs, Devices, & Cosmetics
4052 Bald Cypress Way, Bin #C04
Tallahassee, FL 32399

You may fax a copy of the letter to (850) 413-6982 to expedite our processing; however the authorization letter will not be released until we have an original letter with an original signature in ink of the person responsible for the drugs. We consider the fax to be a copy.

Questions may be directed to Valeria Williams at (850) 245-4292

Legal References:

CHAPTER 499 FLORIDA STATUTES DRUG, COSMETIC, AND HOUSEHOLD PRODUCTS

499.03 Possession of new drugs or legend drugs without prescriptions unlawful; exemptions and exceptions.--

(1) A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to s. 499.003(22), or legend drug as defined in s. 499.003, unless the possession of the drug has been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

(c) A qualified person who uses legend drugs for lawful research, teaching, or testing, and not for resale;

DEPARTMENT OF HEALTH

RULE 64F-12, FLORIDA ADMINISTRATIVE CODE REGULATION FOR DRUGS, DEVICES AND COSMETICS

64F-12.011 Wholesale Distribution of Prescription Drugs - Exceptions and Specific Distributions Authorized.

(4) A person who uses prescription drugs for lawful research, teaching, or testing may obtain a registration number from the department to authorize acquisition of the requisite prescription drugs for this activity. The person must submit correspondence to the department explaining the conditions of the lawful research, teaching, or testing, along with a statement signed by the individual who will be responsible for the prescription drugs that the drugs will be secured, access will be restricted to authorized individuals, and that the prescription drugs are not for resale. If applicable, this correspondence should also identify the name in which purchases will be made, the specific prescription drug(s) required for the activity, the quantity which will ordinarily be purchased, the frequency of the purchases, and the name and state permit or license number of suppliers of the prescription drugs. A letter and registration number will be assigned to the person which authorizes the purchase or other acquisition and possession of prescription drugs. This registration number must be included on invoices as required by s. 499.0121(6)(a).