



# Government of the District of Columbia



Department of Health  
Health Regulation and Licensing Administration  
Pharmaceutical Control Division

## **NON-RESIDENT: DRUG MANUFACTURE AND DISTRIBUTION**

*To expedite the processing of your NEW / RENEWAL licensure application, submit all items on the application checklist below.*

### **CHECKLIST**

- \_\_\_ \$100 Registration biennial Fee in the form of check or money order made payable to DC Treasurer. §22-404.3
- \_\_\_ A completed and signed DC application form. §22-404.4(a)
- \_\_\_ Proof of current approval by the US Food and Drug Administration. (Manufacturers only) §22-404.3(c)
- \_\_\_ Proof of current US Drug Enforcement Administration (DEA) Registration if business activities include controlled substance. §22-404.4(d)
- \_\_\_ Signed Clean Hands form. §47-2861
- \_\_\_ List trade or business names of applicant and the address and telephone number of the place of business for which the applicant seeks a license. §22-404.6
- \_\_\_ A Certificate of good standing in the state where incorporated or where the principal place of business is located (if applicable) §22-404.3(b)
- \_\_\_ List name, address and telephone number of all corporate officers/partners. §22-404.6
- \_\_\_ A copy of your current corporate registration, along with corporate articles of incorporation. §22-404.6
- \_\_\_ List the name, address, and telephone number of contact personnel for all facilities. §22-404.6
- \_\_\_ Detailed description of the activity for which the applicant seeks a license. §22-404.6
- \_\_\_ List of all drugs that the applicant proposes to manufacture, distribute, or wholesale in the District of Columbia. §22-404.6
- \_\_\_ Copy of the most recent inspection report (if applicable). §22-404.6



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- \_\_\_ Email address and fax number for facility. §22-404.6
  
- \_\_\_ Completed Controlled Substances application (if applicable), accompanied by \$130 for the in the form of check or money order made payable to DC Treasurer.
  
- \_\_\_ A complete list of DC Resident Agents who can receive official documentation on behalf of licensee. ([www.registered-agent-listings.com](http://www.registered-agent-listings.com)) §22-404.6
  
- \_\_\_ A Certificate of Occupancy for the facility (if applicable). §22-404.6
  
- \_\_\_ Does the facility provide compounding as a service for their customers? (Yes/No)

### **Additional References:**

- DC Drug Manufacturer and Distribution Licensure Act (D.C. Law 8-137)
- (D.C. Official Code Title 48, Chapter 7) and D.C. Municipal Regulations, Title 22, Chapter 4 is on the website [Laws and Regulations](#)