



**Government of The District of Columbia
Department of Health**

**Health Regulation and Licensing Administration
&
Pharmaceutical Control Division**

899 North Capitol St, NE, 2nd Fl.
Washington, DC 20002
202-724-8800
202-727-8677 (fax)
www.hpla.doh.dc.gov

NON-RESIDENT: DRUG MANUFACTURE AND DISTRIBUTION

To expedite the processing of your new license application please be sure to carefully follow the instructions posted on our website, and address all items in this checklist before mailing your application package.

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. §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](#)