



**Government of the District of Columbia
Department of Health
Health Regulations and Licensing Administration
899 North Capitol Street NE, Washington, DC 20002
www.doh.dc.gov/pcd**



DRUG MANUFACTURE AND DISTRIBUTION LICENSURE APPLICATION

Please print clearly in ink and in upper case letters only. Failure to complete all sections will result in the delay of license issuance

REPORT FRAUD, WASTE, AND ABUSE: To report fraud, waste, or abuse within the District government, contact the DC Office of the Inspector General’s hotline by phone at 1-800-521-1639 (toll free) or 202-724-TIPS (8477), by email at hotline.oig@dc.gov, or by TTY at 711. For additional information, visit the Office of the Inspector General’s website at oig.dc.gov

Application Type: <input type="checkbox"/> New <input type="checkbox"/> Ownership Change <input type="checkbox"/> Name Change <input type="checkbox"/> Relocation <input type="checkbox"/> Renewal (Complete page 1 and answer ONLY questions A, C, D, E, and F)	Current License Number : DM _____
Type of Business Activity the applicant request licensure: <input type="checkbox"/> Manufacturer (Provide current proof of FDA Approval) <input type="checkbox"/> Distributor <input type="checkbox"/> Wholesaler	
Type of Drug <input type="checkbox"/> Prescription <input type="checkbox"/> Over the Counter(OTC) <input type="checkbox"/> Controlled Substance (as defined by federal law/DEA) <input type="checkbox"/> Veterinary Prescription <input type="checkbox"/> Veterinary over the counter (VET OTC)	
Ownership Type <input type="checkbox"/> Sole Proprietorship <input type="checkbox"/> Partnership <input type="checkbox"/> Other <input type="checkbox"/> Corporation <input type="checkbox"/> Limited Liability	
Applicant Information _____ Name of Business (Legal Name) _____ Street No. Street Name Suite No. _____ City State Zip Code _____ Phone Number Fax Number Business Website Address	
Mailing Address for facility, if different from above address _____ Street No. Street Name Suite No. _____ City State Zip Code	

Designated Representative for Business Information

Name and Title

Direct Phone Number

E-mail Address for contact person

SUBMIT ALL REQUIRED DOCUMENTATION. FAILURE TO SUBMIT ALL REQUIRED DOCUMENTATION WILL DELAY TIMELY PROCESSING OF YOUR APPLICATION

<p>A. Has the applicant or any other listed on the application ever been convicted of a felony related to drugs under the DC, state, or federal law, or ever surrendered or had a controlled substances application registration revoked, suspended, or denied? If the applicant is a corporation, association, partnership, has any officer, partner, stockholder or proprietor been convicted of a felony relating to drugs under DC, state, or federal law or ever surrendered or had a controlled substances application registration revoked, suspended or denied?</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>B. (For Manufacturers only)</p> <p>Does the Manufacturing facility hold a current proof of approval from US Food and Drug Administration?</p> <p>If Yes, provide documentation (required), if no submitted written explanation.</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>C. Does the Business currently hold a Certificate of Good Standing in the state where it is incorporated?</p> <p>✓ If No, submit a written explanation.</p> <p>✓ If Yes, submit certificate of good standing documentation (required)</p> <p>✓ Current Home state license. (required)</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>D. Does the Business intend to ship Controlled Substance into the District of Columbia? (22 DCMR§ 22-1002)</p> <p>✓ If yes, submit a Controlled Substance Registration Application and copy of Drug Enforcement Administration (DEA) Registration Note: FEE OF \$130</p> <p>✓ (Visit http://doh.dc.gov/node/187402 to download application)</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>E. Does the Business facility provide compounding as a service for their customers? <input type="checkbox"/> Sterile <input type="checkbox"/> Non-Sterile</p> <p>F. Is the facility registered as a 503B facility</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>

<p>G. Has the Business facility undergone an Inspection within the last 5 Years</p> <p>✓ Provide the most recent Inspection report (required)</p> <p>✓ If No Inspection provide written explanation</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>H. Provide written detailed description of the Business activity for which the applicant seeks a license</p>	<p>Submit written description on a supplementary sheet</p>
<p>I. Provide District of Columbia resident Agent information (required)</p>	<p>Name _____</p> <p>Address _____</p>
<p>J. Provide the name, address and telephone numbers of all corporate officers for the Business</p>	<p>Submit information on a supplementary sheet</p>
<p>K. Provide a list of all drugs the applicant plans to ship into the District of Columbia (required)</p>	<p>Submit information on a supplementary sheet</p>

Submit Application, supporting documentation and FEE of \$100 made payable to "DC TREASURER" to :

**DOH-PHARMACY
P.O.BOX 37803
WASHINGTON, DC 20013**

TO THE APPLICANT:

Please read carefully and completely before signing. A false statement on this certification requires that the Department proceed immediately to revoke the license or permit for which you are now applying and fine you \$1000.00. This certificate is required by the "CLEAN HANDS BEFORE RECEIVING A LICENSE OR PERMIT ACT OF 1996". (Effective May 11, 1996, D.C. Law 11-118, D.C. Code §47-2861 et seq.)

I, _____, certify that as of _____, I do not owe more than \$100.00 to the District of Columbia government as a result of:

1. Fines, penalties or interest assessed pursuant to the Litter Control Administration Action of 1985, effective March 25, 1986 (D.C. Code § 6-2901 et seq.);
2. Fines, penalties or interest assessed pursuant to the Illegal Dumping Enforcement Act of 1994, effective May 20, 1994 (D.C. Law 10-117; D.C. Code § 6-2911 et seq.);
3. Fines, penalties or interest assessed pursuant to the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, effective October 5, 1986 (D.C. Law 6-42; D.C. Code § 6-2701 et seq.); or
4. Past due taxes.

I understand that if I knowingly falsify this Certification, the Department will move to revoke the license or permit for which I am applying, and to fine me \$1,000.00. I further understand that the Department may conduct an investigation to ascertain the veracity of this certification. I understand that this Certification is now required as documentation to accompany my application for a license or permit, and that by completing this Certification, I am not guaranteed that my license or permit will be approved.

Signature of Applicant

Name and Title