

CHECKLIST FOR SUBMITTING DC
RENEWAL LICENSE APPLICATION FOR

(Manufacturers, Distributors and Wholesalers – Facilities)

An out-of-state or in state manufacturer, distributor and wholesalers, including a virtual facility, reverse distributor, 3PL repackager, researcher, warehouse, or any other facility type that intends to **RENEW** a District of Columbia (facility) registration is required to submit the documents below. **To assure timely processing, the renewal application, fee, and required documents can be submitted up to two months prior to the registration's expiration date.** The expiration date and registration number are on the issued DC registration. **An application received one day past the registration's expiration date will be considered late and will be assessed the applicable late fee, as specified in this document.**

The failure of a registrant to receive the renewal notice does not relieve the registrant of the responsibility of renewing the registration in a timely manner. Please submit all documents below with the application.

CHECKLIST FOR SUBMITTING DC LICENSE/REGISTRATION RENEWAL APPLICATION:

___ \$100 (nonresident), \$200 (resident) **non-refundable** annual registration fee (check or money order), made payable to the DC Treasurer. **LATE FEE:** An additional \$50.00 fee must be included for all applications submitted late.

___ Completed DC Drug Manufacturer and Distribution Licensure Application signed and dated.

___ Copy of current home state corporate business license for the location being considered for licensure. (**NOTE:** *If license is not required by home state, provide copy of the state License Exemption Letter and/or the state License Exemption Regulation for the location.*)

___ List of any newly added drugs since last year's renewal the applicant intends to ship to the District of Columbia, if applicable.

___ Full copy of most recent (new) state or federal inspection report for the location being considered for licensure, if applicable. (**NOTE:** *An inspection report that contains deficiencies must be attached to the state or federal re-inspection report, and/or the corrective action plan to show that all deficiencies noted in the inspection report were corrected.*)

Submit the following if you have a DC Controlled Substance Registration that is also up for renewal:

a) A completed DC Controlled Substance Registration Application dated and signed.

b) \$130 **non-refundable** fee (check or money order), made payable to the DC Treasurer.
LATE FEE: An additional \$35.00 fee must be included for all applications submitted late.

c) Current US federal DEA Registration for the location. (*Cannot be expired*)
NOTE TO 3PLs AND VIRTUAL MANUFACTURERS: DEA Registration address must match facility address

d) List of all controlled substance drugs the applicant intends to ship to or within the District of Columbia.

**CHECKLIST FOR SUBMITTING DC RENEWAL LICENSE APPLICATION FOR
(Manufacturers, Distributors, Wholesalers - Facilities) cont'd**

MAILING INSTRUCTIONS FOR RENEWAL LICENSE APPLICATION

BEFORE MAILING YOUR APPLICATION

Please double check to make sure:

- The application is typed or printed clearly and legibly.
- All questions on the application have been answered correctly.
- Page 3 of the application is completed, dated and signed.
- Required application fee(s) and applicable late fees are included.
- The dates on required documents are valid (not expired).
- The fee and all required documents are submitted with the application.

RECORD KEEPING: Please keep a copy of the completed application(s), payment(s), and all submitted documents for your records.

SUBMITTING DOCUMENTS: Each application is considered a stand-alone document that is required to meet the specifications of the checklist prior to mailing. When submitting multiple applications, it is the sole responsibility of the applicant to submit each application with the required fee(s) and document(s), as specified by the checklist.

**MAIL TO: c/o DC HEALTH – PHARMACY
899 North Capitol Street NE, First Floor WASHINGTON, DC 20002**

PROCESSING YOUR APPLICATION: Once we receive the renewal licensure application, **non-refundable** fee and all required documentation, the application will be processed. The registration will be US mailed within 24 – 72 hours of renewing the registration. Allow for appropriate US mailing time to receive the document.

LICENSE VERIFICATION: To verify the status of a DC registration or license, paste the web links below into your web browser:

VERIFICATION WEB LINK FOR MANUFACTURERS, DISTRIBUTORS AND WHOLESALERS

<https://app.hpla.doh.dc.gov/Weblookup/Search.aspx?facility=Y>

VERIFICATION WEB LINK FOR CONTROLLED SUBSTANCE REGISTRATIONS

<https://app.hpla.doh.dc.gov/Weblookupcs/Search.aspx?facility=Y>

DC GOVERNMENT OFFICIAL WEBSITE: DC license applications, forms, checklists, laws and regulations, and questions and answers can be located on the DC Government website at <https://dchealth.dc.gov/pcd>.

IMPORTANT: Applications submitted with incomplete, incorrect, missing or expired documents will be returned via regular US mail. **ALL SUBMITTED FEES ARE NON-REFUNDABLE.**

DRUG MANUFACTURER AND DISTRIBUTOR LICENSURE APPLICATION

Please type or print clearly in ink and in upper case letters **only**. Complete **all** sections and fields of the license application. Attach all documents and non-refundable fee of \$100 (non-resident) or \$200 (resident), payable to DC Treasurer. Mail to: DC HEALTH – PHARMACY 899 North Capitol Street NE, First Floor Washington, DC 20002.

INCOMPLETE APPLICATIONS WILL NOT BE PROCESSED

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: (Check Below) <input type="checkbox"/> New <input type="checkbox"/> Ownership Change <input type="checkbox"/> Name Change <input type="checkbox"/> Location Change <input type="checkbox"/> Renewal (Answer all questions on the application, date and sign)	Current License Number: DM _____ DW _____
Select type of Business Activity the applicant requests licensure for: (Check Below): <input type="checkbox"/> Manufacturer (Provide current proof of FDA Approval) <input type="checkbox"/> Distributor <input type="checkbox"/> Wholesaler	
Type of Drug to be shipped: (Check Below) <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: (Check Below) <input type="checkbox"/> Sole Proprietorship <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation <input type="checkbox"/> Limited Liability <input type="checkbox"/> Other _____ (Specify)	
Applicant Information: _____ Name of Business (Legal Name) _____ Street No. Street Name Suite No. _____ City State Zip _____ 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	

Designated Representative for Business: (required) <hr/> Name and Title <hr/> Direct Phone Number <hr/> Email Address <hr/>	Designated License Contact Representative: (required) <hr/> Name and Title <hr/> Street No. Street Name Suite No. <hr/> City/State/Zip <hr/> Email Address Direct Phone Number <hr/>
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SUBMIT ALL REQUIRED FEES AND DOCUMENTS WITH THE APPLICATION. APPLICATIONS SUBMITTED INCOMPLETE, OR WITH INCORRECT, EXPIRED OR MISSING FEES OR DOCUMENTS WILL BE RETURNED VIA US MAIL.

<p>A. Has the applicant or any other individual listed on the application ever been convicted of a felony related to drugs under 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, or 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>	<input type="checkbox"/> YES <input type="checkbox"/> NO (check one) <input checked="" type="checkbox"/> Provide detailed explanation on separate sheet if any part of question A is “YES”. (required)
<p>B. (For Manufacturers only)</p> <p>Does the Manufacturing facility hold current proof of approval from US Food and Drug Administration?</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO (check one) <input checked="" type="checkbox"/> If “yes”, provide a copy of approval. (required) <input checked="" type="checkbox"/> If “no”, submit a written explanation. (required)
<p>C. Does the Business currently hold a Certificate of Good Standing in the state where it is incorporated?</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO (check one) <input checked="" type="checkbox"/> If “No”, submit a written explanation. (required) <input checked="" type="checkbox"/> If “Yes”, submit <u>current dated</u> Certificate of Good Standing documentation. (required) <input checked="" type="checkbox"/> Submit current Home state business license. (required)
<p>D. Does the Business intend to ship Controlled Substance drugs into the District of Columbia? (22 DCMR §22-1002)</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO If “yes”, submit: <input checked="" type="checkbox"/> Controlled Substance Registration Application <input checked="" type="checkbox"/> Valid copy of Drug Enforcement Registration <input checked="" type="checkbox"/> FEE OF \$130. (required) Visit https://dchealth.dc.gov/pcd to download Application, Forms and DC Laws and Regulations.

