

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/Weblookups/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"/> Renewal (Answer all questions on the application, date and sign) Note: Submit a NEW application for name, location, or ownership change.	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) <table style="width: 100%;"> <tr> <td style="width: 25%;">Street No. _____</td> <td style="width: 45%;">Street Name _____</td> <td style="width: 30%;">Suite No. _____</td> </tr> <tr> <td>City _____</td> <td>State _____</td> <td>Zip _____</td> </tr> <tr> <td>Phone Number _____</td> <td>Fax Number _____</td> <td>Business Website Address _____</td> </tr> </table>		Street No. _____	Street Name _____	Suite No. _____	City _____	State _____	Zip _____	Phone Number _____	Fax Number _____	Business Website Address _____
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: <table style="width: 100%;"> <tr> <td style="width: 25%;">Street No. _____</td> <td style="width: 45%;">Street Name _____</td> <td style="width: 30%;">Suite No. _____</td> </tr> <tr> <td>City _____</td> <td>State _____</td> <td>Zip _____</td> </tr> </table>		Street No. _____	Street Name _____	Suite No. _____	City _____	State _____	Zip _____			
Street No. _____	Street Name _____	Suite No. _____								
City _____	State _____	Zip _____								

Designated Representative for Business: (required) _____ Name and Title _____ Direct Phone Number _____ Email Address	Designated License Contact Representative: (required) _____ Name and Title _____ Street No. Street Name Suite No. _____ City/State/Zip _____ Email Address Direct Phone Number
SUBMIT <u>ALL</u> 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.	
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?	<input type="checkbox"/> YES <input type="checkbox"/> NO (check one) ✓ Provide detailed explanation on separate sheet if any part of question A is “YES”. (required)
B. (For Manufacturers only) Does the Manufacturing facility hold current proof of approval from US Food and Drug Administration?	<input type="checkbox"/> YES <input type="checkbox"/> NO (check one) ✓ If “yes”, provide a copy of approval. (required) ✓ If “no”, submit a written explanation. (required)
C. Does the Business currently hold a Certificate of Good Standing in the state where it is incorporated?	<input type="checkbox"/> YES <input type="checkbox"/> NO (check one) ✓ If “No”, submit a written explanation. (required) ✓ If “Yes”, submit <u>current dated</u> Certificate of Good Standing documentation. (required) ✓ Submit current Home state business license. (required)
D. Does the Business intend to ship Controlled Substance drugs into the District of Columbia? (22 DCMR §22-1002)	<input type="checkbox"/> YES <input type="checkbox"/> NO If “yes”, submit: ✓ Controlled Substance Registration Application ✓ Valid copy of Drug Enforcement Registration ✓ FEE OF \$130. (required) Visit https://dchealth.dc.gov/pcd to download Application, Forms and DC Laws and Regulations.

E. Does the Business facility provide compounding as a service for their customers? <input type="checkbox"/> Sterile <input type="checkbox"/> Non Sterile <input type="checkbox"/> Bulk (check all that apply)	<input type="checkbox"/> YES <input type="checkbox"/> NO (check one)
F. Is the facility registered as a 503B facility with the FDA? (503B must be registered with the FDA)	<input type="checkbox"/> YES <input type="checkbox"/> NO (check one)
G. Has the Business facility undergone an Inspection within the last <u>5</u> Years?	<input type="checkbox"/> YES <input type="checkbox"/> NO (check one) ✓ If “yes”, provide the most recent Inspection Report. (required) ✓ If “No”, provide a written explanation or state license exemption letter and/or law. (required)
H. Provide written detailed description of the Business activity for which the applicant seeks a license. (required)	Submit written description on a supplementary sheet.
I. Provide District of Columbia resident agent information. (Go to: www. registered-agent-listings.com)	Type Agent Information here: (required) Name: _____ Address: _____ City/State/Zip: _____
J. Provide the name, address and telephone number of all corporate officers/owners for the business. (required)	Submit information on a supplementary sheet
K Provide a list of all drugs the applicant intends to ship into the District of Columbia (required)	Submit information on a supplementary sheet
Mail Completed Application with all required documents on the checklist, and attach <u>Non-Refundable</u> Registration Fee of \$100 (non-resident) or \$200 (resident), in the form of check or money order, payable to DC Treasurer. Mail to: DC HEALTH – PHARMACY 899 North Capitol Street NE, First Floor WASHINGTON, DC 20002	
TO THE APPLICANT (Please Read and Complete all Fields Below) Please read this section carefully and completely before signing. A false statement made on this certification requires that the Department proceed immediately to revoke the license, registration or permit for which you are now applying. Additionally, a \$1000.00 fine may also be imposed. As required by the CLEAN HANDS ACT OF 1996, this section is required to be completed by the applicant before a license, registration, or permit can be issued. (D.C. Law 11-118, D.C. Official Code §47-2861 et seq).	
I, _____, certify that as of _____, I (applicant) do not owe more than \$100.00 to the Print Full Name Today's Date	
District of Columbia Government, as a result of: 1) Fine, penalties or interest assessed pursuant to the Litter Control Administration Act 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; DC 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 may fine me \$1,000.00. I further understand that the Department may conduct an investigation to ascertain the veracity of this certification. I further understand that the completion this Certification is a part of the application and that completing the Certification does not guarantee approval or issuance of a DC license, registration, or permit.	
_____ Signature of Applicant /Designated Authority	_____ Position Title