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 much match facility address

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

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
2201 Shannon Place SE, First Floor WASHINGTON, DC 20020

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 MANUFACTUERS, DISTRIBUTORS, WHOLESALERS AND CONTROLLED STANCE REGISTRATIONS:

https://dohenterprise.my.site.com/ver/s/facility-license-verification-page

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.**

2201 Shannon Place SE, 2nd Fl | Washington, DC 20020 | P 202-724-8800 | F 877-862-4252 | dchealth.dc.gov

Revised 3/5/2024

DC HEALTH
Health Regulation & Licensing Administration

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

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 2201 Shannon Place SE, First Floor Washington, DC 20020.

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)
☐ 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):

☐ Manufacturer (Provide current proof of FDA Approval) ☐ Distributor ☐ Wholesaler

Type of Drug to be shipped: (Check Below)

☐ Prescription ☐ Over the Counter (OTC) ☐ Controlled Substance (as defined by federal law/DEA)
☐ Veterinary Prescription ☐ Veterinary Over the Counter (VET OTC)

Ownership Type: (Check Below)

☐ Sole Proprietorship ☐ Partnership ☐ Corporation ☐ Limited Liability ☐ 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)	**Designated License Contact Representative:** (required)
Name and Title Direct Phone Number Email Address	Name and Title Street No. Street Name Suite No. City/State/Zip Email Address Direct Phone Number

SUBMIT ALL REQUIRED FEES AND DOCUMENTS WITH THE APPLICATION. APPLICATIONS SUBMTITED 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?	☐ **YES** ☐ **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?	☐ **YES** ☐ **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?	☐ **YES** ☐ **NO** (check one) ✓ If "No", submit a written explanation. (required) ✓ If "Yes", submit current dated 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)**	☐ **YES** ☐ **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? ☐ Sterile ☐Non Sterile ☐Bulk (check all that apply)	☐ **YES** ☐ **NO** (check one)
F. Is the facility registered as a 503B facility with the FDA? *(503B must be registered with the FDA)*	☐ **YES** ☐ **NO** (check one)
G. Has the Business facility undergone an Inspection within the last **5** Years?	☐ **YES** ☐ **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 Non-Refundable 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 2201 Shannon Place SE, First Floor WASHINGTON, DC 20020

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 Affair 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