

CHECKLIST FOR SUBMITTING DC NEW LICENSE APPLICATION

Manufacturers, Distributors, and Wholesalers (Facilities)

An out-of-state or in state manufacturer, distributor or wholesaler, including a virtual facility, reverse distributor, 3PL, re-packager, researcher, warehouse, or any other facility that intends to ship **prescription drugs, over-the-counter drugs, or controlled substance drugs** to or within the District of Columbia must first obtain a DC registration, by submitting the required application(s), fees, and supporting documentation, as outlined below. **A separate application is required for each location that will ship drug products to or within the District of Columbia.**

INCOMPLETE APPLICATIONS OR THOSE SUBMITTED WITH INCORRECT, MISSING, OR EXPIRED DOCUMENTS WILL NOT BE PROCEEDED.

To be considered for a DC Registration, please submit the documents in the checklist below (Pages 1 – 2):

- _____ \$100 (nonresident), \$200 (resident) **NON-REFUNDABLE** annual application fee in the form of a check or money order, made payable to the DC Treasurer. *(Fee(s) must be submitted with the application)*
- _____ Completed Drug Manufacture and Distribution Licensure Application dated and signed.
- _____ Proof of current approval by the US Food and Drug Administration. *(Manufacturers only)*
- _____ A current dated Certificate of Good Standing from the state where incorporated or where the principal place of business is licensed or located. *(Certificate must be for the current year)*
- _____ List of the names, titles, addresses and telephone numbers of all corporate officers/partners/owners.
- _____ A copy of the current home state corporate business license for the location being considered for licensure. *(If a license is not required by the home state, submit the state issued License Exemption Letter and/or the state License Exemption Regulation for the location.)*
- _____ A detailed description of the activity for which the applicant seeks a DC registration.
- _____ List of all drug products the applicant proposes to ship to the District of Columbia. *(A large product list can be submitted on a flash drive. The flash drive must be labeled with the company's name, placed in an envelope, and securely stapled to the application.)*
- _____ Full copy of the most recent completed state or federal inspection report for the location being considered for a registration, if applicable. *(An inspection report that contains deficiencies must be accompanied by the state or federal re-inspection report and/or the corrective action plan to show all deficiencies noted in the inspection report were corrected.)*

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CONTROLLED SUBSTANCE DRUG REGISTRATION

___ Do you intend to ship Controlled Substance Drugs to the District of Columbia? ___ YES ___ NO

If you checked “yes”, you must also submit all of the documents below:

Schedule II, III, IV and V:

- ___ A completed DC Controlled Substance Registration Application.
- ___ \$130 **non-refundable** application fee (check or money order), made payable to the DC Treasurer.
- ___ Current US federal DEA Registration for the location being considered for a registration.
(Submitted Registration cannot be expired).
- NOTE TO 3PLs AND VIRTUAL MANUFACTURERS:** DEA Registration address must match facility address
- ___ List of all Controlled Substance Drugs the applicant intends to ship to the District of Columbia.
(Large product list can be submitted on a flash drive, labeled with company name).

Schedule I:

If you intend to ship **Schedule I** drugs, you must apply for a **separate** Controlled Substance Registration Application, by submitting the fee and documents below:

- ___ A completed DC Controlled Substance Registration Application.
- ___ \$130 **non-refundable** application fee (check or money order), made payable to the DC Treasurer.
- ___ Current US federal DEA Registration for the location being considered for a registration.
(Submitted Registration cannot be expired).
- ___ List of all Controlled Substance Drugs the applicant intends to ship to the District of Columbia.
(Large product list can be submitted on a flash drive, labeled with company name).
- ___ List of customers (company names/addresses) to which you intend to ship Schedule I drugs.

IMPORTANT INFORMATION: Please submit the application with required **non-refundable** fee(s) and all supporting documentation as specified in the checklist. Incomplete applications, those with no fee(s) enclosed, or with expired documents will be returned via regular US mail.

BEFORE MAILING YOUR APPLICATION

Please double check to make sure:

- The documents are submitted in the order in which they appear on the checklist.
- The application is typed or printed clearly and legibly.
- All questions on the application are answered correctly.
- The application is fully completed, dated and signed.
- The fee is accurate, attached, and made payable to the DC Treasurer.
- The name on the DC application is consistent with the name on the home state business license.
- The documents submitted are for the applicant listed on the application and not a contracting company.
- All required documents are valid and attached to the application.

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BEFORE MAILING YOUR APPLICATION (continued)

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

MAIL TO: c/o DC HEALTH – PHARMACY DIVISION
2201 Shannon Place SE, First Floor WASHINGTON, DC 20020

SUBMITTING DOCUMENTS: Each application is considered a stand-alone document. 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.

PROCESSING THE APPLICATION: It takes approximately 90 days to complete a new application, provided the application is submitted correctly, in accordance with the checklist of requirements. Once your application has been processed in our system, it will remain in “pending” status until we are able to secure an approval. Approval is contingent upon the submittal and accuracy of required documents, as outlined on pages 1 – 2 of this document.

DO NOT SEE YOUR APPLICATION IN OUR DATABASE: DC Pharmaceutical Control reviews a large volume of applications daily. If you do not see your application in our verification database, please check the system weekly, or however often you wish, until you see the document in PENDING Status.

REGISTRATION: Once approved, the registration(s) will be mailed via the US Postal Service within 24 – 72 hours to the mailing address specified on the application, if applicable, or to the facility location listed on the application. Once you receive the registration, please make note of the expiration date on the document for renewal purposes.

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

VERIFICATION LINK FOR FACILITY AND CONTROLLED SUBSTANCE REGISTRATION:

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

DC WEBSITE: License applications, forms, checklists, laws and regulations, and questions and answers are available on the DC government website at <https://dchealth.dc.gov/pcd>.

REFERENCES:

- D.C. Drug Manufacturer and Distribution Licensure Act (D.C. Law 8-137)
- D.C. Municipal Regulations, Title 22, Chapters 4 and 10

IMPORTANT INFORMATION: Please submit the application with required **non-refundable** fee(s) and all supporting documentation, as specified in the checklist and instructions. All DC license applications submitted that are incomplete, incorrect, missing fee(s) or with expired documents will be returned via regular US mail.

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.

<p>Application Type: (Check Below) <input type="checkbox"/> New <input type="checkbox"/> Ownership Change <input type="checkbox"/> Name Change <input type="checkbox"/> Location C hange (Answer <u>all</u> questions on the application, date and sign)</p>	<p>Current License Number: (If Ownership, Name, or Location Change) DM _____ DW _____</p>
<p>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</p>	
<p>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)</p>	
<p>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)</p>	
<p>Applicant Information:</p> <p>_____ Name of Business (Legal Name)</p> <p>_____ Street No. Street Name Suite No.</p> <p>_____ City State Zip</p> <p>_____ Phone Number Fax Number Business Website Address</p>	
<p>Mailing Address for facility, if different from above address:</p> <p>_____ Street No. Street Name Suite No.</p> <p>_____ City State Zip</p>	

<p>Designated Representative for Business: (required)</p> <p>Name and Title</p> <p>_____</p> <p>Direct Phone Number</p> <p>_____</p> <p>Email Address</p> <p>_____</p>	<p>Designated License Contact Representative: (required)</p> <p>Name and Title</p> <p>_____</p> <p>Street No. Street Name Suite No.</p> <p>_____</p> <p>City/State/Zip</p> <p>_____</p> <p>Email Address Direct Phone Number</p> <p>_____</p>
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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 NOT BE PROCESSED.

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

