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 PROCEESED.

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 *(Fee(s) must be submitted online with the application)*

_____Completed Online Drug Manufacture and Distribution Licensure Application.

_____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 <u>all</u> 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 <u>all</u> drug products the applicant proposes to ship to the District of Columbia.

_____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 <u>all</u> 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.

_____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 much match facility address

_____List of all Controlled Substance Drugs the applicant intends to ship to the District of Columbia.

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.

_____Current US federal DEA Registration for the location being considered for registration.
(Submitted Registration cannot be expired).

_____List of all Controlled Substance Drugs the applicant intends to ship to the District of Columbia.

_____List of customers (company names/addresses) to which you intend to ship Schedule I drugs**.**

IMPORTANT INFORMATION: Please submit the online application with required **non-refundable** fee(s) and all supporting documentation as specified in the checklist. Incomplete applications will delay processing time. Any application submitted with missing documents (without appropriate explanation), outdated documents or incorrect documents will not be approved

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