(11/2022 - Rev.) **COMMONWEALTH OF PENNSYLVANIA** (Form H114.614)

DEPARTMENT OF HEALTH-DRUG, DEVICE, COSMETIC APPLICATION

Application is for Registration under the Pennsylvania Controlled Substance, Drug, Device and Cosmetic(DDC) Law and if applicable, Licensure under the Pennsylvania Wholesale Prescription Drug Distributor's Law . Pay fee with check or money order payable to "Pennsylvania Department of Health." Or Major Credit card payment, provide information below. Only one fee, **the highest amount**, is due regardless of the number of applicable category types **unless** your business involves in state facility that is engaged in wholesale distribution of human prescription drugs or reverse distribution, then **both**, the registration fee and a distributor license fee are due.

Check all blocks which apply (If fee-exempt mark only fee-exempt boxes). Return form along with fee(s) to:

PENNSYLVANIA DEPARTMENT OF HEALTH: DRUG & DEVICE REGISTRATION SECTION
2525 North 7TH STREET, SUITE 210D, HARRISBURG, PENNSYLVANIA 17110 or
FAX (717) 231-4790 or **EMAIL** (as PDF): **RA-DDC@pa.gov**
WWW.HEALTH.STATE.PA.US/DDC. Questions: PHONE (717) 787-4779 or Email: RA-DDC@PA.GOV

Check	Type of Enterprise	Fee
☐	**Manufacturer** or Repackager/relabeler, of Prescription Drugs, API, and/or Controlled Substances [2,4]	$400
☐	**Outsourcing Facility (503B)** of Prescription Drugs, Controlled Substances, and/or Non-Prescription Drugs	$400
☐	**Transfiller** of Medical Gas[2,4]	$400
☐	**Manufacturer** or Re-packager/labeler or Non-prescription Drugs or API[2, 4]	$100
☐	**Manufacturer of Cosmetics**[6]	$100
☐	**Wholesale Distributor** (in state only) -of Prescription Drugs and/or Controlled Substances, (**License**)[1 ,4 (See Notes)]	$10
☐	**Distributor (any type excluding gases)** of Prescription drugs, Controlled Substances (**Registration**)[1, 4 (See Notes)]	$100
☐	**Distributor or retailer** of medical gases[6]	$100
☐	**Distributor** of Non-prescription Drugs or Cosmetics[6]	$25
☐	**Devices-**Medical: Manufacturer, Reprocessor, Distributor, or Retailer (Class I ,II, or III, RX or OTC) [2, 5, 6, 7(See Notes)]	$25
☐	**Retailer** of Non-prescription drugs, Medicated Cosmetics, or Medicated,/ Over-the-Counter /OTC drugs	$10
☐	**Fee-exempt** Distributor, Manufacturer, Retailer of Drugs and/or Devices (indicate type of facility) [3, 4 (See Notes)]	None

SEE FOOTNOTES AND ADDITIONAL NOTES ON PAGE 2. NOTE: This application is NOT for in state virtual manufacturers/ distributors, Bulk List I chemical Manufacturers /distributors of unfinished goods, medical marijuana entities, pharmacies, or practitioner's CDS license. Wholesale prescription drug Distributor License, medical Device retailer, or OTC drug Retailer registration is only for in state facilities.

Name of Establishment:_____

List other trade/business names if used: _____

Facility Address/City/Zip Code/County:_____

Facility Telephone no. (including area code) _____

Facility Contact Person/Title and Telephone number[4]:_____

E-mail address for the business (optional):_____

Billing Address/Name if different from above:_____

_____ *(if handled by third party attach Power of Attorney)*

Type of Ownership (corporation, partnership, sole proprietorship, LLC etc)**:**_____
If Incorporated or LLC, list State in which entity is incorporated or LLC founded and date of incorporation_____
Corporate Federal Tax ID (optional): __ __-__ __ __ __ __ __ __
Ownership Name(s): Individual, Partners, or Corporate/Managing Officers and Title (Attach additional document if necessary)
Ne
_____
(If change of ownership please list previous registration no. or name:_____

Has applicant or have any of the officers, agents or employees of the establishment ever been convicted of any violation of federal or Pennsylvania dealing with drugs or controlled substances or had any felony convictions? ☐ **No** ☐**Yes** **If yes, fully describe on other side.**

Has applicant or have any of the officers, agents or employees of the establishment had a license or equivalent authorization previously held for the manufacture or distribution of any drugs denied, suspended, revoked, restricted or subjected to any other sanction or action for disciplinary reasons by a government authority? ☐ **No** ☐**Yes** **If yes, fully describe on other side**

☐ I **have reviewed the applicable federal and state laws and attest as an official representative that the aforementioned facility meets or exceeds minimum standards including but not limited to scope/intent of registration or license, facility standards, and if applicable personnel requirements, policies/procedures, product storage/handling, and records.**
Applicant Signature and Title_____**Date:**_____

Print Name & email or phone number application)_____

Payment by Credit card: __ __ __ __-__ __ __ __-__ __ __ __-__ __ __ __ Exp Date: __ __/__ __ Security Code __ __ __ Zip Code __ __ __ __ __
Type of Card (circle) VISA MC AE DISCOVER (billing zip code)

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DEPARTMENT OF HEALTH-DRUG, DEVICE, COSMETIC (DDC) PROGRAM APPLICATION-FOOTNOTES

[1]Wholesale Distributors of human prescription drugs, located in state, generally need **both** a distributor registration and a wholesale distributor license. Said facilities generally require onsite inspection to be scheduled. Facilities handling only labelled animal drugs, only intra-company transactions, only gases, only filing as out of state U.S. facility, or contract warehouse/3PL generally only need a registration.

[2]Manufacturers, 503B outsourcing facilities, or gas transfillers must obtain their FDA registration or license first before applying for registration with the Pennsylvania Department of Health. Drug or Device manufacturers must have FDA approved US commercial and label code or product approved for compounding prior to submitting application. Attach or provide copy of FDA facility establishment registration. If out of state, provide or attach home state license, DUNS, and FDA product label code or compounding license. If, in- state Virtual manufacturers, please use Certificate of record application.

[3]Fee-exempt: Charitable nonprofit organizations (501-C) and government affiliated organizations may request fee waiver, by providing and attaching supportive documentation (i.e. 501C IRS paperwork). Nonresident U.S. manufacturers with sales representatives (i.e., boots on the ground) in Pennsylvania may request fee waiver but must provide and maintain list of sales representatives working in Pennsylvania. If requested fee waiver, provide cover letter with request for fee waiver, supporting qualifying documentation (i.e., 501C or list of sales representatives) and note type of products to be handled and facility type (i.e. OTC drug retailer, prescription drug manufacturer). If prescription drug manufacturer, see footnote 2.

[4]In-state prescription drug manufacturer or distributor, must attach copy information regarding their onsite designated qualified supervisor. This would include a Pennsylvania pharmacist license, or verifiable resume for person in charge meeting 3-year minimum qualification in a licensed US pharmaceutical distributor or manufacturer, law enforcement criminal background check, and government issued photo ID (i.e., driver's license). Law enforcement criminal background checks may be requested for officers or owners of entity after initial review of application.

[5]No registration is required for out of state medical device retailers shipping direct to consumers only. Such entities need to ensure compliance with applicable federal laws.

[6]The DDC program may need to confirm type of product to be handled and facility is appropriate prior to issuance of registration. If manufacturing, the DDC program may need to confirm compliance with applicable federal laws/regs.

[7]Licensed practitioners (i.e., physicians, optometrists, dentists etc.), pharmacies, and healthcare facilities (i.e., hospitals) do not need separate registration under the Pennsylvania Controlled Substance, Drug, Device and Cosmetic law if prescribing/dispensing drugs and/or devices solely to their own patient (I.e direct patient-practitioner relationship) and acting within their scope of practice law.

GENERAL:

All in-state facilities must intend to physically handle product at the Pennsylvania location and will be physically handling product at the Pennsylvania location after a registration and/or license is approved.

All Facilities should be appropriate business sites and entities should have their business papers filed with Pennsylvania Department of State, Bureau of Corporations.

All Out of State facilities must include their respective home state license or registration or federal license/registration with application or submit via email or fax. If exempted by home state, applicant must provide letter from home state agency noting such facility type is exempt.

All facilities, registrants, licensees, are expected to comply with applicable federal laws and regulations as well Any applicable Pennsylvania laws and regulations. If out of state, compliance is expected with their home state laws and regulations as well.

All in state facilities, registrants or licensees may be subject to inspection.

In general, The Pennsylvania Department of Health Drug Device and Cosmetic (DDC) Program does not oversee or register/license billing only agents, research only organizations, individual researchers, clinical trials, drugs/devices not yet approved by FDA, foreign only based facilities, or device/equipment not classified or defined by FDA as a medical device (i.e., PERS/Personal Emergency Alert Systems). The DDC program does not register or license in state virtual or paper only headquarters or offices