(June 28 -2017 - Rev.) **COMMONWEALTH OF PENNSYLVANIA** (Formerly form H114.120/H114.614)

DEPARTMENT OF HEALTH

Application for Registration under the Drug, Device and Cosmetic Act and Licensure under the Wholesale Prescription Drug Distributor's Act

WWW.HEALTH.STATE.PA.US/DDC

Pay fee with check or money order payable to "Pennsylvania Department of Health." 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 distribution of human prescription drugs, then **both**, the registration fee and a distributor license fee are due. Return form along with fee(s) to:

PENNSYLVANIA DEPARTMENT OF HEALTH: DRUG & DEVICE REGISTRATION SECTION
132 KLINE PLAZA, SUITE A, HARRISBURG, PENNSYLVANIA 17104 PHONE (717) 787-4779 FAX (717) 772-0232

Check all blocks which apply (If fee-exempt mark only fee-exempt boxes)

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

[1]Distributors, located in state, of human prescription drugs generally need **both** a registration and a license. Facilities handling only labelled animal drugs, only intra-company transactions, only gases, and/ or only filing as nonresident U.S. facility generally only need a registration.
[2]Manufacturers or 503B's must provide FDA registration or license (U.S. only). Virtual manufacturers, please contact the office at 717-787-4779
[3]Fee-exempt: Charitable nonprofit organizations (501-C) and government affiliated organizations may request fee waiver, provided supportive documentation is attached. Nonresident U.S. facilities must provide and maintain list of sales representatives working in PA., if requesting fee waiver. Attach cover letter with request for fee waiver, supporting qualifying documentation, type of products to be handled and facility type.
[4]In-state prescription drug manufacturer or distributor, must attach copy of pharmacist license, or verifiable resume for person in charge meeting minimum qualification requirements. All Out of State facilities must include their respective home state license or registration.

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)

____

(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 laws 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.**

Payment by Credit card: __ __ __ __-__ __ __ __-__ __ __ __-__ __ __ __ **Exp Date:** __ __/__ __ **Security Code** __ __ __ **Zip Code** __ __ __ __ __
Type of Card (circle) VISA MC AE DISCOVER (associated with card)

Applicant Signature and Title____**Date:**__________________

Print Name, contact Email or Telephone number below**:** (If different than contact person on application)

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