

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 sales of prescription drugs, controlled substances, or medical gas then both, the distributor license and registration 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)

Table with 3 columns: Check, Type of Enterprise, Fee. Rows include Manufacturer, Outsourcing Facility, Wholesale Distributor, Distributor, and Fee-exempt categories with associated fees.

1Distributors, 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, and/ or only filing as nonresident facility generally only need a registration.

2Manufacturers or 503B's must provide FDA registration or license. Virtual manufacturers, please contact the office at 717-787-4779

3Fee-exempt: Certain charitable nonprofit organizations (501-C) and government affiliated organizations may request fee waiver, provided supportive documentation is attached. Out of State facilities must provide and maintain list of sales representatives working in PA., if requesting fee waiver.

4In-state prescription drug manufacturer or distributor, must attach copy of pharmacist license, or 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: _____

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 establishment is incorporated and date of incorporation _____

Corporate Federal Tax ID (optional): _____

Ownership Name(s): Individual, Partners, or Corporate/Managing Officers (and title): _____

(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, and records. Type of Card (circle) VISA MC AE DISCOVER

If Payment by Credit card: _____ Exp. Date: ____/____ Zip Code _____ (associated with card)

Applicant Signature and Title _____ Date: _____

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