

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH

Application for Letter of Record

This application is for an entity that is performing activities related to the pharmaceutical or medical device industry at the Commonwealth location identified below, which does not handle any actual product (prescription/nonprescription drugs or medical devices) at that location. By signing this form, the applicant is attesting that no product is stored, distributed or manufactured at the location site identified below, that the applicant is adhering to applicable federal and state laws and regulations governing the pharmaceutical and medical device industry, that the information is true and accurate and that the applicant is voluntarily requesting this letter of record.

There is no fee associated with this application. Mail or fax application to the address/fax below:
PENNSYLVANIA DEPARTMENT OF HEALTH: DRUG & DEVICE REGISTRATION SECTION
132 KLINE PLAZA, SUITE A, HARRISBURG, PENNSYLVANIA 17104
PHONE (717) 783-1379 FAX (717) 772-0232

Check all blocks which apply

Table with 3 columns: Check, Type of Enterprise, and an empty column. Rows include: Headquarters or Corporate location for Pharmaceutical or Medical Device Manufacturer or Distributor, Virtual Manufacturer, Internet Business for Pharmaceutical or Medical devices: List Website, and Other: Please Describe.

Print Name of Entity/Business:

List other trade/business names used:

D-U-N-S Number (required) FDA Facility Establishment Identifier Number

Physical Location of Facility/Business in Pennsylvania (Street Address/City/Zip Code/County. No PO BOXES)

Telephone Number (including area code) for Pennsylvania entity:

Contact person, title, and telephone number at Pennsylvania entity:

Mailing address if different from above:

Business Name/ Main Address where product is physically manufactured or handled:

Type of entity (corporation, partnership, sole proprietorship, etc):

Ownership Name(s): Individual, Partners, or Corporate Officers (and title) attach additional papers if needed:

(If change of ownership please list previous record no. or name)

State of Registration/Incorporation: Date of Registration or Incorporation:

- Attach business documentation filed with Pennsylvania Department of State to operate a business in Pennsylvania

Has the applicant or have any of the officers, agents or employees of the entity ever been convicted of any violation of federal or Pennsylvania laws dealing with controlled substances, pharmaceuticals or medical devices? No Yes If yes, fully describe on other side.

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

Please indicate an e-mail address for the entity:

Corporate Federal Tax ID:

Print Applicant Name/Title: Date:

Applicant Signature: