

COMMONWEALTH OF PENNSYLVANIA**DEPARTMENT OF HEALTH****Application for Letter of Record**

This application is for an entity that is performing activities related to the manufacturing 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 or 717-787-4779 FAX (717) 772-0232

Check all blocks which apply

Check	Type of Enterprise	
<input type="checkbox"/>	Headquarters or Corporate location for Pharmaceutical or Medical Device Manufacturer or Distributor	
<input type="checkbox"/>	Virtual Manufacturer or NDA Holder	
<input type="checkbox"/>	Other: Please Describe _____	

Print Name of Entity/Business: _____

List other trade/business names used: _____

D-U-N-S Number (required) _____ **FDA Facility Establishment or Labeler 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 and Date filed: _____ **Federal Tax ID:** ____ - ____ - ____ - ____

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

Q1. 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.**

Q2. 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 or 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 or contact person: _____

Please indicate website the entity: _____

Print Applicant Name/Title: _____ **Date:** _____

Applicant Signature: _____