Form: **HD01330S January 4, 2019**

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH
Application for Letter of Record/ In state Virtual Manufacturers

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, 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 PHONE (717) 787-4779
555 WALNUT STREET-FORUM PLACE-7TH FLOOR, HARRISBURG, PENNSYLVANIA 17101 or FAX (717) 787-3188

Note, all applicants must already be recognized by federal or governmental agency or affiliate (i.e. FDA, DEA ,NABP, NIH, USDA) to qualify for a letter of record. **Check all blocks which apply**

Check	Type of Enterprise	
☐	Virtual Manufacturer or Headquarters/ Corporate location in Pennsylvania for Pharmaceutical or Medical Device Manufacturer of FDA Approved product. (must have at least one product fully approved for commercial use)	
☐	Virtual Manufacturer or Headquarters/ Corporate location in Pennsylvania for Active pharmaceutical ingredient or component of Medical Device Manufacturer of FDA Approved product	
☐	Other entity approved or recognized by FDA or other federal agency: Describe_____	

Print Name of Entity:_____

FDA product label code or federal registration # _____**D-U-N-S Number** _____
(required) (required)

Commonwealth Facility/Business Location (Street Address/City/Zip Code/County. No PO Boxes)
_____

Telephone Number (including area code) for Commonwealth facility_____

Mailing address if different from above: _____

Contact person for entity and telephone number:_____

Contact person's address if different than above: _____

List other trade/business names used: _____

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

A. Print Ownership Name(s): Individual, Partners, or Corporate Officers (and title):_____

_____

B. Type of entity (corporation, partnership, sole proprietorship, etc)**:** _____
(If change of ownership please list previous record no. or name _____***)***

C. State of Registration/Incorporation: _____**Date of Registration or Incorporation:** _____

D. Corporate Federal Tax ID : __ __-__ __ __ __ __ __ __

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: _____

Print Applicant Name/Title: _____

Applicant Signature: _____ Date:_____

Additional Program Information – Visit Our Website! **WWW.HEALTH.STATE.PA.US/DDC**