

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH**

Application for Virtual manufacturer (In-state only)

This application is for an entity that holds FDA product label code and is performing activities related to the pharmaceutical or medical device industry at the Commonwealth location identified below, but does not handle any actual product (prescription/nonprescription drugs or medical devices) at that location. Mail, fax, or email as PDF the application to the address/fax below with \$10 fee:

PENNSYLVANIA DEPARTMENT OF HEALTH: DRUG & DEVICE REGISTRATION SECTION

2525 NORTH 7TH STREET, HARRISBURG, PENNSYLVANIA 17110 or FAX (717) 231-4790 OR EMAIL: RA-DDC@PA.GOV

QUESTIONS: PHONE (717) 787-4779 OR EMAIL: RA-DDC@PA.GOV or visit our website www.health.state.pa.us/ddc

Note, all applicants must already hold a U.S. Commercial FDA product label code. Check all blocks which apply

Check	Type of Enterprise	
<input type="checkbox"/>	Virtual Manufacturer/Facility or Headquarters/ Corporate location in Pennsylvania for Pharmaceutical Manufacturer of FDA Approved product or API/Active pharmaceutical ingredient. (must have at least one product fully approved for commercial use)	
<input type="checkbox"/>	Virtual Manufacturer/Facility or Headquarters/ Corporate location in Pennsylvania for <u>Medical Device</u> Manufacturer of FDA Approved or Classified product or components. (must have at least one product fully approved or classified for commercial use)	
<input type="checkbox"/>	Other entity approved or recognized by FDA or other federal agency: Describe _____	

Name of Virtual Manufacturer/Business: _____

List other trade/business names if used: _____

Facility Street Address & Suite, if applicable (No P.O Box/No personal residence): _____

City/ZIP code/ County _____ Phone no. (including area code) _____

Onsite Contact Person & Phone number: _____

E-mail address for the business: _____

Mailing/Billing Address/Name, if different: _____

FDA product label code(s) #: _____ SAM.Gov/UEI registration # - - - - -

Type of Ownership (S-corp., partnership, sole proprietorship, LLC etc.): _____ Federal Tax ID: - - - - -

If Incorporated or LLC, list State in which entity is incorporated and date of incorporation: State: _____ Date: _____

Ownership Name(s): Individual, Partners, or Corporate/Managing Officers and Title (Attach additional document if necessary)

If this is a change of ownership, please list previous registration #: _____

List one Physical product manufacturing site for label code noted. If CMO, attach documentation of contract.

Name of <u>Physical Manufacturer</u> site/ Contract manufacturer org./CMO:
Address of Physical manufacturing site:
FDA facility identifier/FEI registration # for physical contract or manufacturing site:

- Attach or email business documentation filed with Pennsylvania Department of State to operate a business in Pennsylvania.
- ATTACH OR EMAIL SURETY BOND OF \$100,000 firmly bound to the Pennsylvania Department of Health (Email: ra-ddc@pa.gov)

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? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, fully describe in attached letter/documents.
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? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, fully describe in attached letter/documents.

By signing this form, the applicant is attesting that no commercially available product, other than for research or marked samples, is stored, distributed, or manufactured at the facility/business location site identified, that product promoted or sold by the entity is physically manufactured, repackaged, relabeled, or produced at a facility licensed by the FDA, and that applicant is adhering to applicable federal and state laws and regulations governing the pharmaceutical and medical device industry, and information on application is accurate.

Print Applicant Name/Title: _____

Applicant Signature: _____ Date: _____

Payment by Credit card: _____ Exp Date: ___/___/___ Security Code _____ Zip Code _____
Type of Card (circle) VISA MC AE DISCOVER (billing zip code)