MANUFACTURERS AND VIRTUAL MANUFACTURERS DISTRIBUTING ONLY THEIR OWN PRESCRIPTION DRUGS AND DEVICES APPLICATION INSTRUCTIONS

(*See Md. Code Ann., Health Occ. § 12-6C-03(b)(2) for complete requirements***)**

- Complete the attached Maryland Board of Pharmacy's **Application for Manufacturers and Virtual Manufacturers Distributing Their Own Prescription Drugs and Devices**. Be sure to check the box for the relevant application type (New, Renewal, Ownership Change, Relocation, or Reinstatement).

> **NOTE:** Pursuant to Md. Code Ann., Health Occ. § 12-6C-03(b)(2), manufacturers and virtual manufacturers distributing *only* their own prescription drugs and/or devices approved by the U.S. Food and Drug Administration into or within Maryland are not required to comply with requirements under the Wholesale Distribution Permitting and Prescription Drug Integrity Act beyond those required by federal law. An abbreviated wholesale distributor application and attachments must be completed by these entities in order to be considered for a Maryland wholesale distributor permit.

- Submit the completed application with all attachments and a check made payable to the Maryland Board of Pharmacy in the appropriate amount to:

Maryland Board of Pharmacy, PO BOX 2024, Baltimore, MD 21203-2024.

- Applications sent overnight or through priority mail must be addressed to the appropriate lockbox and sent to:

Wells Fargo Bank, Attn: State of MD – Board of Pharmacy, Lockbox 2024
2005 Market Street 5th Floor
Philadelphia, PA 19103-7042

- The application process must be completed within one year from submission of the initial application. Applicants failing to complete the process within one year will be required to submit a new application. Fees paid for applications that have expired will not be refunded or credited.

- Manufacturers completing this form must satisfy the definition of "manufacturer" as provided in 21 C.F.R. 205.3(d): *Manufacturer means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug*.

- Manufacturers distributing their own prescription drugs approved by the U.S. Food and Drug Administration must provide the following items with their application:

  - A copy of the facility's most recent FDA inspection;
  - Documentation of FDA registration as an establishment approved to distribute prescription drugs; and
  - The appropriate application fee ($1,750 for New, Renewal, Ownership Change, or Relocation applications; $3,250 for Reinstatement applications).

- Virtual manufacturers completing this form must satisfy the definition of "virtual manufacturer" as defined in COMAR 10.34.22.02(new): *Virtual Manufacturer [means] an entity that engages in the manufacture of drug or device products for which it:(i) Owns the NDA or ANDA number, if a prescription drug;(ii) Owns the UDI number, as available, for a prescription device;(iii) Contracts with a contract manufacturing organization for the physical manufacture of the drug or device product; (iv)*

Is not involved in the physical manufacture of the drug or device product; and (v) At no time takes physical possession of, or stores, the drug or device product. A "Virtual Manufacturer" may include entities that are identified as a broker, own-label distributor, sponsor manufacturer, private-label manufacturer, or contract manufacturer.

- The information and qualifications required for Virtual Manufacturers to obtain a permit, beyond that required by federal law, do not apply to a virtual manufacturer that provides the following information to the Board:
    - A list of drug or device products it distributes;
    - A list of the NDA or ANDA numbers associated with each drug it distributes;
    - A list of the UDI numbers, as available, associated with each device it distributes;
    - The name and facility address of the contract manufacturer for each drug or device product it distributes;
    - Verification of current FDA registration for each contract manufacturing facility listed;
    - If the contract manufacturer distributes into this State, the wholesale distributor permit number for the contract manufacturer;
    - If the contract manufacturer does not distribute into this State, the name and Maryland's wholesale distributor permit number for the entity that physically distributes the product into this State;
    - A statement affirming that the virtual manufacturer does not contract the manufacture or distribution for drugs or devices other than those for which it owns the NDA, ANDA, or UDI numbers;
    - An attestation by the owner of the virtual manufacturer that it does not hold product;
    - A copy of existing licensure from the state in which it is located, if applicable;
    - A valid federal licensure or registration, as verified by the Board; and
    - The appropriate application fee ($1,750 for New, Renewal, Ownership Change, or Relocation applications; $3,250 for Reinstatement applications).
    - List of owners/corporate officers, (name(s) title(s) and position(s) all of owners, partners and officers)

NOTE: Please allow two to four weeks for the Board to process your completed application.

NOTE: The application fee is a non-refundable, administrative fee.

NOTE: FDA registered 503(b) Outsourcing Facilities are to complete this application. If the outsourcing facility dispenses patient specific medications per prescription a non-resident pharmacy application is required to be submitted.

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore MD 21215-2299
Phone: 410-764-4755
Fax: 410-358-6207
www.dhmh.maryland.gov/pharmacy

APPLICATION FOR MANUFACTURERS AND VIRTUAL MANUFACTURERS DISTRIBUTING THEIR OWN PRESCRIPTION DRUGS OR DEVICES

Please print clearly in ink or type in upper case letters only.

Complete all application sections and sign. **Incomplete forms will delay the issuance of your permit.**

APPLICATION TYPE				
☐ **New Application**	☐ **New Ownership**	☐ **Renewal**	☐ **Relocation**	☐ **Reinstatement**
Fee: $1,750.00	**Fee: $1,750.00**	**Fee: $1,750.00**	**Fee: $1,750.00**	**Fee: $3,250.00**

Proposed date for ownership or relocation change: _____

1. APPLICANT INFORMATION	
A. Name of Manufacturer: ***(name in which firm is doing business)***	
Maryland Permit Number:	

B. Facility Address ***(physical location of establishment which should be reflected on all sales invoices and shipping documents)*:**					
Street Address:				**Suite #:**	
City:		**State:**		**Zip Code:**	
Telephone #:				**Fax #:**	
Web Site Address:		**Email Address:**			
Federal Tax ID #:					

C. Type of Business (check all that apply):		
☐ Sole Proprietorship	☐ Partnership	☐ C Corporation
☐ S Corporation	☐ LLC	☐ Other (please explain): _____

D. Legal Name (if different from Manufacturer Name):	
State of Incorporation:	
Date of Incorporation:	

E.	**Parent Company Name (to include any and all parent companies that have direct or indirect control over the applicant)**	

F. State and Federal permit/license/registration numbers *(attach additional pages if necessary)*:	
LICENSING BODY	**PERMIT / LICENSE / REGISTRATION NUMBER**

G. Products distributed *(check all applicable boxes)*
*(**Please send a list of the products distributed**--do not send catalogs)*:

☐ **Drugs**

☐Prescription

☐ Non-prescription

☐ Controlled dangerous substances (CDS)

☐ **Devices**

☐ Class I

☐ Class II

☐ Class III

☐ **Registered FDA Outsourcing Facility 503B (complete a – g below)**

a. Date of Registration as an FDA registered Outsourcing Facility _____
b. Registration #_____
c. Does the outsourcing facility engage in HIGH-RISK compounding of sterile drug products? _____ (y/n)
d. Does the outsourcing facility engage in MEDIUM-RISK compounding of sterile drug products? _____ (y/n)
e. Does the outsourcing facility engage in LOW-RISK compounding of sterile drug products? _____ (y/n)
f. Does the outsourcing facility engage in the compounding of NON-STERILE drug products? _____ (y/n)
g. List of Sterile and Non-Sterile products distributed into Maryland, attached? _____ (y/n)

G. Name of Applicant			
Name:		**Title:**	
Phone #:		**Email Address:**	

2. SIGNATURE OF AUTHORIZING OFFICIAL

By signing this application, I solemnly affirm under the penalties of perjury that the company manufactures and distributes (or virtually manufactures and distributes) its own products only. I further certify that the contents of this application are true to the best of my knowledge, information, and belief and that I am aware of and will meet the requirements of the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to wholesale distribution permitting. I understand that a Maryland wholesale distributor permit may be revoked if any statement made in this application is found to be false.

Signature of Authorizing Official:	

Name and Title:	
Date:	

4. LIST OF DESIGNEE

If applicable, list the names of person and/or entity that you authorize the Board to release information about your application:

Name of Organization	Name of Person	Title

5. ATTESTATION FOR VIRTUAL MANUFACTURERS

By signing this attestation, I hereby affirm that the company does not contract the manufacture or distribution of drugs or devices other than those for which it owns the NDA, ANDA, or UDI numbers. I further certify that the company does not hold product.

Signature of Authorizing Official:	

Name and Title:	
Date:	

6. APPLICATION CHECKLIST		
Application Fee ($1,750 or $3,250)	☐YES	☐NO
Proof of FDA Registration	☐YES	☐NO
Most Recent FDA Inspection Report (if applicable)	☐YES	☐NO
Ownership Information (as applicable) **(name(s) title(s) and position(s) all of owners, partners and officers)**	☐YES	☐NO

For Virtual Manufacturers:		
List of NDA, ANDA, and/or UDI Numbers	☐YES	☐NO
List of Drugs and/or Devices	☐YES	☐NO
List of Contract Manufacturers	☐YES	☐NO
List of Contract Distributors (if applicable)	☐YES	☐NO