



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

*Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary*

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MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald Taylor, Board President - LaVerne G. Naesea, Executive Director

NAME  
ADDRESS  
CITY, STATE ZIP

RE: PERMIT #

Dear Out-of-State Wholesale Drug or Device Distributor Renewal Applicant:

Please be advised that § 12-6C-04 of the Wholesale Distribution Permitting and Prescription Drug Integrity Act was amended during the 2010 Maryland legislative session. The new law includes requirements that will affect renewing out-of-state wholesale distributors. Specifically, effective October 1, 2010, out-of-state distributors will fall into one of the two categories listed below and must comply with the instructions listed below each in order to receive a renewal permit:

1. **The wholesale distributor is located in a state that has requirements that are substantially equivalent to Maryland's wholesale distributor requirements (i.e. IN; ND; WY; AZ; CO; FL; GA; ID; IL; KY; NB; NV; NJ; OK—for human drugs only; OR) and includes requirements for pedigrees, routine inspections, operations in a commercial, non-residential facility and security measures.**

- A copy of an inspection report issued by that state's Board of Pharmacy and completed within the previous renewal period must be submitted with the renewal application.
- If the distributor is VAWD-accredited, indicate the VAWD accreditation number on application in lieu of above referenced inspection report.
- All other requirements, including a surety bond and background checks for the designated representative and the designated representative's supervisor are still required.

**OR**

2. **The wholesale distributor is out-of-state and accredited by a Board-recognized accreditation organization.**

- Proof of submission of an accreditation application must be submitted with the renewal application.
- Currently, the National Association of Boards of Pharmacy's (NABP) is the only Board-recognized accreditation organization. The NABP *Verified Accredited Wholesale Distributor* (VAWD) accreditation process includes a physical inspection of the facility and may take six months or more to complete. If you plan to renew your permit, you are encouraged to begin the accreditation process with NABP by June 30, 2010. Proof of submission of an accreditation application must be submitted with the renewal application. VAWD Program requirements may be viewed online at: <http://www.nabp.net/programs/accreditation/vawd/>.

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- If the distributor is already VAWD-accredited, indicate the VAWD accreditation number on the renewal application.
- Failure to comply with NABP's requirements in the accreditation process, including failure to respond to requests for information, will result in denial of your application.
- All other requirements, including a surety bond.

### **Own Label Manufacturers Distributing Their Own Prescription Drugs**

In addition, own label manufacturers distributing their own prescription drugs approved by the U.S. Food and Drug Administration may complete an abbreviated application provided the following items are submitted with their application:

- A copy of the manufacturer's most recent FDA inspection.
- Documentation of FDA registration as an establishment approved to distribute prescription drugs.

### **General Information for All Applicants**

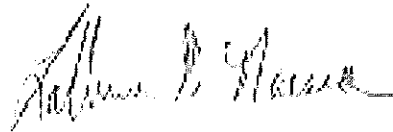
See the Board's website for specific instructions and applications: <http://www.dhmv.state.md.us/pharmacyboard/forms/establish.htm>. All distributors must complete the same form unless they are an out-of-state manufacturer distributing their own prescription drugs. Answers to frequently asked questions are updated regularly and can be found on the Board's website at [www.dhmv.maryland.gov/pharmacyboard](http://www.dhmv.maryland.gov/pharmacyboard).

Please contact NABP at [vawd@nabp.net](mailto:vawd@nabp.net) with questions relating to the wholesale distributor accreditation application.

Please be advised that operating without a permit is punishable by a fine not to exceed \$500,000. Md. Code, Health Occ. § 12-6C-11.

If you have questions after reviewing the Board's website, please contact Summar Goodman, Licensing Manager, at [sjgoodman@dhmv.state.md.us](mailto:sjgoodman@dhmv.state.md.us).

Sincerely,



LaVerne G. Naesea  
Executive Director