



Oregon

Theodore R. Kulongoski, Governor

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971 / 673-0001
Fax: 971 / 673-0002

E-mail: pharmacy.board@state.or.us

Web: www.pharmacy.state.or.us

March 11, 2008

REMINDER TO ALL OREGON REGISTERED CLASS 1 WHOLESALER WITH PRESCRIPTION DRUG OUTLETS

Your Wholesaler Class 1 Registration will expire September 30, 2008. In order to renew your Class 1 Wholesaler Registration you will need to submit the following information with your renewal notice by the postmark deadline of August 31, 2008. Renewal notices will be mailed in early July 2008.

Surety Bond Requirement:

- Evidence of a surety bond or other equivalent means of security for at least \$100,000. Such means of security must provide the Oregon Board of Pharmacy with direct access to secure payment of any administrative penalties that are not paid within 30 days of becoming final. Typically the Board would expect to see an original letter from an insurance company or other financial institution. *See Oregon Administrative Rule OAR 855-065-0006(8)*.

Accreditation Program or Inspection Requirement:

- Confirmation that The National Association of Boards of Pharmacy's Verified Accredited Wholesaler Distributor (VAWD) or other nationally recognized accreditation program or contract inspection service has been obtained. At this time VAWD is currently the only approved accreditation program that the Board is accepting. You may contact the National Association of Boards of Pharmacy regarding their VAWD accreditation process at www.nabp.net or (847) 391- 4406. Please note the Board may recognize other accredited programs and inspection services, however, documentation must be submitted for Board approval and consideration.

A. Wholesalers out of Oregon:

- VAWD or other accreditation program; **or**
- Wholesalers located **outside** of Oregon may submit a copy of their most recent Out-of-State Wholesaler Inspection Report that has been conducted within the last year to meet the requirements of *Oregon Administrative Rule 855-065-0006(5)* so long as their resident state is listed below. Each inspection report will be reviewed on a case-by-case basis. If your Out-of-State Wholesaler Inspection Report has been approved and accepted, VAWD or other nationally recognized accreditation program or contract inspection service will not be required.
 - *Alabama, Colorado, Florida, Kentucky, Louisiana, Missouri, New Hampshire, North Dakota, Oklahoma, South Dakota, Tennessee or Vermont.*
- If your state is not listed above and you have had an inspection within the last three years that you believe meets the requirements of *OAR 855-065-0006(5)* please submit the inspection report for Board consideration.

Continued on Next Page

B. Wholesalers in Oregon:

- VAWD or other accreditation program; **or**
- Wholesalers located **within** Oregon may be inspected by the Oregon Board of Pharmacy in lieu of VAWD or other nationally recognized accreditation program or contract inspection service. However, outlets must be inspected by the Board before August 31, 2008. Please contact our Compliance Department at (971) 673-0001 to schedule an inspection; **or**
- Wholesalers located **in** Oregon which are small businesses and meet the criteria listed below may not have to be VAWD accredited or inspected by the Board so long as they are a small business and meet the criteria listed below. Per *Oregon Revised Statute 183-310(10)* a “small business” is defined as a corporation, partnership, sole proprietorship or other legal entity formed for the purpose of making a profit, which is independently owned and operated from all other businesses and which has 50 or fewer employees. In addition these small outlets must meet the following:
 - Have no affiliation with any out-of-state pharmaceutical company.
 - All owners and principals of the applicant must be Oregon residents.
 - No owner or principal, or close family member of an owner or principal, may have a controlling or business interest in any other pharmaceutical company; and
 - Neither the applicant, nor any of its owners or principals, has ever been found to be in violation of any drug law or regulation in this or any other state.

Note: That a “small business” may be subject to inspection anytime during normal business hours by the Oregon Board of Pharmacy.

Designated Representative Reminder:

- Every Oregon Class 1 Wholesaler must have a Designated Representative physically present at the wholesale distributor during normal business hours. Please be reminded that one individual may not be the Designated Representative for more than one registration without an **exception request approved** by the Board. Failure to submit an exception request caused a delay in the renewal process of many outlets last year. Exception request information may be found on our website under the “FAQ” tab. In addition ensure that your Designated Representative is fully aware of their responsibilities see *Oregon Administration Rule 855-065-0009*.

Please be advised that the postmark deadline for wholesaler renewals is August 31, 2008 and that you must be in compliance with all Oregon Board of Pharmacy Laws and Rules and provide evidence of the aforementioned items to renew your registration. The Oregon Board of Pharmacy will be mailing renewal notices with submission requirements in early July 2008. We are advising all Oregon Class 1 Wholesalers to have all requirements in place prior to this time to avoid complications with the renewal process. If all requirements have not been satisfied your license will not be renewed.

For additional information regarding Oregon wholesaler licensure requirements please refer to the “What’s New” and “FAQ” tabs on our website at www.pharmacy.state.or.us. A complete copy of the wholesaler rules may also be viewed on our website by clicking on the “Laws and Rules” tab under the “Division 65” subsection.