



LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

12046 Justice Avenue, Suite C

Baton Rouge, LA 70816

Phone: 225-295-8567 Fax: 225-295-8568 Website: www.lsbwdd.org email: lsbwdd@bellsouth.net

In-State Licensee Newsletter

April 2006

Welcome

The Board would like to welcome back Mr. Wayne Gremillion who previously served on the Board from August 1994 through June 2004. Mr. Gremillion was reappointed by the Governor in August, 2005 to serve another term on the Board. Mr. Gremillion's current term will expire August 23, 2010. Again, we welcome Mr. Gremillion back and look forward to working again with him.

RULE PROMULGATION

In accordance with the Administrative Procedures Act of Louisiana, the Board has promulgated rule amendments to the Louisiana Administrative Code 46:XCI.101 through 108. The Notice of Intent for the proposed amendments was published in the August 20, 2005 *Louisiana Register*. The amendments were published as final in the March 20, 2006 *Louisiana Register*. The new rules define and clarify terms (definitions) used within the rules for practice and procedure; detail and explain current procedures and practices, licensee requirements and responsibilities, compliance, Board functions, and disciplinary procedures. The new rules will support the Board's ability to effectively regulate wholesale drug and device distribution within the state in its effort to safeguard life and health and promote the public welfare.

A copy of the revised rules can be found on the Board's website at www.lsbwdd.org or you can contact the Board office to receive a copy at 225-295-8567 or by email at lsbwdd@bellsouth.net. A mailing to distribute copies of the current statutes and rules to in-state licensees is planned in the near future.

Summary of Rule Amendments

- New definitions have been added.
- Licensure requirement of those companies that wholesale/distribute legend devices have been added.
- Application and renewal requirements and qualifications have been updated.
- License renewal procedures have been changed.
- License compliance requirements have been modified.
- New disciplinary procedures have been added.

IGNORANCE OF THE LAW IS NO EXCUSE

State statutes and Board promulgated rules can be viewed on the Board's website at www.lsbwdd.org and a copy of the statutes and rules can be obtained by contacting the Board's administrative office at 12046 Justice Avenue, Suite C, Baton Rouge, LA 70816, 225-295-8567, fax 225- 295-8568, email lsbwdd@bellsouth.net. THE BOARD ENCOURAGES YOU TO KEEP A COPY HANDY FOR FUTURE REFERENCE.

NEW LICENSE RENEWAL PROCEDURES

In accordance with new rule amendments implemented in LAC 46:XCI.301 and effective with the upcoming 2007 license renewal period starting in October 2006, licenses must be timely and properly

renewed annually by submitting application and other pertinent information requested along with payment of the license renewal fee of \$200 to the Board office *on or before* December 31 each calendar year. Those licenses not timely and properly renewed shall promptly expire on December 31 each calendar year. If a license is not timely and properly renewed on or before December 31 and the license expires, the licensee may apply for reinstatement of the expired license by submitting the renewal application and other pertinent information requested along with payment of the license renewal fee of \$200 and an additional reinstatement fee of \$200. During the period the license is expired after December 31, the licensee may not lawfully operate as a wholesale drug or device distributor in Louisiana. There will no longer be a grace period for completing license renewals.

COMPLETION OF 2006 LICENSE RENEWAL

At the end of the 2006 license renewal period, there were twenty-seven (27) "Cease & Desist" letters sent out to licensees who did not renew or complete renewal of their Louisiana license - *ASAP Meds Inc., Fort Lauderdale, FL; Boehringer Ingleheim Pharmaceuticals Inc., Columbus, OH; Caladon Inc., Las Vegas, NV; Chemserv Industries Inc., New Orleans, LA; Dawn Wholesale Pharmaceuticals, Glenview, IL; Direct Fulfillment LP, Robbinsville, NJ; Drougueria Caballero Del Caribe Inc., Bayamon, PR; Healthsource Distributors LLC, Baltimore, MD; LL Horizons Inc., Tampa, FL; Medical Supplies Depot Inc., Mobile, AL; Milburn Distributions Inc., Phoenix, AZ; NX Generation Ltd, Commack, NY; Oceanmar Marine Supply Inc., New Orleans, LA; Pharmakon Labs Inc., Tampa, FL; RDI Specialty Corp, Foley, AL; Respiratory Distributors Inc., Foley, AL; RPL Oil Distributor & Supply LLC, Gretna, LA; Symphony Respiratory Services Inc., Pensacola, FL; Sysco Corporation, Jackson, MS; Tersco LLC, New Orleans, LA; The Blood Center, New Orleans, LA; Tyco Healthcare Group LP, St. Louis, MO; Ultimate Pharmaceuticals, Memphis, TN; Wellsprings Pharmaceutical Corp, Neptuen, NJ;*

Wockhardt USA Inc., Toms River, NJ; World Ship Supply Inc., New Orleans, LA; and Zylex Pharmaceuticals, San Clemente, CA. Please note that at the time of printing, these companies do not currently hold valid licensure to sell or ship legend drugs or devices in and into Louisiana. Please check with the Board office or check on the license verification page of the Board's website in the event a license may be reinstated after late completion of the renewal requirement.

If you purchase legend drugs or devices from any of these companies at these unlicensed location, you would be in violation of the Board's statutes and/or rules.

Currently there are approximately 1,086 facilities licensed as wholesale drug distributors by Louisiana. Of these, 982 are full line wholesale/distributors - 90 of which are located in Louisiana; and 114 are wholesale/distributors of medical gas - 55 of which are located in Louisiana.

UNLICENSED SUPPLIERS

As per Board promulgated regulation, specifically LAC 46:XCI.311.F, wholesalers located in Louisiana are responsible for verifying that their legend drug or device product suppliers are licensed by the Louisiana Board of Wholesale Drug Distributors to ship or sell product into Louisiana. Wholesalers are also responsible for notifying the Board of any unlicensed wholesalers.

The PREFERRED method of notification of a supplier of legend drugs or devices that is not licensed by the Louisiana Board of Wholesale Drug Distributors to sell or ship product into Louisiana is for the receiving company to mail or fax a copy of the invoice from that unlicensed supplier to the LBWDD Board office so the company can be contacted and provided with licensing information.

AUTHORIZED RECIPIENTS

In accordance with Louisiana Revised Statute 37:3480, sales and distribution of drugs or devices must be made to an authorized recipient - i.e., an individual, corporation, or entity that is authorized by law or regulation to

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procure or possess such drugs or devices. In addition, any location to which legend drugs or devices are sent must also be authorized to procure or possess such drugs or devices. In accordance with Board promulgated regulation, LAC 46.XCI.311.D and to ensure that the customers you sell/distribute to are authorized to procure or possess legend drugs or devices, you are required to maintain copies of licenses for all customers that are shipped or sold legend drugs or devices.

There are different types of licenses or permits that the Board will accept as verification of an authorized recipient of legend drugs or devices. These are as follows:

D.E.A License

Louisiana Controlled Dangerous Substance (Drug) License

Medical Examiner's License

Dental License

Veterinarian License

Pharmacy License (Do not use Drug Kit Permit)

Louisiana Wholesale Drug Distributors License

Louisiana Dept. of Health & Hospitals Permit:

Food & Drug Permit 461 - OTC & Prescription Drugs

Food & Drug Permit 462 - OTC, Prescription Drugs and Controlled Substances

Food & Drug Permit 463 - Prescription Drugs

Food & Drug Permit 464 - Prescription & Controlled Substances

Food & Drug Permit 465 - Controlled Substances

Food & Drug Permit 467 - Prescription Generic Drugs

Food & Drug Permit 468 - OTC Generic & Prescription Generic Drugs

Food & Drug Permit 480 - Medical Devices

The types of licenses, permits, and certifications that can be used as verification of an authorized recipient of medical gases including medical grade oxygen are the ones listed above as well as:

Emergency Medical Technician (EMT) Certification

First Responder Certification

Louisiana Dept. of Health & Hospitals

Food & Drug Permit 473 - Medical Gases

A Divers Alert Network (DAN) certificate or a certificate issued by the American Red Cross cannot be used and is not medical authorization for the holder to refill oxygen cylinders with medical grade oxygen in Louisiana. These two certificates are not acceptable.

For nursing homes and hospitals, you *cannot* use copies of the Louisiana Department of Health and Hospitals license to operate/occupational license (is generally, a 3-digit license number) that specifies a licensed capacity number on file.

INSPECTIONS

BOARD INSPECTOR(S) DO NOT ANNOUNCE OR SCHEDULE INSPECTIONS IN ADVANCE.

Your facility will be inspected during your normal business hours. During that time, there must be someone available that can produce records and assist the Board inspector with the inspection. If the owner/manager is not at the facility when the inspector arrives for the inspection, there must be someone designated to act in his or her place to

allow an inspection as authorized in R.S. 37:3470 to take place. It is your responsibility to be in compliance when the inspector arrives. Non-compliance issues that are corrected while the inspector is present will be considered as violations found and reported to the Board's compliance officer.

PERPETUAL INVENTORY

As per Board promulgated regulation, specifically LAC 46:XCI.311.A which reads:

“Wholesale drug or device distributors shall establish and maintain perpetual inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs or devices. These records shall include the following information:

1. source of the drugs or devices, the name and principle address of the seller or transferor, and the address of the facility or physical location from which the drugs or devices were shipped;
2. the identity and quantity of the drugs or devices received and distributed or disposed of; and
3. the dates of receipt and distribution of the drugs or devices.”

Medical gas distributors should note that you are not required to maintain a perpetual inventory on oxygen, but you are required to maintain perpetual inventories on all other medical gases.

You can see full versions on the state statutes and board promulgated regulations governing wholesale drug distributors on the Board’s website at www.lsbwdd.org.

ARE ALL OF YOUR LOCATIONS LICENSED

Both sales locations and the distribution locations (if different) for your company are required to be licensed as wholesale drug distributors. Each location must be licensed on its own. If you have multiple locations that either sell or distribute legend drug or device product, be sure they are all licensed.

DISPOSAL OF EXPIRED OR QUARANTINED DRUGS OR DEVICES

Do not forget that disposals of legend drugs or devices must be fully documented for a complete inventory record. In addition, legend drugs or devices should only be transferred to authorized recipients. “Reverse Distributors” with a physical location within Louisiana that receive legend drugs or devices or store legend drugs or devices for destruction purposes must be licensed by this Board.

CHANGE OF LICENSED FACILITY INFORMATION

Changes in any information regarding your licensed facility must be submitted to the Board. If you are planning to move your facility to a new location or if your facility has a change in ownership, you must notify this Board. Licenses are issued to facilities locations by owner and are not-transferable. A new location requires inspection and issuance of a new license. All license information changes must be submitted to the Board within 60 days of such change as per LAC 46:XCI.303.C.

DISCIPLINARY ACTIONS - 2005

Disciplinary Docket No. 200501 - Voluntary Consent Agreement - Licensee was found to be in violation of LAC 46:XCI.311.D - copies of licenses for customers who are authorized by law or regulation to procure or possess federal legend

drugs were not being maintained for all customers that were shipped or sold federal legend drugs. The licensee signed a consent agreement and was assessed a fine of \$1,000.

REGULATORY COMPLIANCE TRAINING

If your company has a change in management at the facility licensed by the Louisiana Board of Wholesale Drug Distributors, you may contact the Board's administrative office at (225) 295-8567 or by email at lsbwdd@bellsouth.net and schedule a time

for Mr. John Liggio, Executive Director/Inspector, to come to your facility and speak with the new management team regarding regulatory compliance issues relative to the Louisiana wholesale drug distributor license.

BOARD WEBSITE

The BOARD'S WEBSITE AT www.lsbwdd.org has many active functions and helpful links. You can print an application form, view previous newsletters to licensees, view a list of the current Board Members and staff, view and print the state statutes & Board rules, verify license information of wholesale drug distributors licensed by the Board, and do various inquiries, such as verify and print licenses, using the links to other agencies such as the Louisiana Board of Pharmacy, Louisiana Board of Dentistry, Louisiana Board of Medical Examiners, and the Louisiana Controlled Dangerous Substance Program. The license

information printed from these sites can be kept on file as customer license verification copies for wholesalers in Louisiana. You can even download a spreadsheet list of all Louisiana licensed wholesale drug distributors.

There is a link to the FDA website so you can use it to review recalls and safety alerts issued by the FDA. You can get information on applying for a license with the Louisiana Controlled Dangerous Substance Program. There is also a link to the NDC directory.

Please pass this newsletter around so that all of your employees can have the benefit of learning more about regulation of the industry.

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