



LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

12046 Justice Avenue, Suite C

Baton Rouge, LA 70816

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In-State Licensee Newsletter

May 2005

Welcome

The Board would like to welcome two new Board members recently appointed by the Governor on April 27, 2005. Mr. Hersh Paul will fill the vacant seat left by the non-confirmation of Ms. Judith Camp. Mr. Paul's term will expire January 8, 2008. Mr. Andy Milligan will fill the vacant (expired) seat of Mr. Fred King. Mr. Milligan's term will expire April 27, 2010. Again, we welcome our new members and look forward to working with them.

PERPETUAL INVENTORY

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

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

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

Therefore, your company will be found in violation of this regulation and could be assessed a fine if during an inspection it is found that no perpetual inventory of product is being kept or is not readily available and current.

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.

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 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 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.

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 non-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.

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.

IGNORANCE OF THE LAW IS NO EXCUSE

State statutes and Board promulgated regulations 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. A statute and regulation booklet was prepared and mailed to all in-state licensees with the renewed license certificate. THE BOARD ENCOURAGES YOU TO KEEP THIS BOOKLET HANDY FOR YOUR FUTURE REFERENCE.

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 during the inspection will still be considered as violations found.

COMPLETION OF 2005 LICENSE RENEWAL

At the end of the 2005 license renewal period, there were seven (7) "cease & desist" letters sent out to licensees who did not renew their Louisiana license - *Adams Laboratories, Fort Worth, TX; Amarin Pharmaceuticals, Mill Valley, CA; National Pharmaceuticals, Hatboro, PA; PPS Medical Marketing Group, Pinebrook, NJ; Promex Medical, Niagara Falls, NY; T-N-T Sales Corp, Lancaster, PA; and Women First Healthcare, San Diego, CA.* Please note that these companies are no longer licensed to distribute/ship legend drugs in and into Louisiana.

If you purchase legend drugs from any of these companies at these unlicensed locations, you would be in violation of the Boards statutes and/or rules.

Currently there are 1,100 facilities licensed as wholesale drug distributors by Louisiana. Of these 982 are full line wholesalers, 90 of which are located in Louisiana; while 118 are medical gas wholesalers, 90 of these are located in Louisiana.

DISPOSAL OF EXPIRED OR QUARANTINED Rx DRUGS

Do not forget that disposals of legend/prescription (Rx) drugs must be fully documented for a complete inventory record. In addition, legend/prescription (Rx) drugs should only be transferred to authorized recipients. "Reverse Distributors" with a physical location within Louisiana that receives legend/prescription (Rx) drugs or stores legend/prescription (Rx) drugs for destruction purposes must be licensed by this Board.

AUTHORIZED RECIPIENTS

In accordance with Louisiana Revised Statute 37:3480, all sales and distribution of prescription drugs must be made to an authorized recipient. In addition, any location to which prescription drugs are sent must be authorized to possess prescription drugs. In accordance with Board promulgated regulation, LAC 46:XCI.311.D, to ensure that the customers you sell/distribute to are authorized to purchase and possess legend drugs, copies of licenses for customers must be maintained for all customers that are shipped or sold legend drugs.

There are different types of licenses or permits that the Board will accept as verification of an authorized recipient of prescription/legend drugs (excluding medical gases - see below). These are as follows:

D.E.A License

Controlled Drug Substance 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

Food & Drug Permit 462

Food & Drug Permit 463

Food & Drug Permit 464

Food & Drug Permit 465

Food & Drug Permit 467

Food & Drug Permit 468

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 one listed above as well as:

Emergency Medical Technician (EMT) Certification

First Responder Certification

Louisiana Dept. of Health & Hospitals

Food & Drug Permit 473

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.

DISCIPLINARY ACTIONS - 2004

Disciplinary Docket No. 200406 - 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.

ARE ALL OF YOUR LOCATIONS LICENSED

Both sales/corporate 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/prescription drug product, be sure they are all licensed.

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 regulations, 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. There is a link to get information on product registration from the DHH, Office of Public Health, Food and Drug Program. You can also 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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