



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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NOTICE REGARDING MULTIPLE PRODUCT LICENSES

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This notice is to advise you the Texas Legislature modified the Texas Food Drug and Cosmetic Act, Health and Safety Code (HSC), Chapter 431, by changing the way the Department will license drug manufacturers and distributors. House Bill 164 (79th Session) created several new license categories, including separate licenses for firms that distribute prescription drugs and those that distribute non-prescription drugs. The process for obtaining a license to distribute over-the-counter drugs remains essentially unchanged, however, in order to obtain a license to distribute prescription drugs, the applicant must now go through a more rigorous application process. There are also new, albeit less complex, requirements for those firms that manufacture and distribute oxygen. These amended sections may be found in HSC Chapter 431, and include the following: subchapter I, §431.241-252, regarding wholesale distributors of non-prescription drugs and subchapter N, §431.419-430, wholesale distributors of prescription drugs.

New regulations, Title 25 Texas Administrative Code, §229.241-430, which clarify the law and amend the fee structure, were published in the January 26, 2007 edition of the *Texas Register*. A copy of the new regulations may be found at www.dshs.state.tx.us/dmd. If you have questions or need additional interpretation of the new regulations, please call the Drugs and Medical Devices Group at (512) 834-6755.

Enclosed, you will find your new multiple product licenses application for licensing as a wholesale distributor of compressed medical gases, non prescription drugs, medical devices and/or food. Please read the application carefully to make sure you have the correct application. The new drug rules do not allow for the distribution of prescription drugs other than compressed medical gases under the multiple product licenses. If you do not distribute compressed medical gases **you will** need a different multiple product licenses application. If you are distributing prescription drugs other than compressed medical gases under your current multiple product licenses **you will** need to license as a drug distributor and may not be qualified for the multiple product licenses. You will be required to obtain a food wholesaler license or a device distributor license as well as the drug distributor license if you are distributing prescription drugs and one other product under your current multiple product licenses. If you have questions about completing the application, please contact the Food and Drug Licensing Group at (512) 834-6626 or visit the Food and Drug Licensing webpage at <http://www.dshs.state.tx.us/fdlicense>.