Texas Department of Health

William R. Archer III, M.D.
Commissioner

Drugs and Medical Devices Division
1100 West 49th Street
Austin, Texas 78756-3199
512/ 719-0237

Charles E. Bell, M.D.
Executive Deputy Commissioner

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IMPORTANT NOTICE FOR MEDICAL DEVICE MANUFACTURERS

This notice is to advise you that the Texas Department of Health (TDH) has adopted new sections to 25 Texas Administrative Code (TAC), §§91.101 - 91.601, concerning Bloodborne Pathogen Control. The proposed rules were approved by the Texas Board of Health and published in the March 10, 2000, issue of the *Texas Register* (25 TexReg 1941). Following a 45 day public comment period, final rules were adopted and published in the August 11, 2000, issue of the *Texas Register* (25 TexReg 7704). The rules became effective on September 1, 2000. A copy of the rules is enclosed for your reference. We encourage you to read and become familiar with the new sections.

These sections were required by Health and Safety Code, Chapter 81, Subchapter H, which was added by Chapter 1411 (House Bill 2085), §§26.01 - 26.03, 76th Legislature, to extend the protections provided to employees of private entities by Occupational Safety and Health Administration (OSHA) rules, to employees of state and local governments, and for related purposes.

The new rules include provisions that require the TDH to establish and maintain a list of registered needleless system devices and sharps devices with engineered sharps injury protection in order to assist state and local governments in implementing bloodborne pathogen control programs. The devices included on this list are believed to be commercially available and as such shall have conformed to any applicable marketing clearance requirements established by the U.S. Food and Drug Administration and in effect at the time of their introduction into commerce. This list contains only those devices that are the subject of a registration application submitted to and reviewed by TDH prior to inclusion on the list. Annual registration of a device is voluntary and does not constitute an endorsement or recommendation of such device by TDH.

If you are interested in registering a needless system device or sharps device with engineered sharps injury protection, please complete the enclosed application form and submit with the appropriate registration fee to the Texas Department of Health, 1100 W. 49th Street, Austin, Texas 78756. If you have any questions regarding this notice or desire additional information concerning device registration, please contact the Bureau of Food and Drug Safety's Drugs and Medical Devices Division at (512) 719-0237 or visit our Internet Website at *http://www.tdh.state.tx.us/bfds/dmd/bloodborne.html*.