



FDA News

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FDA Provides Information on Investigation into Human Tissue for Transplantation

The Food and Drug Administration (FDA) is notifying the public of its investigation of human tissue recovered by Biomedical Tissue Services, Ltd. (BTS) of Ft. Lee, NJ, and sent to tissue processors. Some of this tissue may have been implanted into patients from early 2004 to September 2005. The tissue was recovered by BTS from human donors who may not have met FDA donor eligibility requirements and who may not have been properly screened for certain infectious diseases. At this time, the implicated tissues from BTS include human bone, skin, and tendons. These products represent only a small percentage of the overall U.S. tissue supply.

While no adverse reactions related to these tissues have been reported to FDA at this time, because of the potential lack of proper screening of the tissue donors, some recipients of the tissues may be at increased risk of infections that could potentially be transmitted through tissues. FDA and the Centers for Disease Control and Prevention (CDC) believe the risks from these tissues are low because the tissues were routinely processed using methods that help to reduce the risk of infectious disease; however, the actual infectious risk is unknown.

FDA's requirements to determine donor eligibility include important steps to ensure that donors do not harbor infections that could be transmitted to recipients. These steps include reviewing the donor's medical history and other factors, physically assessing the donor, and testing for relevant communicable diseases that may place the donor at an increased risk of infections that could then unintentionally be transmitted to recipients through the tissues.

The following tissue processors received tissue from BTS:

- LifeCell Corporation of Branchburg, NJ
- Lost Mountain Tissue Bank of Kennesaw, GA
- Blood and Tissue Center of Central Texas in Austin, TX
- Tutogen Medical, Inc., of Alachua, FL
- Regeneration Technologies, Inc., of Alachua, FL

These firms already have voluntarily recalled all unused tissue remaining in inventory and are working cooperatively with FDA to ensure that the implanting physicians whose patients may have received the products are properly notified. Physicians who implanted tissue from BTS should have been contacted at this time by the receiving health care facility.

FDA and CDC recommend that implanting physicians inform their patients that they may have received tissue from a donor for whom an adequate donor eligibility determination was not performed. While the overall infectious risk is likely low, FDA and CDC recommend that physicians offer to provide patients access to appropriate infectious disease testing. The relevant communicable diseases for which a tissue donor is required to be tested are HIV-1 and 2 (the viruses that cause AIDS), hepatitis B virus, hepatitis C virus, and syphilis. Physicians who still have concerns or questions about the source of the tissue should contact the health care facility where the procedure was performed. FDA will continue its investigation into this matter and will issue further public health updates, as

needed.

Patients and physicians should report any infectious disease possibly related to a tissue transplant to the processing firms, who then should notify FDA. Patients and physicians who wish to notify FDA directly of such infectious disease should report via FDA's MedWatch reporting program at <http://www.fda.gov/medwatch>.

Additional information is available on FDA's web site at <http://www.fda.gov/cber/recalls.htm> and by calling 1-800-835-4709.

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