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FDA Orders Biomedical Tissue Services, Ltd., to Cease Manufacturing and to Retain Existing Inventories of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)

Under its comprehensive framework for ensuring the safety of human tissue products, the U.S. Food and Drug Administration (FDA) today ordered Biomedical Tissue Services, Ltd. (BTS), of Fort Lee, NJ, a human tissue-recovery firm, and its CEO and Executive Director of Operations, Michael Mastromarino, D.D.S., to immediately cease all manufacturing operations. All tissue products initially recovered from human donors by BTS were recalled. FDA is carefully monitoring these recalls to account for all of the tissue distributed.

"FDA's investigation of BTS revealed serious and widespread deficiencies in their manufacturing practices that provide the agency reason to believe that allowing the firm to manufacture would present a danger to public health by increasing the risk of communicable disease transmission," said Margaret O'K. Glavin, FDA's Associate Commissioner for Regulatory Affairs.

"FDA's current regulatory framework for Human Tissue and Cellular and Tissue Based Products (HCT/Ps) provides strong measures that the agency can utilize to prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps, and require firms to screen and test donors for relevant communicable disease agents and diseases and to ensure that HCT/Ps are processed in a way that prevents communicable disease contamination and cross-contamination," added Jesse L. Goodman, MD, MPH, director of FDA's Center for Biologics Evaluation and Research.

The FDA order to cease manufacturing and to retain HCT/Ps requires BTS to suspend any and all manufacturing steps, including but not limited to the recovery and shipment of HCT/Ps. FDA's inspection of BTS uncovered serious violations of the regulations governing donor screening and record keeping practices, as well as failures to follow their own standard operating procedures (SOPs), failure to recover HCT/Ps in a manner that does not cause contamination or cross-contamination during recovery, and failure to adequately control environmental conditions. Despite records maintaining otherwise, the firm had inadequately screened donors for risk factors for, or clinical evidence of, relevant communicable disease agents and diseases. In addition, FDA found numerous instances where death certificates maintained in BTS' files were at variance with the death certificates FDA obtained from the state where the death occurred, on important information such as cause, place, and time of death, and the identity of the next of kin. After initially focusing efforts on assessing the safety of distributed tissues and facilitating the appropriate recalls, the Agency has determined that these violations, because of their serious nature, constitute a danger to health and is taking this unprecedented action.

FDA continues to investigate BTS' activities and to work cooperatively with tissue processors and appropriate federal, state and local authorities, and will take further actions as needed.

You can view a copy of the BTS Order of Cessation at: www.fda.gov/cber/compl/bts013106.htm.

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