




# South Texas Blood & Tissue Center

“Serving the community for over 30 years”

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543 Expiration Date: 8/31/10

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> <small>(See reverse side for instructions)</small>		1. REGISTRATION NUMBER (Field Establishment Identifier)  FEI: 0001676815	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA: 22-DEC-2009 DISTRICT: Dallas PRINTED BY FDA: 23-FEB-2010																																																																																																																																																																																																																																													
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>																																																																																																																																																																																																																																															
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. FEI: 0001676815 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps			11. HCT/PS DESCRIBED IN 21 CFR 1271.10 12. HCT/PS REGULATED AS MEDICAL DEVICES 13. HCT/PS REGULATED AS BIOLOGICAL DRUGS 14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																												
4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code) South Texas Blood & Tissue Center 6211 IH 10 West at First Part Ten Blvd San Antonio, Texas 78201  a. PHONE 210-731-5555 EXT 1541 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<table border="1"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> <tbody> <tr><td>a. Bone</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr> <tr><td>b. Cartilage</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td>X</td><td>X</td><td>X</td></tr> <tr><td>c. 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5. ENTER CORRECTIONS TO ITEM 4		6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, county, and post office code) South Texas Blood and Tissue Center Attn: Norman D. Kalmin, MD 6211 IH 10 West at First Part Ten Blvd San Antonio, Texas 78201  a. PHONE 210-731-5565 EXT _____																																																																																																																																																																																																																																															
7. ENTER CORRECTIONS TO ITEM 6		8. U.S. AGENT  a. E-MAIL _____ b. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Norman D. Kalmin, MD b. E-MAIL patricia.cappelli@bloodtissue.org c. TITLE President/CEO & Medical Director d. DATE 18-DEC-2009																																																																																																																																																																																																																																															

FORM FDA 3156 (4/08)



Main Office: 6211 IH 10 West at First Part Ten Blvd. • San Antonio, Texas 78201 • (210) 731-5555 • 1-800-292-5534 • FAX (210) 731-5505  
Victoria Branch: 1109 Sam Houston Drive • Victoria, Texas 77901 • (361) 576-3651 • 1-800-345-4967 • FAX (361) 573-1621