

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(Field Establishment Identifier)

FEI: 3000779542

2. REASON FOR SUBMISSION

- a. INITIAL REGISTRATION / LISTING
- b. ANNUAL REGISTRATION / LISTING
- c. CHANGE IN INFORMATION
- d. INACTIVE

VALIDATION—FOR FDA USE ONLY

VALIDATED BY FDA:08-DEC-2010
DISTRICT: Dallas
PRINTED BY FDA:08-DEC-2010

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																
<p>3. OTHER FDA REGISTRATIONS</p> <p>a. BLOOD FDA 2830 NO. _____</p> <p>b. DEVICES FDA 2891 NO. _____</p> <p>c. DRUG FDA 2656 NO. _____</p> <p>4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Bone Bank Allografts 4808 Research Drive San Antonio, Texas 78240</p> <p>a. PHONE 210-696-7616 EXT _____</p> <p>b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)</p> <p>c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY</p> <p>5. ENTER CORRECTIONS TO ITEM 4</p> <p>6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Bone Allografts Attn: Jerry Y. Chang 4808 Research Drive San Antonio, Texas 78240</p> <p>a. PHONE 352-256-2707 EXT _____</p> <p>7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____</p> <p>8. U.S. AGENT</p> <p>a. E-MAIL _____</p> <p>9. REPORTING OFFICIAL'S SIGNATURE</p> <p>a. TYPED NAME Jerry Y. Chang</p> <p>b. E-MAIL jchang@bonebank.com</p> <p>c. TITLE Director of QA/Regulatory Affairs d. DATE 18-NOV-2010</p>	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 DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)			
Types of HCT / Ps	Establishment Functions																
Recover	Screen	Test	Package	Process	Store	Label	Distribute	11	12	13							
a. Bone						X	X	X	X								
b. Cartilage						X	X	X	X								
c. Cornea																	
d. Dura Mater																	
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
f. Fascia						X	X	X	X								
g. Heart Valve																	
h. Ligament						X	X	X	X								
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
j. Pericardium						X	X	X	X								
k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
l. Sclera																	
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
n. Skin						X	X	X	X								
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
p. Tendon						X	X	X	X								
q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
r. Vascular Graft																	
s.																	
t.																	
u.																	
v.																	