

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> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3006226621	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:22-JUN-2011 DISTRICT: Dallas PRINTED BY FDA:22-JUN-2011
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION								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)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											
a. BLOOD FDA 2830 NO. _____  b. DEVICES FDA 2891 NO. _____  c. DRUG FDA 2656 NO. _____	Establishment Functions											
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute			
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Texas Human Biologics 14805 Omicron Drive Suite 102 San Antonio, Texas 78245  a. PHONE 210-798-2442 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone				X	X	X	X		X		
	b. Cartilage				X	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		X		
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	g. Heart Valve											
	h. Ligament											
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Texas Human Biologics Attn: Jerry Y. Chang 14805 Omicron Drive Suite 102 San Antonio, Texas 78245  a. PHONE 800-397-0088 EXT _____ b. PHONE _____	j. Pericardium				X	X	X	X		X		
	k. Peripheral Blood Stem <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											
<b>7. ENTER CORRECTIONS TO ITEM 6</b>	n. Skin									D		
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
<b>8. U.S. AGENT</b>  a. E-MAIL _____	p. Tendon				X	X	X	X		X		
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
	r. Vascular Graft											
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Jerry Y. Chang b. E-MAIL jchang@bonebank.com c. TITLE Director, QA/RA d. DATE 21-JUN-2011	s.											
	t.											
	u.											
	v.											