

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 (FDA Establishment Identifier) FEI: 3006226621	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:18-NOV-2016 DISTRICT: Dallas PRINTED BY FDA:15-DEC-2016
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION												14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS	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		
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Establishment Functions												
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
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			
	g. Heart Valve												
	h. Ligament				X	X	X	X		X			
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	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												
5. ENTER CORRECTIONS TO ITEM 4	n. Skin				X	X	X	X		X			
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	p. Tendon				X	X	X	X		X			
Texas Human Biologics Attn: Shonnah D. Schlabach 14805 Omicron Drive Suite 102 San Antonio, Texas 78245 a. PHONE 800.397.0088 EXT _____ b. PHONE _____	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
7. ENTER CORRECTIONS TO ITEM 6	r. Vascular Graft												
8. U.S. AGENT	s. Placenta				X	X	X	X		X			
9. REPORTING OFFICIAL'S SIGNATURE	t. Amniotic Fluid				X	X	X	X		X			
a. TYPED NAME Shonnah D. Schlabach b. E-MAIL sschlabach@bonebank.com c. TITLE Quality Assurance Team Lead d. DATE 17-NOV-2016	u.												
	v.												