

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: 1000507143	2. REASON FOR SUBMISSION 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	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:13-JAN-2017 DISTRICT: Atlanta PRINTED BY FDA:03-FEB-2017
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------

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					
	Establishment Functions																	
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute									
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Xytex Laboratories 1100 Emmett Street Augusta, Georgia 30904 a. PHONE 706-733-0130 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone																	
	b. Cartilage																	
	c. Cornea																	
	d. Dura Mater																	
	e. Embryo <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous							X			X		X					
	f. Fascia																	
	g. Heart Valve																	
	h. Ligament																	
	i. Oocyte <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input type="checkbox"/> Anonymous										X		X		X			
	j. Pericardium																	
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																		
l. Sclera																		
m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous	X	X			X	X	X	X	X	X								
n. Skin																		
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																		
8. U.S. AGENT	p. Tendon																	
a. E-MAIL 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME James T. Spradlin, M.D. b. E-MAIL tspradlin@xytex.com c. TITLE Chief Medical & Laboratory Director d. DATE 12-JAN-2017	q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X	X			X	X	X	X	X								
	r. Vascular Graft																	
	s. Testicular Tissue								X		X		X					
	t. Umbilical Cord	X	X			X	X	X	X	X								
	u.																	
v.																		