

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> (FDA Establishment Identifier)  FEI: 1000507143	<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	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:13-JAN-2017 DISTRICT: Atlanta PRINTED BY FDA:03-FEB-2017
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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					
	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) 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																	
<b>5. ENTER CORRECTIONS TO ITEM 4</b>  <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Xytex Laboratories Attn: James T. Spradlin, M.D. 1100 Emmett Street Augusta, Georgia 30904  a. PHONE 706-733-0130 EXT _____ <b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____	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	X							
	n. Skin																	
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
	p. Tendon																	
	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	X	X							
	r. Vascular Graft																	
	s. Testicular Tissue							X			X	X						
	t. Umbilical Cord	X	X		X	X	X	X	X	X	X							
u.																		
v.																		