

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> <i>(See reverse side for instructions)</i>		<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3001237886	<b>2. REASON FOR SUBMISSION</b> 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:29-DEC-2010 DISTRICT: Atlanta PRINTED BY FDA:05-JAN-2011									
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>			11. HCT/PS DESCRIBED IN 21 CFR 127.110 12. HCT/PS REGULATED AS MEDICAL DEVICES 13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS 14. PROPRIETARY NAME(S)								
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>											
<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i> Georgia Eye Bank, Inc. 5605 Glenridge Drive, NE Suite 250 Atlanta, Georgia 30342  a. PHONE 404-264-1900 EXT 228 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY  <b>5. ENTER CORRECTIONS TO ITEM 4</b>  <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Georgia Eye Bank, Inc. Attn: Susan A. Littlefield, MS 5605 Glenridge Drive, NE Suite 250 Atlanta, Georgia 30342  a. PHONE 404-264-1900 EXT 228 <b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____  <b>8. U.S. AGENT</b>  a. E-MAIL _____ <b>9. REPORTING OFFICIAL'S SIGNATURE</b> <i>Susan A. Littlefield</i> a. TYPED NAME Susan A. Littlefield, MS b. E-MAIL susan@georgiaeyebank.org c. TITLE Manager, Quality Services d. DATE 22-DEC-2010		<b>Establishment Functions</b>											
		<b>Types of HCT / Ps</b>				Recover	Screen	Test	Package	Process	Store	Label	Distribute
		a. Bone											
		b. Cartilage											
		c. Cornea	X	X			X	X	X	X	X	X	
		d. Dura Mater											
		e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		f. Fascia											
		g. Heart Valve											
		h. Ligament											
i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
j. Pericardium													
k. Peripheral Blood Stem Cells	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
l. Sclera	X	X		X	X	X	X	X	X				
m. Semen	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
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 Stem Cells	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
r. Vascular Graft													
s.													
t.													
u.													
v.													