

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: 3000215032	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:02-DEC-2016 DISTRICT: New Orleans PRINTED BY FDA:15-DEC-2016
---	--	--	--

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION	11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																																														
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2">11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10</th> <th rowspan="2">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> </table>					Types of HCT / Ps	Establishment Functions								11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																																									
Types of HCT / Ps	Establishment Functions								11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																																							
	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																																																											
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Baton Rouge Regional Eye Bank 7777 Hennessy Blvd., Ste. 1005 Baton Rouge, Louisiana 70808 a. PHONE 225-766-8996 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:30%;">a. Bone</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>b. Cartilage</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>c. Cornea</td> <td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td></td><td></td> </tr> <tr> <td>d. Dura Mater</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>f. Fascia</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>g. Heart Valve</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>h. Ligament</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>j. Pericardium</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>l. Sclera</td> <td></td><td></td><td></td><td></td><td></td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td></td><td></td> </tr> <tr> <td>m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>n. Skin</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>p. Tendon</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>r. Vascular Graft</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>s.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>t.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>u.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>v.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>					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 <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													l. Sclera						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 <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													r. Vascular Graft													s.													t.													u.													v.												
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 <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																			
l. Sclera						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 <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																			
r. Vascular Graft																																																																																																																																																																																																																																																																																																			
s.																																																																																																																																																																																																																																																																																																			
t.																																																																																																																																																																																																																																																																																																			
u.																																																																																																																																																																																																																																																																																																			
v.																																																																																																																																																																																																																																																																																																			

5. ENTER CORRECTIONS TO ITEM 4					
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Baton Rouge Regional Eye Bank Attn: Jamie H. Collier, MA, CEBT 7777 Hennessy Blvd., Ste. 1005 Baton Rouge, Louisiana 70808 a. PHONE 225-766-8996 EXT _____					
7. ENTER CORRECTIONS TO ITEM 6	b. PHONE _____				
8. U.S. AGENT a. E-MAIL _____					
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Jamie H. Collier, MA, CEBT b. E-MAIL jamie.collier@ololrnc.com c. TITLE Executive Director	d. DATE 01-DEC-2016				