

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: 3010125286	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:30-NOV-2017 DISTRICT: New Jersey PRINTED BY FDA:27-JAN-2018
---	--	--	---

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION	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	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 CFR 1271.10</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 CFR 1271.10	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 CFR 1271.10	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) New York Blood Center 825 Route 73 North Suite H Marlton, New Jersey 08053 a. PHONE 732-220-7002 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>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></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>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</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 colspan="13"> <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous </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</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 colspan="13"> <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous </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</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 colspan="13"> <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic </td></tr> <tr><td>l. Sclera</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>m. Semen</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 colspan="13"> <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous </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</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 colspan="13"> <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic </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</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 colspan="13"> <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic </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													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 checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic													l. Sclera													m. Semen													<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													n. Skin													o. Somatic Cell Therapy Products													<input checked="" 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																																																																																																																																																																																																																																																																																																																																																																																	
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 checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																	
l. Sclera																																																																																																																																																																																																																																																																																																																																																																																	
m. Semen																																																																																																																																																																																																																																																																																																																																																																																	
<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																	
n. Skin																																																																																																																																																																																																																																																																																																																																																																																	
o. Somatic Cell Therapy Products																																																																																																																																																																																																																																																																																																																																																																																	
<input checked="" 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) New York Blood Center Attn: Christine Driscoll 1200 Prospect Avenue Westbury, New York 11590 a. PHONE 516-478-5264 EXT _____ b. PHONE _____					
7. ENTER CORRECTIONS TO ITEM 6					
8. U.S. AGENT a. E-MAIL _____					
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Christine Driscoll b. E-MAIL cdriscoll@nybc.org c. TITLE Director, Regulatory Affairs d. DATE 29-NOV-2017					