

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
 (field Establishment Identifier)
FEI: 3000718321

2. REASON FOR SUBMISSION
 a. INITIAL REGISTRATION / LISTING
 b. ANNUAL REGISTRATION / LISTING
 c. CHANGE IN INFORMATION
 d. INACTIVE

VALIDATION - FOR FDA USE ONLY
 VALIDATED BY FDA: 9-NOV-2011
 DISTRICT: Detroit
 PRINTED BY FDA: 23-NOV-2011

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543, Expiration Date: 1/31/14

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION																																																																																																																																																																																																																																																																																																																														
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS																																																																																																																																																																																																																																																																																																																														
2. BLOOD FDA 2830 NO. _____		<table border="1"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="10">Establishment Functions</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> <th>11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th>12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th>13. HCT/PS REGULATED AS BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</th> </tr> </thead> <tbody> <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>X</td> <td>X</td> <td></td> <td>X</td> <td>X</td> <td>X</td> <td>X</td> <td>X</td> <td>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</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</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 Cells</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>X</td> <td>X</td> <td></td> <td>X</td> <td>X</td> <td>X</td> <td>X</td> <td>X</td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>m. Spleen</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</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 Stem Cells</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> </tbody> </table>										Types of HCT / Ps	Establishment Functions										Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)	a. Bone													b. Cartilage													c. Cornea	X	X		X	X	X	X	X	X				d. Dura Mater													e. Embryo													f. Fascia													g. Heart Valve													h. Ligament													i. Oocyte													j. Pericardium													k. Peripheral Blood Stem Cells													l. Sclera	X	X		X	X	X	X	X	X				m. Spleen													n. Skin													o. Somatic Cell Therapy Products													p. Tendon													q. Umbilical Cord Blood Stem Cells													r. Vascular Graft													s. _____													t. _____													u. _____													v. _____												
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