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eHCTERS - Registration Information

Submitted Registration Information

This information has been submitted to the FDA
 Please Remember Your Confirmation Number to Reference this FORM FDA - 3356 Submission
YOUR CONFIRMATION NUMBER IS: 39343
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 This application is no longer accessible using your pre-confirmation number.

FEI: 3004125629

Other FDA Registrations

- Blood FDA 2830
- Devices FDA 2891
- Drug FDA 2656

Reason for Submission

- Initial Registration/Listing
- Annual Registration/Listing
- Change in Information
- In-Activate Registration

Physical Location

Legal Name: DCI Donor Services dba Tennessee Donor Services (Knoxville)
 Street Address: 7015 Middlebrook Pike
 City: Knoxville
 State: Tennessee
 Postal Code: 37909
 Country: United States
 Phone: 865-588-1031 ext.

Reporting Official Information

First Name: Monika
 Last Name: Liggins
 Title: Manager of Quality and Compliance
 Phone: 615-564-3660 Ext.
 E-Mail Address: mliggens@dcids.org

Mailing Address of Reporting Official

Institution Name: Tennessee Donor Services
 Street Address: 1600 Hayes St.
 Suite 300
 City: Nashville
 State: Tennessee
 Postal Code: 37203
 Country: United States

HCT/P Listing Information

	Types of HCT/P's	HCT/P's Described in 21 CFR 1271.10	HCT/P's Regulated as Medical Devices	HCT/P's Regulated as Drugs or	Proprietary Names

				Biological Drugs
a. Bone	X			
b. Cartilage	X			
c. Cornea	X			
d. Dura Mater				
e. Embryo				
f. Fascia	X			
g. Heart Valve	X			
h. Ligament	X			
i. Oocyte				
j. Pericardium	X			
k. Peripheral Blood Stem Cells				
l. Sclera	X			
m. Semen				
n. Skin	X			
o. Somatic Cell Therapy Products				
p. Tendon	X			
q. Umbilical Cord Blood Stem Cells				
r. Vascular Graft	X			
s. Nerve Tissue	X			

HCT/P Listing - Function Information

	Types of HCT/P's	Recover	Screen	Test	Package	Process	Store	Label	Distribute
a. Bone			<input checked="" type="checkbox"/>						
b. Cartilage			<input checked="" type="checkbox"/>						
c. Cornea			<input checked="" type="checkbox"/>						
d. Dura Mater									
e. Embryo									
f. Fascia			<input checked="" type="checkbox"/>						
g. Heart Valve			<input checked="" type="checkbox"/>						
h. Ligament			<input checked="" type="checkbox"/>						
i. Oocyte									
j. Pericardium			<input checked="" type="checkbox"/>						
k. Peripheral Blood Stem Cells									
l. Sclera			<input checked="" type="checkbox"/>						
m. Semen									
n. Skin			<input checked="" type="checkbox"/>						
o. Somatic Cell Therapy Products									
p. Tendon			<input checked="" type="checkbox"/>						
q. Umbilical Cord Blood Stem Cells									
r. Vascular Graft			<input checked="" type="checkbox"/>						
s. Nerve Tissue			<input checked="" type="checkbox"/>						

HCT/P Listing - Donor Information

	Types of HCT/P's	SIP	Directed	Anonymous	Autologous	Family Related	Allogeneic
e. Embryo							
i. Oocyte							
k. Peripheral Blood Stem Cells							
m. Semen							
o. Somatic Cell Therapy Products							
q. Umbilical Cord Blood Stem Cells							

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)

eHCTERS v02.08.00
Updated 06/27/2014

FORM FDA - 3356 (7/17) FORM APPROVED:OMB No.0910-0543
Expiration Date: 6/30/2020

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