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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: 39923

Please print this document and maintain as confirmation of your submission.
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FEI: 3005233711

Other FDA Registrations

- Blood FDA 2830 3006611631
- 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: The Blood Center
Street Address: 1310 J.W. Davis Drive
City: Hammond
State: Louisiana
Postal Code: 70403
Country: United States
Phone: 985-340-2323 ext.

Reporting Official Information

First Name: Lucretia
Last Name: Boudreaux MT(ASCP) CQA (ASQ)
Title: Director, QA and Compliance
Phone: 985-340-2323 Ext.
E-Mail Address: lboudreaux@thebloodcenter.org

Mailing Address of Reporting Official

Institution Name: The Blood Center
Street Address: 1310 J. W. Davis Drive
City: Hammond
State: Louisiana
Postal Code: 70403
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 Biological Drugs	Proprietary Names
a.	Bone	X			
b.	Cartilage	X			

c.	Cornea	X			
d.	Dura Mater	X			
e.	Embryo	X			
f.	Fascia	X			
g.	Heart Valve	X			
h.	Ligament	X			
i.	Oocyte	X			
j.	Pericardium	X			
k.	Peripheral Blood Stem Cells	X		X	
l.	Sclera	X			
m.	Semen	X			
n.	Skin	X			
o.	Somatic Cell Therapy Products	X		X	
p.	Tendon	X			
q.	Umbilical Cord Blood Stem Cells	X		X	
r.	Vascular Graft	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			<input checked="" type="checkbox"/>					
e.	Embryo			<input checked="" type="checkbox"/>					
f.	Fascia			<input checked="" type="checkbox"/>					
g.	Heart Valve			<input checked="" type="checkbox"/>					
h.	Ligament			<input checked="" type="checkbox"/>					
i.	Oocyte			<input checked="" type="checkbox"/>					
j.	Pericardium			<input checked="" type="checkbox"/>					
k.	Peripheral Blood Stem Cells			<input checked="" type="checkbox"/>					
l.	Sclera			<input checked="" type="checkbox"/>					
m.	Semen			<input checked="" type="checkbox"/>					
n.	Skin			<input checked="" type="checkbox"/>					
o.	Somatic Cell Therapy Products			<input checked="" type="checkbox"/>					
p.	Tendon			<input checked="" type="checkbox"/>					
q.	Umbilical Cord Blood Stem Cells			<input checked="" type="checkbox"/>					
r.	Vascular Graft			<input checked="" type="checkbox"/>					

HCT/P Listing - Donor Information

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

Select New Establishment

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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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