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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 registration submission YOUR CONFIRMATION NUMBER IS: 69327

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

This application is no longer accessible using your pre-confirmation number.									
		FEI: (0002577603						
Other FDA Registration	ons		Reason for Subr	nission					
Blood Devices Drug	0002577603 ☐ Initial Registration/Listing ☐ Annual Registration/Listing ☐ Change in Information ☐ In-Activate Registration								
Physical Location									
		of Delmarva, A Division	of New York Blood C	Center Inc.					
Street Address:		Drive							
•	Newark								
	Delaware								
Postal Code:	UNITED ST	ATEC							
•	302-737-84								
		03 EXI.730							
Reporting Official In									
Last Name:		Jessica A.							
		Solano Regulatory & Audit Compliance Specialist							
	302-737-84		Joianst						
E-Mail Address:									
Mailing Address of		-							
•		of Delmarva, A Division	of New York Blood (Center Inc					
Street Address:			or now ronk blood c	70.11.01, 1110.					
	Newark								
State: Delaware									
Postal Code: 19713									
Country: UNITED STATES									
HCT/P Listing Information									
Types of HC	T/Ps	HCT/Ps Described in 21 CFR 1271.10	Date of Discontinuance (mm/dd/yyyy)	Date of Resumption (mm/dd/yyyy)	Proprietary Names				
Amniotic Membrane									

Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Date of Discontinuance (mm/dd/yyyy)	Date of Resumption (mm/dd/yyyy)	Proprietary Names
Amniotic Membrane				
Blood Vessel				
Bone				
Cardiac Tissue - non-valved				
Cartilage				

Cornea			
Dura Mater			
Embryo			
Fascia			
Heart Valve			
HPC Apheresis	Х		
HPC Cord Blood			
Ligament			
Nerve Tissue			
Oocyte			
Ovarian Tissue			
Pancreatic Islet Cells -			
autologous			
Parathyroid			
Pericardium			
Peripheral Blood Mononuclear			
Cells			
Peritoneal Membrane			
Sclera			
Semen			
Skin			
Tendon			
Testicular Tissue			
Tooth Pulp			
Umbilical Cord Tissue			

HCT/P Listing - Function Information

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane								
Blood Vessel								
Bone								
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis	ے	lacksquare		lacktriangledown			V	lacksquare
HPC Cord Blood								
Ligament								
Nerve Tissue								
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium								
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera								
Semen								
Skin								
Tendon								
Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue								

HCT/P Listing - Donor Information

Types of HCT/Ps SIP Directed Anonymous Autologous Family Relate					
	SIP	Directed	Anonymous	Autologous	Family Related

Embryo			
HPC Apheresis		lacksquare	
HPC Cord Blood			
Oocyte			
Peripheral Blood Mononuclear Cells			
Semen			

Select New Establishment CBER On-Line Main Menu

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 v02.13.04 Updated 07/29/2024

OMB Control Number 0910-0543; Expiration Date 08/31/2026 See OMB Burden Statement

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