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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: 63546

Please print this document and maintain as confirmation of your submission. This application is no longer accessible using your pre-confirmation number.							
	FEI: 3	3001518813					
Other FDA Registrations		Reason for Sub	mission				
□ Blood		☐ Initial Pegis	tration/Listing				
Devices		✓ Annual Reg	-				
Drug		Change in I	•				
Diug			Registration				
		□ III-Activate	Registration				
Physical Location							
Legal Nam	ne: Lions Eye Bank for l	Long Island					
Street Addres	ss: Northwell Health						
	900 Franklin Avenue	e					
	ty: Valley Stream						
	te: New York						
Postal Cod							
	ry: UNITED STATES						
	ne: 516-256-6990 ext.						
Reporting Official Information							
First Nam	ne: Kristen D.						
	ne: Conte						
Tit	le: Executive Director						
Phor	ne: 516-256-6690 Ext.	e: 516-256-6690 Ext.					
E-Mail Addres	E-Mail Address: kconte1@northwell.edu						
Mailing Address of Reporting O	fficial						
Institution Nam	ne: Lions Eye Bank for l	Long Island					
Street Addres	ss: Northwell Health						
	900 Franklin Avenue	Э					
Ci	ty: Valley Stream						
Sta	te: New York						
Postal Cod	de: 11580						
Count	ry: UNITED STATES						
HCT/P Listing Information							
	HCT/Ps	Date of	Date of	,			
Types of HCT/Ps	Described in 21 CFR 1271.10	Discontinuance (mm/dd/yyyy)	Resumption (mm/dd/yyyy)	Proprietary Names			
Amniotic Membrane	117 Z 1 O1 10 127 1.10	(IIIII/GG/yyy)	(iiiii/dd/yyyy)				
Blood Vessel							

Bone

Cardiac Tissue - non-valved			
Cartilage			
Cornea	Х		
Dura Mater	Λ		
Embryo			
Fascia			
Heart Valve			
HPC Apheresis			
HPC Cord Blood			
Ligament			
Nerve Tissue			
Oocyte			
Ovarian Tissue			
Pancreatic Islet Cells -			
autologous			
Parathyroid			
Pericardium			
Peripheral Blood Mononuclear			
Cells			
Peritoneal Membrane			
Sclera	X		
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	lacksquare	\mathbf{V}	lacksquare	ے	lacksquare	\blacksquare	lacksquare	lacksquare
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis								
HPC Cord Blood								
Ligament								
Nerve Tissue								
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium								
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera	\mathbf{V}	\mathbf{V}	lacksquare	lacksquare	lacksquare	$\overline{\mathbf{V}}$	lacksquare	lacksquare
Semen								
Skin								
Tendon								
Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue								

HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis					
HPC Cord Blood					
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

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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 v02.13.02 Updated 10/13/2023

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

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