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FEI: 3014623201

Pre-Confirmation Number: 64578

Legal Name: Lucina BioSciences, LLC

Today's Date: 02/19/2024

Registration | Address | Reporting Official | U.S. Agent | Importer | HCT/P Listing | Function | Donor | Additional Info | Report | Save

eHCTERS - Registration Information

Preview your Registration Information

**THIS INFORMATION HAS NOT BEEN SUBMITTED TO THE FDA
PLEASE REVIEW YOUR REGISTRATION INFORMATION
PRESS THE "SUBMIT TO FDA" BUTTON at the bottom of the page TO CONTINUE**

Note: The registration information has been saved but not submitted to the FDA. Unfinished submissions are accessible for 30 days. If the registration is not completed and submitted in that period, data will be archived and will not be accessible.

Your Pre-Confirmation Number is 64578

Enter this number on the main screen to access your unfinished submission.

FEI: 3014623201

Other FDA Registrations

- Blood
 Devices
 Drug

Reason for Submission

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

Physical Location

Legal Name: Lucina BioSciences, LLC
Street Address: 14707 E 2nd Avenue GL150
CO
City: Aurora
State: Colorado
Postal Code: 80011
Country: UNITED STATES
Phone: 303-954-0034 ext.

Reporting Official Information

First Name: Tracee
Last Name: Gruber
Title: Chief Operating Officer
Phone: 303-954-0034 Ext.
E-Mail Address: tgruber@lucinabio.org

Mailing Address of Reporting Official

Institution Name: Lucina BioSciences, LLC
Street Address: 14707 E 2nd Avenue GL150
CO
City: Aurora
State: Colorado
Postal Code: 80011
Country: UNITED STATES

HCT/P Listing Information

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	X			Procenta, proMATRIX, ProSTA

Blood Vessel				
Bone				
Cardiac Tissue - non-valved				
Cartilage				
Cornea				
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				
Semen				
Skin				
Tendon				
Testicular Tissue				
Tooth Pulp				
Umbilical Cord Tissue	X			

HCT/P Listing - Function Information

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Blood Vessel								
Bone								
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
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								
Semen								
Skin								
Tendon								
Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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					

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 v02.13.01
 Updated 10/13/2023

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

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