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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: 44357

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This application is no longer accessible using your pre-confirmation number.

FEI: 3005168462

Other FDA Registrations

- Blood
 Devices 3005168462
 Drug

Reason for Submission

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

Physical Location

Legal Name: Bacterin International Inc.
 Street Address: 600 Cruiser Lane
 City: Belgrade
 State: Montana
 Postal Code: 59714
 Country: United States
 Phone: 406-388-0480 ext.1128

Reporting Official Information

First Name: Casey M.
 Last Name: Ming CTBS
 Title: QA/RA Director
 Phone: 406-388-0480 Ext.1128
 E-Mail Address: cming@xtantmedical.com

Mailing Address of Reporting Official

Institution Name: Bacterin International, Inc.
 Street Address: 600 Cruiser Lane
 City: Belgrade
 State: Montana
 Postal Code: 59714
 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
	X			

Amniotic Membrane				
Blood Vessel				
Bone	X			OsteoSponge, OsteoSelect DBM Putty (and Plus), OsteoWrap, Orbital Wrap HD, OsteoLock, BacFast HD, OsteoSTX, 3Demin
Cardiac Tissue - non-valved				
Cartilage	X			
Cornea				
Dura Mater				
Embryo				
Fascia	X			hMatrix
Heart Valve				
HPC Apheresis				
HPC Cord Blood				
Ligament	X			
Nerve Tissue				
Oocyte				
Ovarian Tissue				
Pancreatic Islet Cells - autologous				
Parathyroid				
Pericardium	X			
Peripheral Blood Mononuclear Cells				
Peritoneal Membrane				
Sclera				
Semen				
Skin	X			hMatrix Dermis, hMatrix PR
Tendon	X			SportMatrix
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						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Blood Vessel								
Bone		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Cardiac Tissue - non-valved								
Cartilage		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Cornea								
Dura Mater								
Embryo								
Fascia		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Heart Valve								
HPC Apheresis								
HPC Cord Blood								
Ligament		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Nerve Tissue								
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								

Sclera								
Semen								
Skin		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Tendon		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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					

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 v02.10.00
11/09/2018

FDA information collection OMB Control number: 0910-0543
Expiration Date: 6/30/2020

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