

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 0001372065	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:07-APR-2017 DISTRICT: New York PRINTED BY FDA:20-APR-2017
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION									11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
	Types of HCT / Ps	Establishment Functions											
		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
a. BLOOD FDA 2830 NO. <u>FEI: 0001372065</u> b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	a. Bone			X						X			
	b. Cartilage			X						X			
	c. Cornea			X						X			
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) University of Roch-Strong Memorial Hospital 601 Elmwood Avenue Box 608 Rochester, New York 14642-0001 a. PHONE 585-275-3189 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input checked="" type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	d. Dura Mater			X						X			
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	f. Fascia			X						X			
	g. Heart Valve			X						X			
	h. Ligament			X						X			
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium			X						X			
	k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X			X	X	X	X	X	X	X		X
	l. Sclera			X						X			
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) University of Rochester Medical Center Attn: Neil Blumberg, MD 601 Elmwood Avenue Box 608 Rochester, New York 14642-0001 a. PHONE 585-275-3189 EXT _____	n. Skin			X						X			
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	p. Tendon			X						X			
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____ 8. U.S. AGENT a. E-MAIL _____	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic					X	X	X		X		X	
	r. Vascular Graft			X						X			
	s. Nerve Tissue			X						X			
	t. Parathyroid	X				X	X	X				X	
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Neil Blumberg, MD b. E-MAIL Neil_Blumberg@urmc.rochester.edu c. TITLE Director Transfusion Medicine d. DATE 06-APR-2017	u. Therapeutic Cells	X			X	X	X	X	X			X	
	v. Adipose Tissue			X						X			