

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: 3013537032	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:29-NOV-2017 DISTRICT: New York PRINTED BY FDA:27-JAN-2018
---	--	--	--

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION														14. PROPRIETARY NAME(S)		
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps									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					
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute				Establishment Functions				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) New York Blood Center 3 Lyon Place Room 200 Ogdensburg, New York 13669 a. PHONE 914-784-4602 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone																
	b. Cartilage																
	c. Cornea																
	d. Dura Mater																
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
	f. Fascia																
	g. Heart Valve																
	h. Ligament																
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
	j. Pericardium																
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) New York Blood Center, Inc. Attn: Christine Driscoll 1200 Prospect Avenue Westbury, New York 11590 a. PHONE 516-478-5264 EXT _____ b. PHONE _____	k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X				X				X				X			
	l. Sclera																
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
	n. Skin																
	o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X					X				X				X		
	p. Tendon																
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
	r. Vascular Graft																
	7. ENTER CORRECTIONS TO ITEM 6 8. U.S. AGENT a. E-MAIL _____	s.															
		t.															
u.																	
v.																	
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Christine Driscoll b. E-MAIL cdriscoll@nybc.org c. TITLE Director, Regulatory Affairs d. DATE 29-NOV-2017																	