


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3006199266	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:17-NOV-2017 DISTRICT: New York PRINTED BY FDA:27-JAN-2018
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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					
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Manhattan Cryobank Inc.  211 East 43rd Street, Suite 1701 New York, New York 10017  a. PHONE 212-396-2796 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 checked="" type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous						X		X	X				
	f. Fascia													
	g. Heart Valve													
	h. Ligament													
	i. Oocyte <input checked="" type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous						X		X	X				
	j. Pericardium													
5. ENTER CORRECTIONS TO ITEM 4	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
	l. Sclera													
	m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous	X	X		X	X	X	X	X	X				
	n. Skin													
	6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Manhattan Cryobank Inc. Attn: Grace M. Centola, Ph.D., HCLD (ABB) 211 East 43rd Street, Suite 1701 New York, New York 10017  a. PHONE 212-396-2796 EXT _____ b. PHONE _____	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
		p. Tendon												
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
		r. Vascular Graft												
		s. Ovarian Tissue						X		X	X			
		t. Testicular Tissue				X	X	X	X	X	X			
u.														
v.														
7. ENTER CORRECTIONS TO ITEM 6														
8. U.S. AGENT  a. E-MAIL _____														
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Grace M. Centola, Ph.D., HCLD (ABB) b. E-MAIL gcentola@manhattancryobank.com c. TITLE Tissue Bank Director d. DATE 16-NOV-2017														

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PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION  
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**ADDITIONAL INFORMATION:**

Testicular Tissue - SIP only

**Proprietary Name(s):**