

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: 3011828815	<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:18-NOV-2015 DISTRICT: Int'l Operations Group PRINTED BY FDA:03-DEC-2015
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION	11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)								
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>												
	<b>Types of HCT / Ps</b>	<b>Establishment Functions</b>											
		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Cryobank Israel LTD  80, Sheshet Hayamim St. Ramat Hasharon 4711201, Israel  a. PHONE 00972 3 5407517 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  k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic  l. Sclera  m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous												
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	n. Skin  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												
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Cryobank Israel LTD Attn: Grace M. Centola, Ph.D. 80, Sheshet Hayamim St. Ramat Hasharon 4711201, Israel  a. PHONE 585-683-1043 EXT _____	s.  t.  u.  v.												
<b>7. ENTER CORRECTIONS TO ITEM 6</b> a. PHONE _____ b. PHONE _____	a. E-MAIL centolag@yahoo.com 585-683-1043												
<b>8. U.S. AGENT</b> Grace M. Centola, Ph.D. Reproductive Laboratory and Tissue Bank Consultant 5125 Delfa Lane, Macedon, New York 14502  a. E-MAIL centolag@yahoo.com 585-683-1043	<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Grace M. Centola, Ph.D. b. E-MAIL centolag@yahoo.com c. TITLE Tissue Bank Consultant d. DATE 17-NOV-2015												