

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
(Field Establishment Identifier)
FEI: 3004561638

2. REASON FOR SUBMISSION
a. INITIAL REGISTRATION / LISTING
b. ANNUAL REGISTRATION / LISTING
c. CHANGE IN INFORMATION
d. INACTIVE

VALIDATION—FOR FDA USE ONLY
VALIDATED BY FDA: 16-NOV-2011
DISTRICT: Detroit
PRINTED BY FDA: 23-NOV-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. _____
b. DEVICES FDA 2891 NO. _____
c. DRUG FDA 2656 NO. _____

4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code)
International Cryogenics, Inc.
189 Townsend Street
Suite 203
Birmingham, Michigan 48009

a. PHONE 248-644-5822 EXT _____
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)
c. TESTING FOR MICRO-ORGANISMS ONLY


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)
International Cryogenics, Inc.
Attn: Kara L. Denham
189 Townsend Street
Suite 203
Birmingham, Michigan 48009

a. PHONE 248-644-5822 EXT _____ b. PHONE _____

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT
a. E-MAIL _____

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Kara L. Denham
b. E-MAIL icinfo@sbcbglobal.net
c. TITLE Laboratory Director
d. DATE 15-NOV-2011

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS

Types of HCT / Ps	Establishment Functions					14. PROPRIETARY NAME(S)					
	Recover	Screen	Test	Package	Process		Store	Label	Distribute		
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 Cells <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	X	
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 Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
r. Vascular Graft											
s.											
t.											
u.											
v.											