See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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: 0002246948

2. REASON FOR SUBMISSION

a. [ ] INITIAL REGISTRATION / LISTING
b. [X] ANNUAL REGISTRATION / LISTING
c. [ ] CHANGE IN INFORMATION
d. [ ] INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:23-DEC-2008
DISTRICT: Florida
PRINTED BY FDA:05-JAN-2009

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)*

Cryo-Cell International, Inc.
700 Brooker Creek Boulevard
Suite 1800
Oldsmar, Florida 34677

a. PHONE 813-749-2100 EXT 2108
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)*

Cryo-Cell International
Attn: Alphonso V. Everett
700 Brooker Creek Boulevard
Suite 1800
Oldsmar, Florida 34677

a. PHONE 813-749-2108 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

A. V. Everett

a. TYPED NAME Alphonso V. Everett
b. E-MAIL aeverett@cryo-cell.com
c. TITLE Director, Quality and Regulatory Affairs d. DATE 03-DEC-2008

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium												
k. Peripheral Blood Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic												
l. Sclera												
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin												
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon												
q. Umbilical Cord Blood Stem Cells [X] Autologous [X] Family Related [ ] Allogeneic	X	X		X	X	X	X	X	X			
r. Vascular Graft												
s.												
t.												
u.												
v.												