See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 1000305999

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:04-DEC-2011
DISTRICT: Cincinnati
PRINTED BY FDA:15-DEC-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)*

AlloSource
615 Elsinore Place, Suite 400
Cincinnati, Ohio 45202

a. PHONE 513-381-2630 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)*

AlloSource
Attn: Jennifer A. Wesbrook,
6278 S. Troy Circle
Centennial, Colorado 80111

a. PHONE 720.873.0213 EXT 2753

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Jennifer A. Wesbrook,

b. E-MAIL jwesbrook@allosource.org

c. TITLE Regulatory Affairs Specialist d. DATE 02-DEC-2011

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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