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: 3000215346

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:04-DEC-2011
DISTRICT: Denver
PRINTED BY FDA:15-DEC-2011

## PART I - ESTABLISHMENT INFORMATION

**3. OTHER FDA REGISTRATIONS**
a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO. FEI: 3000215346
c. DRUG FDA 2656 NO.

**4. PHYSICAL LOCATION** *(Include legal name, number and street, city, state, country, and post office code)*
AlloSource
6278 South Troy Circle
Centennial, Colorado 80111

a. PHONE 720-873-0213 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 South 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 | X | X | X | X | | |
| b. Cartilage | | X | | X | X | X | X | X | X | | | DeNovo NT |
| c. Cornea | | | | | | | | | | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo [ ] SIP [ ] Directed [ ] Anonymous | | | | | | | | | | | | |
| f. Fascia | | X | | X | X | X | X | X | X | | | |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | X | | X | X | X | 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 | X | X | X | X | | | |
| o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic | | | | | | | | | | | | |
| p. Tendon | | X | | X | X | X | X | X | X | | | |
| q. Umbilical Cord Blood Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. Amniotic Membrane | | X | | X | X | X | X | X | X | | | |
| t. Placenta | | X | | | X | | | | X | | | |
| u. Adipose Tissue | | X | | | X | | | | X | | | |
| v. | | | | | | | | | | | | |