

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**  
(FDA Establishment Identifier)

FEI: 3001779663

**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:20-NOV-2014  
DISTRICT: Dallas  
PRINTED BY FDA:04-DEC-2014

**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)

Arkansas Regional Organ Recovery Agency

1701 Aldersgate Road, Suite 4  
Little Rock, Arkansas 72205

- a. PHONE 501-907-9131 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)

Arkansas Regional Organ Recovery Agency  
Attn: Patricia A. Gottschall  
1701 Aldersgate Road, Suite 4  
Little Rock, Arkansas 72205

- a. PHONE 501-749-5731 EXT \_\_\_\_\_
- 7. ENTER CORRECTIONS TO ITEM 6** b. PHONE \_\_\_\_\_

**8. U.S. AGENT**

a. E-MAIL \_\_\_\_\_

**9. REPORTING OFFICIAL'S SIGNATURE**

*Patricia A. Gottschall*  
12/5/2014

- a. TYPED NAME Patricia A. Gottschall
- b. E-MAIL pgottschall@arora.org
- c. TITLE Director of Quality Assurance
- d. DATE 19-NOV-2014

**PART II - PRODUCT INFORMATION**

**10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps**

Types of HCT / Ps	Establishment Functions									11. HCT/PS DESIGNED OR L21:10	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			
b. Cartilage	X	X		X				X		X			
c. Cornea													
d. Dura Mater													
e. Embryo													
<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
f. Fascia	X	X		X				X		X			
g. Heart Valve	X	X		X				X		X			
h. Ligament	X	X		X				X		X			
i. Oocyte													
<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
j. Pericardium	X	X		X				X		X			
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 type="checkbox"/> Anonymous													
n. Skin	X	X		X				X		X			
o. Somatic Cell Therapy Products													
<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
p. Tendon	X	X		X				X		X			
q. Umbilical Cord Blood													
<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
r. Vascular Graft	X	X		X				X		X			
s.													
t.													
u.													
v.													