

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

VALIDATED BY FDA: 19-NOV-2016
DISTRICT: Dallas
PRINTED BY FDA: 16-DEC-2016

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2630 NO. _____
b. DEVICES FDA 2691 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 _____
b. PHONE _____

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL
b. TYPED NAME Patricia A. Gottschall
c. E-MAIL pgottschall@arora.org
d. DATE 18-NOV-2016

PART II - PRODUCT INFORMATION

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				
a. Bone	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>						<input checked="" type="checkbox"/>
b. Cartilage	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>						<input checked="" type="checkbox"/>
c. Cornea										
d. Dura Mater										
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
f. Fascia	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>						<input checked="" type="checkbox"/>
g. Heart Valve	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>						<input checked="" type="checkbox"/>
h. Ligament	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>						<input checked="" type="checkbox"/>
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
j. Pericardium	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>						<input checked="" type="checkbox"/>
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	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>						<input checked="" type="checkbox"/>
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
p. Tendon	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>						<input checked="" type="checkbox"/>
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
r. Vascular Graft	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>						<input checked="" type="checkbox"/>
s.										
t.										
u.										
v.										