See instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 0001671794

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:20-DEC-2016
DISTRICT: Dallas
PRINTED BY FDA:28-DEC-2016

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. FEI: 0001671794

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)

We Are Blood-DBA United Tissue Resources

4300 N. Lamar Blvd.
Austin, Texas 78756

a. PHONE 512-206-1266 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)

We Are Blood
Attn: Wendy R. Bailey, CQA (ASQ)
4300 N. Lamar Blvd.
Austin, Texas 78756

a. PHONE 512-206-1134 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

Wendy R Bailey 01-04-17

a. TYPED NAME Wendy R. Bailey, CQA (ASQ)

b. E-MAIL wbailey@tcms.com

c. TITLE Senior QA Manager d. DATE 19-DEC-2016

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	X	X				X		X	X	X		
b. Cartilage	X	X				X		X	X			
c. Cornea												
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X	X				X		X	X			
g. Heart Valve	X	X				X		X	X	X		
h. Ligament	X	X				X		X	X			
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium	X	X				X		X	X			
k. Peripheral Blood Stem [X] Autologous [ ] Family Related [ ] Allogeneic						X			X			
l. Sclera												
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin	X	X				X		X	X			
o. Somatic Cell Therapy Products [X] Autologous [ ] Family Related [ ] Allogeneic	X			X							X	
p. Tendon	X	X				X		X	X	X		
q. Umbilical Cord Blood [ ] Autologous [ ] Family Related [ ] Allogeneic												
r. Vascular Graft	X	X				X		X	X			
s. Amniotic Membrane						X		X	X			
t. Nerve Tissue	X	X				X		X	X			
u.												
v.												