

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: 3006226621

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

13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS

12. HCT/PS REGULATED AS MEDICAL DEVICES

11. HCT/PS DESCRIBED IN 21 CFR 1271.10

14. PROPRIETARY NAME(S)

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)
 Texas Human Biologics
 14805 Omicron Drive
 Suite 200
 San Antonio, Texas 78245

a. PHONE 210-798-2442 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)
 Texas Human Biologics
 Attn: Russell Adams
 14805 Omicron Drive
 Suite 200
 San Antonio, Texas 78245

a. PHONE 800-397-0088 EXT _____
 b. PHONE _____

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL _____

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Russell Adams
 b. E-MAIL radams@bonebank.com
 c. TITLE Director, QA/RA
 d. DATE 15-DEC-2008

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS

Establishment Functions

Types of HCT / PS	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	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	X			
g. Heart Valve												
h. Ligament				X	X	X	X	X	X			
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
j. Pericardium									D			
k. Peripheral Blood Stem Cells <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	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	X			
q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
r. Vascular Graft												
s.												
t.												
u.												
v.												