South Texas Blood & Tissue Center

"Serving the community for over 30 years"

See Instructions for OMB Statement — FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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: 0001676815

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

VALIDATION–FOR FDA USE ONLY 1
VALIDATED BY FDA:02-JAN-2009
DISTRICT: Dallas
PRINTED BY FDA:05-JAN-2009

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. FEI: 0001676815
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)*
South Texas Blood & Tissue Center
6211 IH 10 West at First Park Ten Blvd
San Antonio, Texas 78201

a. PHONE 210-731-5555 EXT 1541
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)*
South Texas Blood and Tissue Center
Attn: Norman D. Kalmin, MD
6211 IH 10 West at First Park Ten Blvd
San Antonio, Texas 78201

a. PHONE 210-731-5565 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE
Norman D. Kalmin
a. TYPED NAME Norman D. Kalmin, MD
b. E-MAIL patricia.cappelli@bloodntissue.org
c. TITLE President/CEO & Medical Diretor d. DATE 08-DEC-2008

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

FORM FDA 3356 (4/08)

ISO REGISTERED FIRM

Main Office: 6211 IH 10 West at First Part Ten Blvd. • San Antonio, Texas 78201 • (210) 731-5555 • 1-800-292-5534 • FAX (210) 731-5505
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