

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: 3005233711

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: 15-DEC-2017
 DISTRICT: New Orleans
 PRINTED BY FDA: 27-JAN-2018

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION										14. PROPRIETARY NAME(S)							
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										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			
a. BLOOD FDA 2830 NO. FEI: 3006611631		Types of HCT / Ps																	
b. DEVICES FDA 2691 NO.		Establishment Functions																	
c. DRUG FDA 2656 NO.		Recover	Screen	Test	Package	Process	Store	Label	Distribute										
a. Bone			X																
b. Cartilage			X																
c. Cornea			X																
d. Dura Mater			X																
e. Embryo			X		<input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous														
f. Fascia			X																
g. Heart Valve			X																
h. Ligament			X																
i. Oocyte			X		<input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous														
j. Pericardium			X																
k. Peripheral Blood Stem			X		<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic														
l. Sclera			X																
m. Semen			X		<input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous														
n. Skin			X																
o. Somatic Cell Therapy Products			X		<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic														
p. Tendons			X																
q. Umbilical Cord Blood			X		<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic														
r. Vascular Graft			X																
s.																			
t.																			
u.																			
v.																			

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
 The Blood Center
 1310 J.W. Davis Drive
 Hammond, Louisiana 70403

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)
 The Blood Center
 Attn: Lucretia Boudreaux, MT(ASCP) CQA (ASQ)
 1310 J. W. Davis Drive
 Hammond, Louisiana 70403

7. ENTER CORRECTIONS TO ITEM 6

a. PHONE 985-340-2323 EXT. b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

 a. TYPED NAME Lucretia Boudreaux, MT(ASCP) CQA (ASQ)
 b. E-MAIL lboudreaux@thebloodcenter.org
 c. TITLE Director, QA and Compliance d. DATE 14-DEC-2017

FORM FDA - 3356 (7/17)