

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: 0001873403

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

VALIDATION--FOR FDA USE ONLY
 * 072403 *
 VALIDATED BY: FDA-12/03/07
 PRINTED BY: FDA-12/07/07
 DISTRIBUTOR: Detroit

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. FEI: 0001873403
 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)
 Indiana Blood Center
 3450 N. Meridian Street
 Indianapolis, Indiana 46208

a. PHONE 317-916-5140 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)
 Indiana Blood Center
 Attn: Kerry W. Mettert, MBA, MT(ASCP)
 3450 N. Meridian Street
 Indianapolis, Indiana 46208

a. PHONE 317-916-5140 EXT _____
 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____

8. U.S. AGENT
 a. E-MAIL
 9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Kerry W. Mettert, MBA, MT(ASCP)
 b. E-MAIL kmtertert@indianablood.org
 c. TITLE Director, Regulatory Affairs
 d. DATE 16-NOV-2007

FORM FDA 3356 (9/07) PREVIOUS EDITION IS OBSOLETE.

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND 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 BIOLOGICAL DRUGS OR DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store				
No HCT / P Specified										
a. Bone			X				X			
b. Cartilage			X				X			
c. Cornea			X				X			
d. Dura Mater										
e. Embryo										
f. Fascia			X				X			
g. Heart Valve			X				X			
h. Ligament			X				X			
i. Oocyte			X				X			
j. Pericardium			X				X			
k. Peripheral Blood Stem Cells			X				X	X		
l. Sclera			X				X			
m. Semen			X				X			
n. Skin			X				X			
o. Somatic Cells										
p. Tendon			X				X			
q. Umbilical Cord Blood Stem Cells			X				X	X		
r. Vascular Graft			X				X			
s. Peripheral Nerves			X				X			
t.										
u.										
v.										

Types of HCT / Ps

a. SIP
 Directed
 Anonymous

b. SIP
 Directed
 Anonymous

c. SIP
 Directed
 Anonymous

d. SIP
 Directed
 Anonymous

e. Autologous
 Family Related
 Allogeneic

f. Autologous
 Family Related
 Allogeneic

g. SIP
 Directed
 Anonymous

h. Autologous
 Family Related
 Allogeneic

i. Autologous
 Family Related
 Allogeneic

j. Autologous
 Family Related
 Allogeneic

k. Autologous
 Family Related
 Allogeneic

l. Autologous
 Family Related
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m. Autologous
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n. Autologous
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o. Autologous
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q. Autologous
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s. Autologous
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