

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: 3003652672

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

14. PROPRIETARY NAME(S)

12. HCT/PS REGULATED AS MEDICAL DEVICES

13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS

11. HCT/PS DESCRIBED IN 21 CFR 1271.10

PART II - PRODUCT INFORMATION		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps						
Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute
a. Bone								
b. Cartilage								
c. Cornea								
d. Dura Mater								
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous								
f. Fascia								
g. Heart Valve								
h. Ligament								
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous								
j. Pericardium								
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic		X	X					X
l. Sclera								
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous								
n. Skin								
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic								
p. Tendon								
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic								
r. Vascular Graft								
s.								
t.								
u.								
v.								

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. FEI: 3003652672
 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)
 Bio-Reference Laboratories, Inc.
 481 Edward H. Ross Drive
 Elmwood Park, New Jersey 07407

a. PHONE 1-800-229-5227 EXT 8351
 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)
 BioReference Laboratory
 Attn: Nick Cetani, VP
 481 Edward H. Ross Drive
 Elmwood Park, New Jersey 07407

a. PHONE 1-800-229-5227 EXT 8351
 b. PHONE _____

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL _____

9. REPORTING OFFICIAL'S SIGNATURE
 a. TYPED NAME Nick Cetani, VP
 b. E-MAIL ncetani@bioreference.com
 c. TITLE VP, Adm. Director
 d. DATE 09-JAN-2018