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: 3002719998

2. REASON FOR SUBMISSION

a. [ ] INITIAL REGISTRATION / LISTING
b. [X] ANNUAL REGISTRATION / LISTING
c. [ ] CHANGE IN INFORMATION
d. [ ] INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:19-NOV-2009
DISTRICT: Florida
PRINTED BY FDA:19-NOV-2009

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO. FEI: 3002719998
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

RTI Biologics, Inc.
11621 Research Circle
Alachua, Florida 32615

a. PHONE 386-418-8888 EXT 4564
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)*

RTI Biologics, Inc.
Attn: Cheryl L. Bagwell
11621 Research Circle
Alachua, Florida 32615

a. PHONE 386-418-8888 EXT 4564

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Cheryl L. Bagwell
b. E-MAIL cbagwell@rtix.com
c. TITLE Director of Compliance d. DATE 17-NOV-2009

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	X		
b. Cartilage		X	X	X	X	X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia		X	X	X	X	X	X	X	X			
g. Heart Valve												
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												
l. Sclera		X	X	X	X	X	X	X	X			
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin		X	X	X	X	X	X	X	X			
o. Somatic Cell 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												
r. Vascular Graft												
s.												
t.												
u.												
v.												

FORM FDA 3356 (4/08)