See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 3000233845

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:09-DEC-2011
DISTRICT: Denver
PRINTED BY FDA:15-DEC-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO.

b. DEVICES FDA 2891 NO.

c. DRUG FDA 2656 NO. FEI: 0001721109

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

Nelson Laboratories, Inc
6280 South Redwood Road
Salt Lake City, Utah 84123

a. PHONE 801-290-7500 EXT

b. [ ] SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO._____

c. [X] 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)*

Nelson Laboratories, Inc
Attn: Sherri L. Robbins, B.S., SM(NRM)
6280 South Redwood Road
Salt Lake City, Utah 84123

a. PHONE 801-290-7642 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Sherri L. Robbins, B.S., SM(NRM)

b. E-MAIL srobbins@nelsonlabs.com

c. TITLE Director Regulatory Affairs d. DATE 08-DEC-2011

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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 DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
a. Bone					X				X	X		
b. Cartilage					X				X			
c. Cornea					X				X			
d. Dura Mater					X				X			
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia					X				X			
g. Heart Valve					X				X			
h. Ligament					X				X			
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium					X				X			
k. Peripheral Blood Stem Cells [X] Autologous [X] Family Related [X] Allogeneic					X				X			
l. Sclera					X				X			
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin					X				X			
o. Somatic Cell Therapy Products [X] Autologous [X] Family Related [X] Allogeneic					X				X			
p. Tendon					X				X			
q. Umbilical Cord Blood Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic												
r. Vascular Graft					X				X	X		
s.												
t.												
u.												
v.												