

1. REGISTRATION NUMBER
 (FDA Establishment Identifier)
FEI: 3006216356

2. REASON FOR SUBMISSION
 INITIAL REGISTRATION / LISTING
 ANNUAL REGISTRATION / LISTING
 CHANGE IN INFORMATION
 INACTIVE

VALIDATION--FOR FDA USE ONLY
 VALIDATED BY FDA: 19-NOV-2014
 DISTRICT: Int'l Operations Group
 PRINTED BY FDA: 04-DEC-2014

See Instructions for OMB Statement. FORM APPROVED: OMB No. 0910-0543. Expiration Date: 3/31/2017

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. _____
 b. DEVICES FDA 2891 NO. _____
 c. DRUG FDA 2856 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
 Dpt. of Immunology and Immunogenetics, IndRE, Secretary of Health
 Francisco P. Miranda
 #177 Colonia Lomas de Plateros
 Del. Alvaro Obregon
 Mexico City, D.F., 01480
 Mexico

a. PHONE +52-55-63830041 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)
 Dpt. of Immunology and Immunogenetics, IndRE, Secretary of Health
 Attn: Clara Gorodezky, PhD, DSc
 Francisco P. Miranda
 #177 Colonia Lomas de Plateros
 Del. Alvaro Obregon
 Mexico City, D.F., 01480
 Mexico

a. PHONE +52-55-63830041 EXT _____
 b. PHONE _____
 7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT John Miller, M.D.
 NMDP
 3001 Broadway St NE, Suite 100, Minneapolis, Minnesota 55413

a. E-MAIL: jmillers@nmpp.org 1-612-627-5800

9. REPORTING OFFICIAL'S SIGNATURE
 a. TYPED NAME Clara Gorodezky, PhD, DSc
 b. E-MAIL: clargag@uminn.mn
 c. TITLE: Head of the Department
 d. DATE: 18-NOV-2014

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				
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. Peripherical Blood Stem	<input checked="" type="checkbox"/> Autologous	<input checked="" type="checkbox"/> Family Related	<input checked="" type="checkbox"/> Allogeneic	X	X	X	X	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 checked="" type="checkbox"/> Family Related	<input checked="" type="checkbox"/> Allogeneic	X	X	X	X	X	X	X
r. Vascular Graft										
s.										
t.										
u.										
v.										

