

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: 3005565760

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

FORM APPROVED - OMB No. 0910-0543 Expiration Date: 8/31/10  
 VALIDATION - FOR FDA USE ONLY  
 VALIDATED BY FDA-25-NOV-2009  
 PRINTED BY FDA-02-DEC-2009

**PART I - ESTABLISHMENT INFORMATION**

3. OTHER FDA REGISTRATIONS  
 a. BLOOD FDA 2830 NO  
 b. DEVICES FDA 2891 NO FEI: 3005565760  
 c. DRUG FDA 2656 NO

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)  
 Nanotherapeutics, Inc.  
 13859 Progress Blvd, Suite 300  
 Alachua, Florida 35615

a. PHONE 386-462-9663 EXT 304  
 b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. TESTING FOR MICRO-ORGANISMS ONLY)  
 c. 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)  
 Nanotherapeutics, Inc.  
 Attn: Dennis Tomisaka  
 13859 Progress Blvd, Suite 300  
 Alachua, Florida 35615

a. PHONE 386-462-9663 EXT 304  
 b. PHONE  
 7. ENTER CORRECTIONS TO ITEM 6

**8. U.S. AGENT**

a. E-MAIL  
**9. REPORTING OFFICIAL'S SIGNATURE**  
 a. TYPED NAME Dennis Tomisaka  
 b. E-MAIL dtomisaka@nanotherapeutics.com  
 c. TITLE Sr. VP of Operations  
 d. DATE 24-NOV-2009

**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				X	X				
c. Cornea									
d. Dura Mater									
e. Embryo									
f. Fascia									
g. Heart Valve									
h. Ligament									
i. Oocyte									
j. Pericardium									
k. Peripheral Blood Stem									
l. Sclera									
m. Semen									
n. Skin									
o. Somatic Cell Therapy Products									
p. Tendon									
q. Umbilical Cord Blood Stem Cells									
r. Vascular Graft									
s.									
t.									
u.									
v.									

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*(Paid Establishment Identifier)*

FBI: 3005565760

**ADDITIONAL INFORMATION:**

**Proprietary Name(s):**

- a. Bone      Origen DBM with BioActive Glass and NanoFUSE  
                 DBM