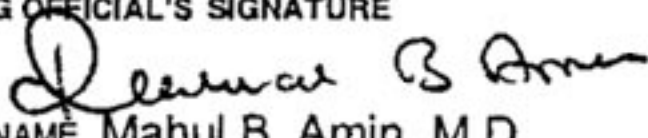


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier): FEI: 2073862	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION—FOR FDA USE ONLY
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PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICE FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ 4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Cedars-Sinai Medical Center Department of Pathology and Laboratory Medicine 8700 Beverly Boulevard, Room 3719 Los Angeles, CA 90048 a. PHONE (310) 423-5335 5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> a. PHONE _____ 7. ENTER CORRECTIONS TO ITEM 6 8. U.S. AGENT a. E-MAIL ADDRESS _____ b. PHONE _____ 9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Mahul B. Amin, M.D. b. E-MAIL ADDRESS AminM@cshs.org c. TITLE Chairman, Pathology/Lab Med d. DATE 12/4/06	PART II - HCT/P INFORMATION 10. ESTABLISHMENT FUNCTIONS: <input type="checkbox"/> RECOVER <input checked="" type="checkbox"/> TEST <input type="checkbox"/> PROCESS <input type="checkbox"/> LABEL <input type="checkbox"/> SCREEN <input type="checkbox"/> PACKAGE <input type="checkbox"/> STORE <input type="checkbox"/> DISTRIBUTE <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:15%;">TYPES OF HCT/Ps</th> <th style="width:15%;">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th style="width:15%;">12. HCT/Ps REGULATED AS MEDICAL DEVICES, DRUGS OR BIOLOGICAL DRUGS</th> <th style="width:55%;">13. PROPRIETARY NAME(S)</th> </tr> </thead> <tbody> <tr><td>a. Bone</td><td></td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td></td><td></td></tr> <tr><td>c. Cornea</td><td></td><td></td><td></td></tr> <tr><td>d. Dura Mater</td><td></td><td></td><td></td></tr> <tr><td>e. Embryo</td><td></td><td></td><td></td></tr> <tr><td>f. Fascia</td><td></td><td></td><td></td></tr> <tr><td>g. Heart Valve</td><td></td><td></td><td></td></tr> <tr><td>h. Ligament</td><td></td><td></td><td></td></tr> <tr><td>i. Oocyte</td><td></td><td></td><td></td></tr> <tr><td>j. Pericardium</td><td></td><td></td><td></td></tr> <tr><td>k. Peripheral Blood Stem Cells</td><td></td><td></td><td></td></tr> <tr><td>l. Sclera</td><td></td><td></td><td></td></tr> <tr><td>m. Semen</td><td></td><td></td><td></td></tr> <tr><td>n. Skin</td><td></td><td></td><td></td></tr> <tr><td>o. Somatic Cells</td><td></td><td></td><td></td></tr> <tr><td>p. Tendon</td><td></td><td></td><td></td></tr> <tr><td>q. Umbilical Cord Blood Stem Cells</td><td></td><td></td><td></td></tr> <tr><td>r. Vascular Graft</td><td></td><td></td><td></td></tr> <tr><td>s.</td><td></td><td></td><td></td></tr> <tr><td>t.</td><td></td><td></td><td></td></tr> <tr><td>u.</td><td></td><td></td><td></td></tr> <tr><td>v.</td><td></td><td></td><td></td></tr> </tbody> </table>	TYPES OF HCT/Ps	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES, DRUGS OR BIOLOGICAL DRUGS	13. PROPRIETARY NAME(S)	a. Bone				b. Cartilage				c. Cornea				d. Dura Mater				e. Embryo				f. Fascia				g. Heart Valve				h. Ligament				i. Oocyte				j. Pericardium				k. Peripheral Blood Stem Cells				l. Sclera				m. Semen				n. Skin				o. Somatic Cells				p. Tendon				q. Umbilical Cord Blood Stem Cells				r. Vascular Graft				s.				t.				u.				v.			
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