

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
(FDA Establishment Identifier)
FEI: 3002515992

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

VALIDATION FOR FDA USE ONLY
VALIDATED BY FDA: 16-NOV-2017
DISTRICT: Los Angeles
PRINTED BY FDA: 27-JAN-2018

See instructions for OMB Statement. FORM APPROVED: OMB No. 0910-0543. Expiration Date: 6/30/2020

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION												
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
a. BLOOD FDA 2890 NO. _____		Types of HCT / Ps												
b. DEVICES FDA 2891 NO. _____		Establishment Functions												
c. DRUG FDA 2856 NO. _____		Recover	Screen	Test	Package	Process	Store	Label	Distribute	11 HCT/PS DESCRIBED IN 21 CFR 1271.10	12 HCT/PS REGULATED AS BIOLOGICAL DRUGS OR DRUGS	13 HCT/PS REGULATED AS MEDICAL DEVICES	14. PROPRIETARY NAME(S)	
4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code) San Diego Eye Bank 9246 Lightwave Avenue, Suite 120 San Diego, California 92123		a. Bone												
5. ENTER CORRECTIONS TO ITEM 4		b. Cartilage												
6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code) San Diego Eye Bank Attn: Jeffrey G. Penta, MBA, CEBT 9246 Lightwave Avenue, Suite 120 San Diego, California 92123		c. Cornea	X	X		X	X	X	X	X				
7. ENTER CORRECTIONS TO ITEM 6		d. Dura Mater												
8. U.S. AGENT		e. Embryo												
9. REPORTING OFFICIAL'S SIGNATURE		f. Fascia												
a. TYPED NAME Jeffrey G. Penta, MBA, CEBT		g. Heart Valve												
b. E-MAIL jeffpenta@scdeb.org		h. Ligament												
c. TITLE Executive Director		i. Oocyte												
d. DATE 15-NOV-2017		j. Pericardium												
		k. Peripheral Blood Stem												
		l. Sclera	X	X		X	X	X	X	X				
		m. Semen												
		n. Skin												
		o. Somatic Cell Therapy Products												
		p. Tendon												
		q. Umbilical Cord Blood												
		r. Vascular Graft												
		s.												
		t.												
		u.												
		v.												