


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: 3003413152	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:23-JUL-2018 DISTRICT: Kansas City PRINTED BY FDA:14-SEP-2018											
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION							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)			
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps													
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) AlloSource 9 Worthington Access Maryland Heights, Missouri 63043 a. PHONE 314-781-0246 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Types of HCT / Ps	Establishment Functions												
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) AlloSource Attn: Trevor Wright 6278 South Troy Circle Centennial, Colorado 80111 a. PHONE 720.873.4733 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6		a. Bone							X		X	X	X		
		b. Cartilage								X		X	X		
		c. Cornea													
		d. Dura Mater													
		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		f. Fascia								X		X	X		
		g. Heart Valve													
		h. Ligament								X		X	X		
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		j. Pericardium													
		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
		l. Sclera													
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		n. Skin								X		X	X		
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
p. Tendon								X		X	X	X			
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
r. Vascular Graft															
s. Amniotic Membrane								X		X	X				
t.															
u.															
v.															
8. U.S. AGENT a. E-MAIL		9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Trevor Wright b. E-MAIL twright@allosource.org c. TITLE Director of Regulatory Affairs d. DATE 23-JUL-2018													