


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: 1000305999	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: Cincinnati 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 615 Elsinore Place, Suite 400 Cincinnati, Ohio 45202 a. PHONE 513-381-2630 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		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
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 _____		a. Bone						X		X	X	X	
7. ENTER CORRECTIONS TO ITEM 6		b. Cartilage						X		X	X		
b. PHONE _____		c. Cornea											
8. U.S. AGENT		d. Dura Mater											
a. E-MAIL _____		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
9. REPORTING OFFICIAL'S SIGNATURE 		f. Fascia						X		X	X		
a. TYPED NAME Trevor Wright, b. E-MAIL twright@allosource.org c. TITLE Director of Regulatory Affairs d. DATE 23-JUL-2018		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.											