

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: 3000215349	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 VALIDATED BY FDA:19-NOV-2016 DISTRICT: Denver PRINTED BY FDA:15-DEC-2016																																																																																																																																																																																																																																																				
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 <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="9">Establishment Functions</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> <th></th> </tr> </thead> <tbody> <tr> <td>a. Bone</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>b. Cartilage</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>c. Cornea</td> <td>X</td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td> </tr> <tr> <td>d. Dura Mater</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>f. Fascia</td> <td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td> </tr> <tr> <td>g. Heart Valve</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>h. Ligament</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>j. Pericardium</td> <td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td> </tr> <tr> <td>k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>l. Sclera</td> <td>X</td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td> </tr> <tr> <td>m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>n. Skin</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>p. Tendon</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>r. Vascular Graft</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>s. Amniotic Membrane</td> <td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td> </tr> <tr> <td>t.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>u.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>v.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </tbody> </table>						Types of HCT / Ps	Establishment Functions									Recover	Screen	Test	Package	Process	Store	Label	Distribute		a. Bone										b. Cartilage										c. Cornea	X	X		X	X	X	X	X	X	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										i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										j. Pericardium						X		X	X	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										l. Sclera	X	X		X	X	X	X	X	X	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										n. Skin										o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										p. Tendon										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.											
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4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Utah Lions Eye Bank 6056 Fashion Square Drive Suite 200 Murray, Utah 84107 a. PHONE 801-581-2039 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY																																																																																																																																																																																																																																																								
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6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Utah Lions Eye Bank Attn: Chris Hanna, CEBT 6056 Fashion Square Drive Suite 200 Murray, Utah 84107 a. PHONE 801-581-3484 EXT _____																																																																																																																																																																																																																																																								
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9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Chris Hanna, CEBT b. E-MAIL chris.hanna@hsc.utah.edu c. TITLE Executive Director d. DATE 18-NOV-2016										*** See full text on next page																																																																																																																																																																																																																																														

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PUBLIC HEALTH SERVICE

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ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/TPs)**
(See reverse side for Instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FBI: 3000215349

ADDITIONAL INFORMATION:

Proprietary Name(s):

Amniotic Membrane AmbioDry (tm), Bio Tissue (IOP Ophthalmics)