

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> <i>(See reverse side for instructions)</i>		<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3003367577	<b>2. REASON FOR SUBMISSION</b> 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:02-JAN-2009 DISTRICT: New England PRINTED BY FDA:05-JAN-2009																																																																																																																																																																																																																																																																																																																																																																																																																																	
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>							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)																																																																																																																																																																																																																																																																																																																																																																																																																									
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="text-align: center;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2"></th> <th rowspan="2"></th> <th rowspan="2"></th> <th rowspan="2"></th> </tr> <tr> <th style="text-align: center;">Recover</th> <th style="text-align: center;">Screen</th> <th style="text-align: center;">Test</th> <th style="text-align: center;">Package</th> <th style="text-align: center;">Process</th> <th style="text-align: center;">Store</th> <th style="text-align: center;">Label</th> <th style="text-align: center;">Distribute</th> </tr> </thead> <tbody> <tr><td>a. 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<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i> California Cryobank, Inc. 950 Massachusetts Ave. Cambridge, Massachusetts 02139  a. PHONE 617-497-8646 EXT 12 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<b>5. ENTER CORRECTIONS TO ITEM 4</b>							<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> California Cryobank, Inc. Attn: Diana C. Schillinger 950 Massachusetts Avenue Cambridge, Massachusetts 02139  a. PHONE 310-443-5244 EXT 1160		<b>7. ENTER CORRECTIONS TO ITEM 6</b>		b. PHONE																																																																																																																																																																																																																																																																																																																																																																																																																								
<b>8. U.S. AGENT</b>  a. E-MAIL		<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Diana C. Schillinger b. E-MAIL dschillinger@cryobank.com c. TITLE Compliance Manager							d. DATE 10-DEC-2008																																																																																																																																																																																																																																																																																																																																																																																																																												