

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) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3000718538	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:16-DEC-2009 DISTRICT: Minneapolis PRINTED BY FDA:18-DEC-2009
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																																																																																																																																																																																																																																																																																																																																																																																																																																		
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps	Establishment Functions									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)																																																																																																																																																																																																																																																																																																																																																																																																																					
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:15%;">Types of HCT / Ps</th> <th style="width:5%;">Recover</th> <th style="width:5%;">Screen</th> <th style="width:5%;">Test</th> <th style="width:5%;">Package</th> <th style="width:5%;">Process</th> <th style="width:5%;">Store</th> <th style="width:5%;">Label</th> <th style="width:5%;">Distribute</th> <th style="width:5%;"></th> <th style="width:5%;"></th> <th style="width:5%;"></th> <th style="width:5%;"></th> <th style="width:5%;"></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><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><td></td><td></td><td></td><td></td></tr> <tr><td>c. 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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Minnesota Lions Eye Bank 1000 Westgate Drive Suite 260 St. Paul, Minnesota 55114 a. PHONE 612-625-5159 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	5. ENTER CORRECTIONS TO ITEM 4																																																																																																																																																																																																																																																																																																																																																																																																																																		
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Minnesota Lions Eye Bank Attn: Jackie Malling 1000 Westgate Drive Suite 260 St. Paul, Minnesota 55114 a. PHONE 612-625-5159 EXT _____	7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____																																																																																																																																																																																																																																																																																																																																																																																																																																		
8. U.S. AGENT a. E-MAIL _____	9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Jackie Malling b. E-MAIL vanho004@umn.edu c. TITLE Executive Director d. DATE 15-DEC-2009																																																																																																																																																																																																																																																																																																																																																																																																																																		