


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> (See reverse side for instructions)		<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3000718080	<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: 16-NOV-2016 DISTRICT: Philadelphia PRINTED BY FDA: 15-DEC-2016																																																																																																																																																																																																																																																																													
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>			11. HCT/PS 12. HCT/PS 13. HCT/PS	<b>14. PROPRIETARY NAME(S)</b>																																																																																																																																																																																																																																																																											
<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> </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. Bone</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>b. 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<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Lions Eye Bank of Delaware Valley  401 North 3rd Street Suite 305 Philadelphia, Pennsylvania 19123  a. PHONE 215-563-1679 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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<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Lions Eye Bank of Delaware Valley Attn: Jim Quirk, CEBT 401 North 3rd Street Suite 305 Philadelphia, Pennsylvania 19123  a. PHONE 215-563-1679 EXT 125																																																																																																																																																																																																																																																																																	
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a. E-MAIL  <b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Jim Quirk, CEBT b. E-MAIL jqquirk@lcbdv.org c. TITLE President/CEO d. DATE 15-NOV-2016																																																																																																																																																																																																																																																																																	