


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: 3000718080	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-NOV-2016 DISTRICT: Philadelphia PRINTED BY FDA: 15-DEC-2016																																																																																																																																																																																																																																																																																																																																																																				
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION			11. HCT/PS 12. HCT/PS 13. HCT/PS	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" style="text-align: center;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2" style="text-align: center;">11. HCT/PS CFR 1271.10</th> <th rowspan="2" style="text-align: center;">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="text-align: center;">13. 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4. PHYSICAL LOCATION (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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6. MAILING ADDRESS OF REPORTING OFFICIAL (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 9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Jim Quirk, CEBT b. E-MAIL jqquirk@lcbdv.org c. TITLE President/CEO d. DATE 15-NOV-2016																																																																																																																																																																																																																																																																																																																																																																								