

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: 0002276020	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:29-NOV-2017 DISTRICT: New Jersey PRINTED BY FDA:27-JAN-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION	11. HCT/Ps DESCRIBED IN 21 OF 171.10	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. FEI: 0002276020 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="width:30%;">Types of HCT / Ps</th> <th colspan="9" style="text-align: center;">Establishment Functions</th> </tr> <tr> <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> </tr> </thead> </table>					Types of HCT / Ps	Establishment Functions									Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																																																																																																																																																
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4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) New York Blood Center 167 New Street New Brunswick, New Jersey 08901 a. PHONE 732-220-7000 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<table border="1" style="width:100%; border-collapse: collapse;"> <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. Cornea</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>d. 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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) New York Blood Center Attn: Christine Driscoll 1200 Prospect Avenue Westbury, New York 11590 a. PHONE 516-478-5264 EXT _____ b. PHONE _____																																																																																																																																																																																																																																																																																																																																																																																																							
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9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Christine Driscoll b. E-MAIL cdriscoll@nybc.org c. TITLE Director, Regulatory Affairs d. DATE 29-NOV-2017																																																																																																																																																																																																																																																																																																																																																																																																							