


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING</b>	<b>1. REGISTRATION NUMBER</b> FEI: 2473015 CFN: 2473015 <hr/> <b>2. U.S. LICENSE NUMBER</b> 465	<b>3. REASON FOR SUBMISSION</b> .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> CHANGE IN INFORMATION	FOR FDA USE ONLY  DISTRICT OFFICE: New York VALIDATED BY FDA: 06-DEC-2017 PRINTED BY FDA: 08-JAN-2018																																																																																																																																																																																																																																						
PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in item 4, and any changes in your mailing address in item 6. Print all entries and make all corrections in red ink, if possible. Enter your phone number in item 8.3 and the phone number of your actual location in item 4.1. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.																																																																																																																																																																																																																																									
<b>ENTER ALL CHANGES IN RED INK AND CIRCLE.</b>																																																																																																																																																																																																																																									
<b>4. LEGAL NAME AND LOCATION</b> (Include legal name, number and street, city, state, country, and post office code)  New York Blood Center, Inc. 45-01 Vernon Blvd. Long Island City, NY 11101  4.1 PHONE 718-752-4601	<b>9. TYPE OF OWNERSHIP</b> .1 <input type="checkbox"/> SINGLE PROPRIETORSHIP .2 <input type="checkbox"/> PARTNERSHIP .3 <input checked="" type="checkbox"/> CORPORATION profit___ non-profit <input checked="" type="checkbox"/> .4 <input type="checkbox"/> COOPERATIVE ASSOCIATION .5 <input type="checkbox"/> FEDERAL (non-military) .6 <input type="checkbox"/> U.S. MILITARY .7 <input type="checkbox"/> STATE .8 <input type="checkbox"/> COUNTY/MUNICIPAL/HOSPITAL AUTHORITY .9 <input type="checkbox"/> OTHER (Specify) : _____		<b>10. TYPE ESTABLISHMENT</b> (Check all boxes that describe routine or autologous operations.) .1 <input type="checkbox"/> COMMUNITY (NON-HOSPITAL) BLOOD BANK .2 <input type="checkbox"/> HOSPITAL BLOOD BANK .3 <input type="checkbox"/> PLASMAPHERESIS CENTER .4 <input type="checkbox"/> PRODUCT TESTING LABORATORY a. ___ INDEPENDENT ___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK .5 <input type="checkbox"/> HOSPITAL TRANSFUSION SERVICE a. ___ APPROVED FOR MEDICARE REIMBURSEMENT ___ NOT APPROVED FOR MEDICARE REIMBURSEMENT .6 <input checked="" type="checkbox"/> COMPONENT PREPARATION FACILITY .7 <input type="checkbox"/> COLLECTION FACILITY .8 <input checked="" type="checkbox"/> DISTRIBUTION CENTER .9 <input type="checkbox"/> BROKER/WAREHOUSE .10 <input type="checkbox"/> OTHER (Specify) : _____																																																																																																																																																																																																																																						
<b>5. OTHER NAMES USED AT THIS LOCATION</b> (Include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration number.)  New York Blood Services	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:55%;"></th> <th style="width:5%;">COLLECT</th> <th style="width:5%;">MANUAL APHERESIS</th> <th style="width:5%;">AUTOMATED APHERESIS</th> <th style="width:5%;">PREPARE</th> <th style="width:5%;">LEUKOCYTES REDUCED</th> <th style="width:5%;">IRRADIATED</th> <th style="width:5%;">DONOR RETESTED</th> <th style="width:5%;">TEST</th> <th style="width:5%;">STORE and DISTRIBUTE to OTHERS</th> </tr> <tr> <th style="text-align: center;"> <input checked="" type="checkbox"/> ALLOGENEIC                                <input checked="" type="checkbox"/> AUTOLOGOUS                                <input checked="" type="checkbox"/> DIRECTED                         </th> <th style="text-align: center;">(1)</th> <th style="text-align: center;">(2)</th> <th style="text-align: center;">(3)</th> <th style="text-align: center;">(4)</th> <th style="text-align: center;">(5)</th> <th style="text-align: center;">(6)</th> <th style="text-align: center;">(7)</th> <th style="text-align: center;">(8)</th> <th style="text-align: center;">(9)</th> </tr> </thead> <tbody> <tr> <td>WHOLE BLOOD</td> <td style="text-align: center;">1</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> </tr> <tr> <td>RED BLOOD CELLS (RBC)</td> <td style="text-align: center;">2</td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>RBC FROZEN</td> <td style="text-align: center;">3</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>RBC DEGLYCEROLIZED</td> <td style="text-align: center;">4</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>RBC REJUVENATED</td> <td style="text-align: center;">5</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>RBC REJUVENATED FROZEN</td> <td style="text-align: center;">6</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>RBC REJUVENATED DEGLYCEROLIZED</td> <td style="text-align: center;">7</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>CRYOPRECIPITATED AHF</td> <td style="text-align: center;">8</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>PLATELETS</td> <td style="text-align: center;">9</td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>LEUKOCYTES/GRANULOCYTES</td> <td style="text-align: center;">10</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>PLASMA</td> <td style="text-align: center;">11</td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>PLASMA CRYOPRECIPITATE REDUCED</td> <td style="text-align: center;">12</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>FRESH FROZEN PLASMA</td> <td style="text-align: center;">13</td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>LIQUID PLASMA</td> <td style="text-align: center;">14</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>THERAPEUTIC EXCHANGE PLASMA</td> <td style="text-align: center;">15</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>SOURCE LEUKOCYTES</td> <td style="text-align: center;">16</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>SOURCE PLASMA</td> <td style="text-align: center;">17</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>RECOVERED PLASMA</td> <td style="text-align: center;">18</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>BLOOD PRODUCTS FOR DIAGNOSTIC USE</td> <td style="text-align: center;">19</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>BLOOD BANK REAGENTS</td> <td style="text-align: center;">20</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>OTHER</td> <td style="text-align: center;">21</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>				COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS	<input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	WHOLE BLOOD	1	X			X	X		X	X	RED BLOOD CELLS (RBC)	2		X	X	X	X			X	RBC FROZEN	3			X					X	RBC DEGLYCEROLIZED	4			X					X	RBC REJUVENATED	5			X					X	RBC REJUVENATED FROZEN	6			X					X	RBC REJUVENATED DEGLYCEROLIZED	7			X					X	CRYOPRECIPITATED AHF	8			X					X	PLATELETS	9		X	X		X			X	LEUKOCYTES/GRANULOCYTES	10			X					X	PLASMA	11		X	X		X			X	PLASMA CRYOPRECIPITATE REDUCED	12			X					X	FRESH FROZEN PLASMA	13		X	X		X			X	LIQUID PLASMA	14			X					X	THERAPEUTIC EXCHANGE PLASMA	15									SOURCE LEUKOCYTES	16								X	SOURCE PLASMA	17								X	RECOVERED PLASMA	18			X					X	BLOOD PRODUCTS FOR DIAGNOSTIC USE	19			X					X	BLOOD BANK REAGENTS	20								X	OTHER	21								
	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS																																																																																																																																																																																																																																
<input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)																																																																																																																																																																																																																																
WHOLE BLOOD	1	X			X	X		X	X																																																																																																																																																																																																																																
RED BLOOD CELLS (RBC)	2		X	X	X	X			X																																																																																																																																																																																																																																
RBC FROZEN	3			X					X																																																																																																																																																																																																																																
RBC DEGLYCEROLIZED	4			X					X																																																																																																																																																																																																																																
RBC REJUVENATED	5			X					X																																																																																																																																																																																																																																
RBC REJUVENATED FROZEN	6			X					X																																																																																																																																																																																																																																
RBC REJUVENATED DEGLYCEROLIZED	7			X					X																																																																																																																																																																																																																																
CRYOPRECIPITATED AHF	8			X					X																																																																																																																																																																																																																																
PLATELETS	9		X	X		X			X																																																																																																																																																																																																																																
LEUKOCYTES/GRANULOCYTES	10			X					X																																																																																																																																																																																																																																
PLASMA	11		X	X		X			X																																																																																																																																																																																																																																
PLASMA CRYOPRECIPITATE REDUCED	12			X					X																																																																																																																																																																																																																																
FRESH FROZEN PLASMA	13		X	X		X			X																																																																																																																																																																																																																																
LIQUID PLASMA	14			X					X																																																																																																																																																																																																																																
THERAPEUTIC EXCHANGE PLASMA	15																																																																																																																																																																																																																																								
SOURCE LEUKOCYTES	16								X																																																																																																																																																																																																																																
SOURCE PLASMA	17								X																																																																																																																																																																																																																																
RECOVERED PLASMA	18			X					X																																																																																																																																																																																																																																
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19			X					X																																																																																																																																																																																																																																
BLOOD BANK REAGENTS	20								X																																																																																																																																																																																																																																
OTHER	21																																																																																																																																																																																																																																								
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code)  New York Blood Center, Inc. ATTN: Christine Driscoll, Director, Regulatory Affairs 1200 Prospect Avenue Westbury, NY 11590	<b>7. U.S. AGENT</b> (Include name, institution name if applicable, number and street, city, state, and zip code)																																																																																																																																																																																																																																								
7.1 E-MAIL ADDRESS 7.2 PHONE	<b>8. REPORTING OFFICIAL'S SIGNATURE</b>  8.1 TYPED NAME Christine Driscoll, Director, Regulatory Affairs 8.2 E-MAIL ADDRESS cdriscoll@nybc.org 8.3 PHONE 516-478-5264                      8.4 DATE																																																																																																																																																																																																																																								