


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING	1. REGISTRATION NUMBER FEI: 1870308 CFN: 1870308 2. U.S. LICENSE NUMBER 248	3. REASON FOR SUBMISSION .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: Detroit VALIDATED BY FDA: 23-NOV-2016 PRINTED BY FDA: 19-DEC-2016																																																																																																																																																																																																																																						
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.																																																																																																																																																																																																																																									
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4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code) South Bend Medical Foundation, Inc. 530 N. Lafayette Boulevard South Bend, IN 46601-1098 4.1 PHONE 574-234-4176 x4522	9. TYPE OF OWNERSHIP .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) : _____		10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.) .1 <input checked="" 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 type="checkbox"/> COMPONENT PREPARATION FACILITY .7 <input type="checkbox"/> COLLECTION FACILITY .8 <input type="checkbox"/> DISTRIBUTION CENTER .9 <input type="checkbox"/> BROKERWAREHOUSE .10 <input type="checkbox"/> OTHER (Specify) : _____ U.S. LICENSE NUMBER OF PARENT FIRM _____																																																																																																																																																																																																																																						
5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration number.) Central Blood Bank The Medical Foundation	11. PRODUCTS <table border="1" style="width:100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th></th> <th>COLLECT (.1)</th> <th>MANUAL APHERESIS (.2)</th> <th>AUTOMATED APHERESIS (.3)</th> <th>PREPARE (.4)</th> <th>LEUKOCYTES REDUCED (.5)</th> <th>IRRADIATED (.6)</th> <th>DONOR RETESTED (.7)</th> <th>TEST (.8)</th> <th>STORE and DISTRIBUTE to OTHERS (.9)</th> </tr> <tr> <th></th> <th>ALLOGENEIC</th> <th>AUTOLOGOUS</th> <th>DIRECTED</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> </tr> </thead> <tbody> <tr><td>WHOLE BLOOD</td><td>1</td><td>X</td><td></td><td></td><td>X</td><td></td><td></td><td>X</td><td></td></tr> <tr><td>RED BLOOD CELLS (RBC)</td><td>2</td><td></td><td></td><td>X</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td></tr> <tr><td>RBC FROZEN</td><td>3</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td>X</td><td>X</td></tr> <tr><td>RBC DEGLYCEROLIZED</td><td>4</td><td></td><td></td><td>X</td><td></td><td>X</td><td></td><td>X</td><td>X</td></tr> <tr><td>RBC REJUVENATED</td><td>5</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED FROZEN</td><td>6</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED DEGLYCEROLIZED</td><td>7</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>CRYOPRECIPITATED AHF</td><td>8</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td>X</td><td>X</td></tr> <tr><td>PLATELETS</td><td>9</td><td></td><td></td><td>X</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td></tr> <tr><td>LEUKOCYTES/GRANULOCYTES</td><td>10</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLASMA</td><td>11</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td>X</td><td>X</td></tr> <tr><td>PLASMA CRYOPRECIPITATE REDUCED</td><td>12</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td>X</td><td>X</td></tr> <tr><td>FRESH FROZEN PLASMA</td><td>13</td><td></td><td></td><td>X</td><td>X</td><td></td><td></td><td>X</td><td>X</td></tr> <tr><td>LIQUID PLASMA</td><td>14</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>THERAPEUTIC EXCHANGE PLASMA</td><td>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>16</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>SOURCE PLASMA</td><td>17</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RECOVERED PLASMA</td><td>18</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td>X</td><td>X</td></tr> <tr><td>BLOOD PRODUCTS FOR DIAGNOSTIC USE</td><td>19</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>BLOOD BANK REAGENTS</td><td>20</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>OTHER</td><td>21</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>				COLLECT (.1)	MANUAL APHERESIS (.2)	AUTOMATED APHERESIS (.3)	PREPARE (.4)	LEUKOCYTES REDUCED (.5)	IRRADIATED (.6)	DONOR RETESTED (.7)	TEST (.8)	STORE and DISTRIBUTE to OTHERS (.9)		ALLOGENEIC	AUTOLOGOUS	DIRECTED							WHOLE BLOOD	1	X			X			X		RED BLOOD CELLS (RBC)	2			X	X	X		X	X	RBC FROZEN	3			X				X	X	RBC DEGLYCEROLIZED	4			X		X		X	X	RBC REJUVENATED	5									RBC REJUVENATED FROZEN	6									RBC REJUVENATED DEGLYCEROLIZED	7									CRYOPRECIPITATED AHF	8			X				X	X	PLATELETS	9			X	X	X		X	X	LEUKOCYTES/GRANULOCYTES	10									PLASMA	11			X				X	X	PLASMA CRYOPRECIPITATE REDUCED	12			X				X	X	FRESH FROZEN PLASMA	13			X	X			X	X	LIQUID PLASMA	14									THERAPEUTIC EXCHANGE PLASMA	15									SOURCE LEUKOCYTES	16									SOURCE PLASMA	17									RECOVERED PLASMA	18			X				X	X	BLOOD PRODUCTS FOR DIAGNOSTIC USE	19									BLOOD BANK REAGENTS	20									OTHER	21								
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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) South Bend Medical Foundation, Inc. ATTN: Christine D. Saitz BS, MLT (ASCP) 530 N. Lafayette Boulevard South Bend, IN 46601-1098	7. U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code) Christine D. Saitz 8.1 TYPED NAME Christine D. Saitz BS, MLT (ASCP) 8.2 E-MAIL ADDRESS csaitz@sbfm.org 8.3 PHONE 574-234-4176 x4522 8.4 DATE _____																																																																																																																																																																																																																																								