
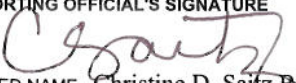


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING</b>		<b>1. REGISTRATION NUMBER</b> FEI: 1872515 CFN: 1872515	<b>3. REASON FOR SUBMISSION</b> .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> CHANGE IN INFORMATION	<b>FOR FDA USE ONLY</b>   DISTRICT OFFICE: Detroit VALIDATED BY FDA: 30-NOV-2017 PRINTED BY FDA: 12-DEC-2017																																																																																																																																																																																																																																																																																														
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.		This form is authorized by Sections 510(b), (j) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p)) and can result in a fine of up to \$1,000 or imprisonment up to one year or both, pursuant to Section 303(a) of the Act (Title 21, United States Code 33.3(a)).																																																																																																																																																																																																																																																																																																
<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)  South Bend Medical Foundation, Inc. Elkhart Donor Center 600 East Boulevard Elkhart, IN 46514-1329  4.1 PHONE 574-523-3329		<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 checked="" 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"/> 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.)  The Medical Foundation		<b>11. PRODUCTS</b> <table border="1" style="width:100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th></th> <th>ALLOGENEIC <input checked="" type="checkbox"/></th> <th>AUTOLOGOUS <input checked="" type="checkbox"/></th> <th>DIRECTED <input checked="" type="checkbox"/></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> </thead> <tbody> <tr><td>WHOLE BLOOD</td><td></td><td></td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RED BLOOD CELLS (RBC)</td><td></td><td></td><td></td><td></td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC FROZEN</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>RBC DEGLYCEROLIZED</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>RBC REJUVENATED</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>RBC REJUVENATED FROZEN</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>RBC REJUVENATED DEGLYCEROLIZED</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>CRYOPRECIPITATED AHF</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>PLATELETS</td><td></td><td></td><td></td><td></td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>LEUKOCYTES/GRANULOCYTES</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>PLASMA</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>PLASMA CRYOPRECIPITATE REDUCED</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>FRESH FROZEN PLASMA</td><td></td><td></td><td></td><td></td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>LIQUID PLASMA</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>THERAPEUTIC EXCHANGE PLASMA</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>SOURCE LEUKOCYTES</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>SOURCE PLASMA</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>RECOVERED PLASMA</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>BLOOD PRODUCTS FOR DIAGNOSTIC USE</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>BLOOD BANK REAGENTS</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>OTHER</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> </tbody> </table>				ALLOGENEIC <input checked="" type="checkbox"/>	AUTOLOGOUS <input checked="" type="checkbox"/>	DIRECTED <input checked="" type="checkbox"/>	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)	WHOLE BLOOD				X									RED BLOOD CELLS (RBC)						X							RBC FROZEN													RBC DEGLYCEROLIZED													RBC REJUVENATED													RBC REJUVENATED FROZEN													RBC REJUVENATED DEGLYCEROLIZED													CRYOPRECIPITATED AHF													PLATELETS						X							LEUKOCYTES/GRANULOCYTES													PLASMA													PLASMA CRYOPRECIPITATE REDUCED													FRESH FROZEN PLASMA						X							LIQUID PLASMA													THERAPEUTIC EXCHANGE PLASMA													SOURCE LEUKOCYTES													SOURCE PLASMA													RECOVERED PLASMA													BLOOD PRODUCTS FOR DIAGNOSTIC USE													BLOOD BANK REAGENTS													OTHER												
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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)  South Bend Medical Foundation, Inc. ATTN: Christine D. Saitz BS, MLT (ASCP) 530 N. Lafayette Boulevard South Bend, IN 46601-1098		U.S. LICENSE NUMBER OF PARENT FIRM: <u>248</u>																																																																																																																																																																																																																																																																																																
<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 D. Saitz BS, MLT (ASCP) 8.2 E-MAIL ADDRESS csaitz@sbfm.org 8.3 PHONE 574-234-4176 x5422      8.4 DATE																																																																																																																																																																																																																																																																																																