

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER
FEI: 3007701926
CFN:
2. U.S. LICENSE NUMBER
248

3. REASON FOR SUBMISSION
.1 ANNUAL REGISTRATION
.2 INITIAL REGISTRATION
.3 CHANGE IN INFORMATION

FOR FDA USE ONLY



DISTRICT OFFICE: Detroit
VALIDATED BY FDA: 30-NOV-2011
PRINTED BY FDA: 12-DEC-2011

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)).

ENTER ALL CHANGES IN RED INK AND CIRCLE.

4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code)

South Bend Medical Foundation, Inc.
Marion Donor Center
330 N. Wabash Avenue
Marion, IN 46952

4.1 PHONE 765-662-4630

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.)

9. TYPE OF OWNERSHIP

.1 SINGLE PROPRIETORSHIP
.2 PARTNERSHIP
.3 CORPORATION profit___ non-profit
.4 COOPERATIVE ASSOCIATION
.5 FEDERAL (non-military)
.6 U.S. MILITARY
.7 STATE
.8 COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
.9 OTHER (Specify): _____

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)

.1 COMMUNITY (NON-HOSPITAL) BLOOD BANK
.2 HOSPITAL BLOOD BANK
.3 PLASMAPHERESIS CENTER
.4 PRODUCT TESTING LABORATORY
a. ___ INDEPENDENT
___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
.5 HOSPITAL TRANSFUSION SERVICE
a. ___ APPROVED FOR MEDICARE REIMBURSEMENT
___ NOT APPROVED FOR MEDICARE REIMBURSEMENT
.6 COMPONENT PREPARATION FACILITY
.7 COLLECTION FACILITY
.8 DISTRIBUTION CENTER
.9 BROKER/WAREHOUSE
.10 OTHER (Specify): _____

U.S. LICENSE NUMBER OF PARENT FIRM _____

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: Robert J. Tomec, MD
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)

7.1 E-MAIL ADDRESS

7.2 PHONE

8. REPORTING OFFICIAL'S SIGNATURE



8.1 TYPED NAME Robert J. Tomec, MD

8.2 E-MAIL ADDRESS rtomec@sbfm.org

8.3 PHONE 574-234-4176

8.4 DATE 12/13/2011

11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS		
										ALLOGENEIC	AUTOLOGOUS
<input checked="" type="checkbox"/> WHOLE BLOOD	1	<input checked="" type="checkbox"/>									
RED BLOOD CELLS (RBC)	2										
RBC FROZEN	3										
RBC DEGLYCEROLIZED	4										
RBC REJUVENATED	5										
RBC REJUVENATED FROZEN	6										
RBC REJUVENATED DEGLYCEROLIZED	7										
CRYOPRECIPITATED AHF	8										
PLATELETS	9										
LEUKOCYTES/GRANULOCYTES	10										
PLASMA	11										
PLASMA CRYOPRECIPITATE REDUCED	12										
FRESH FROZEN PLASMA	13										
LIQUID PLASMA	14										
THERAPEUTIC EXCHANGE PLASMA	15										
SOURCE LEUKOCYTES	16										
SOURCE PLASMA	17										
RECOVERED PLASMA	18										
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19										
BLOOD BANK REAGENTS	20										
OTHER	21										