

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

1. REGISTRATION NUMBER
FEI: 3000204209
CFN: 1835281

2. U.S. LICENSE NUMBER
248

3. REASON FOR SUBMISSION

1 ANNUAL REGISTRATION
2 INITIAL REGISTRATION
3 CHANGE IN INFORMATION

FOR FDA USE ONLY 91



DISTRICT OFFICE: Detroit
VALIDATED BY FDA: 30-NOV-2009
PRINTED BY FDA: 02-DEC-2009

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.

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.
118 W. Edison Road
Mishawaka, IN 46545-3143

4.1 PHONE 574-273-8879

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.)

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)).

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
 - * INDEPENDENT
 - ___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
- 5 HOSPITAL TRANSFUSION SERVICE
 - * 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): _____

248
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

Robert J. Tomec

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 12/15/09

11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS		
										ALLOGENEIC	AUTOLOGOUS
WHOLE BLOOD	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<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			<input checked="" type="checkbox"/>							
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										