

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

**1. REGISTRATION NUMBER**

FEI: 1872515

CFN: 1872515

**2. U.S. LICENSE NUMBER**

248

**3. REASON FOR SUBMISSION**

- .1  ANNUAL REGISTRATION
- .2  INITIAL REGISTRATION
- .3  CHANGE IN INFORMATION

FOR FDA USE ONLY

15



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)).

DISTRICT OFFICE: Detroit  
VALIDATED BY FDA: 20-FEB-2010  
PRINTED BY FDA: 01-MAR-2010

**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.  
Elkhart General Hospital Blood Bank  
600 East Boulevard  
Elkhart, IN 46514-1329

4.1 PHONE 574-295-6160

**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):

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**

8.1 TYPED NAME Robert J. Tomec, MD

8.2 E-MAIL ADDRESS rtomec@smbf.org

8.3 PHONE 574-234-4176

8.4 DATE

**11. PRODUCTS**

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