

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

1. REGISTRATION NUMBER

FEI 1070186
CFN 1070186

2. U.S. LICENSE NUMBER

1288

3. REASON FOR SUBMISSION

- ANNUAL REGISTRATION
- INITIAL REGISTRATION
- CHANGE IN INFORMATION

FOR FDA USE ONLY



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 333(a)).

DISTRICT OFFICE: Florida
VALIDATED BY FDA: 14-DEC-2017
PRINTED BY FDA: 08-JAN-2018

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)

Suncoast Communities Blood Bank, Inc.
1875 Arlington Street
Sarasota, FL 34239

4.1 PHONE 941-955-2956

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

- SINGLE PROPRIETORSHIP
- PARTNERSHIP
- CORPORATION profit non-profit
- COOPERATIVE ASSOCIATION
- FEDERAL (non-military)
- U.S. MILITARY
- STATE
- COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
- OTHER (Specify):

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

- COMMUNITY (NON-HOSPITAL) BLOOD BANK
- HOSPITAL BLOOD BANK
- PLASMAPHERESIS CENTER
- PRODUCT TESTING LABORATORY
 - a INDEPENDENT
 - ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
- HOSPITAL TRANSFUSION SERVICE
 - a APPROVED FOR MEDICARE REIMBURSEMENT
 - NOT APPROVED FOR MEDICARE REIMBURSEMENT
- COMPONENT PREPARATION FACILITY
- COLLECTION FACILITY
- DISTRIBUTION CENTER
- BROKER/WAREHOUSE
- 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)

Suncoast Communities Blood Bank, Inc.
ATTN: Scott M. Bush, CEO
1760 Mound Street
Sarasota, FL 34236-7740

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 Scott M. Bush, CEO

8.2 E-MAIL ADDRESS sbush@scbb.org

8.3 PHONE 941-954-1600 x1014

8.4 DATE

11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS		
										ALLOGENEIC	AUTOLOGOUS
WHOLE BLOOD	1					X		X	X		
RED BLOOD CELLS (RBC)	2				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 DEGLYCEROL ZED	7										
CRYOPRECIPITATED AHF	8							X	X		
PLATELETS	9				X	X		X	X		
LEUKOCYTES/GRANULOCYTES	10					X		X	X		
PLASMA	11										
PLASMA CRYOPRECIPITATE REDUCED	12							X	X		
FRESH FROZEN PLASMA	13							X	X		
LIQUID PLASMA	14										
THERAPEUTIC EXCHANGE PLASMA	15							X	X		
SOURCE LEUKOCYTES	16										
SOURCE PLASMA	17										
RECOVERED PLASMA	18										
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19										
BLOOD BANK REAGENTS	20										
OTHER bacterial detection device to re-label apha	21			X				X	X		