## DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION

## **BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING**

1. REGISTRATION NUMBER

FEI: 1000124910 CFN: 2077913 2. U.S. LICENSE NUMBER

201

.1 🗸 ANNUAL REGISTRATION .2 INITIAL REGISTRATION

3. REASON FOR SUBMISSION

.3 CHANGE IN INFORMATION

	<b>                                    </b>	

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. Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a

FOR FDA USE ONLY

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.	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: Los Angeles VALIDATED BY FDA: 21-DEC-2016 PRINTED BY FDA: 18-JAN-2017											
ENTER ALL CHANGES IN RED INK AND CIRCLE.	9. TYPE OF OWNERSHIP			10. TY	PE ESTABI	ISHMEN	Check all b	oxes that desc	ibe routine or	autologous c	perations.)	
4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code)  San Diego Blood Bank 776 Arnele Avenue El Cajon, CA 92020	.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):			.2 [ .3 [ .4 [ .5 [	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  201							
4.1 PHONE 619-400-8254				.8	.7 ☑ COLLECTION FACILITY .8 ☐ DISTRIBUTION CENTER  201 u.s. LICENSE NUMBER OF PARENT FIRM							
<ol> <li>OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business- as, previous names, and other firms co-located. If applicable, include registration number.)</li> </ol>					BROKERN OTHER (S		E					
East County Donor Center	11. PRODUCTS		COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and	
								( -			DISTRIBUTE to OTHERS	
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if	ALLOGENEIC AUTOLOGOUS DIRECTED		(.1)	(.2)	(.3)	(.4)	(.5)	(.6)	(.7)	(8.)	(.9)	
applicable, number and street, city, state, country, and post office code)	WHOLE BLOOD	1	х									
San Diego Blood Bank	RED BLOOD CELLS (RBC)	2			Х							
ATTN: Helen A. Bixenman	RBC FROZEN	3			-							
3636 Gateway Center Ave. Suite 100	RBC DEGLYCEROLIZED	4			-							
San Diego, CA 92102	RBC REJUVENATED	5			-							
	RBC REJUVENATED FROZEN	6										
	RBC REJUVENATED DEGLYCEROLIZED	7										
THO ACENT (L. L. L. L. C. C. C. L. L. L. L. L. C. C. C. C. L. L. L. C.	CRYOPRECIPITATED AHF	8										
<ol> <li>U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code)</li> </ol>	PLATELETS	9			X		Х					
,,	LEUKOCYTES/GRANULOCYTES	10										
	PLASMA	11			Х							
	PLASMA CRYOPRECIPITATE REDUCED	12										
	FRESH FROZEN PLASMA	13			-							
	LIQUID PLASMA	14										
	THERAPEUTIC EXCHANGE PLASMA	15										
7.1 E-MAIL ADDRESS	SOURCE LEUKOCYTES	16										
7.2 PHONE	SOURCE PLASMA	17										
8. REPORTING OFFICIAL'S SIGNATURE	RECOVERED PLASMA	18										
	BLOOD PRODUCTS FOR DIAGNOSTIC USE	19										
II 1 A D'	BLOOD BANK REAGENTS	20										
8.1 TYPED NAME Helen A. Bixenman	OTHER	21								<del></del>		
8.2 E-MAIL ADDRESS hbixenman@sandiegobloodbank.org										l .		

8.4 DATE

8.3 PHONE 619-400-8254