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

BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGIS	STRATION NUMBER
FEI:	2075359
CFN:	2075359

2. U.S. LICENSE NUMBER

.1 ANNUAL REGISTRATION

3. REASON FOR SUBMISSION

.2 | INITIAL REGISTRATION





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: Los Angeles VALIDATED BY FDA: 21-DEC-2016 PRINTED BY FDA: 18-JAN-2017

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)

San Diego Blood Bank 3636 Gateway Center Avenue, Suite 100 San Diego, CA 92102

4.1 PHONE 619-400-8254

5. OTHER NAMES U	ISED 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 PROPRIETOR

.2 PARTNERSHIP

.3 CORPORATION profit

.4 COOPERATIVE ASSOCIATION

.5 FEDERAL (non-military) .6 U.S. MILITARY

.7 STATE

.8 COUNTY/MUNICIPAL/HOSPITAL AUTHORITY

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
aAPPROVED FOR MEDICARE REIMBURSEMENT
NOT APPROVED FOR MEDICARE REIMBURSEMENT
.6 COMPONENT PREPARATION FACILITY
.7 COLLECTION FACILITY
.8 DISTRIBUTION CENTER U.S. LICENSE NUMBER OF PARENT FIRM
.9 BROKER/WAREHOUSE
10 OTHER (Specify):

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)

San Diego Blood Bank ATTN: Helen A. Bixenman 3636 Gateway Center Ave. Suite 100 San Diego, CA 92102

١	
l	7.1 E-MAIL ADDRESS

7. U.S. AGENT (Include name, institution name if applicable, number and street, city,	PLATELETS	9		
state, and zip code) 7.1 E-MAIL ADDRESS 7.2 PHONE	LEUKOCYTES/GRANULOCYTES	10		
	PLASMA	11		
	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	8	
	BLOOD PRODUCTS FOR DIAGNOSTIC USE	19	х	
	BLOOD BANK REAGENTS	20		
8.1 TYPED NAME Helen A. Bixenman	OTHER	21		
8.2 E-MAIL ADDRESS hbixenman@sandiegobloodbank.org				
8.3 PHONE 619-400-8254 8.4 DATE				
FORM FDA 2830 (05/2015) PREVIOUS EDITION IS OBSOLETE				

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