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

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

REGISTRATION NUMBER	3. REASON FOR SUBMISSION
FEI: 3007422916	.1 🗸 ANNUAL REGISTRATION
CFN:	.2 INITIAL REGISTRATION
2. U.S. LICENSE NUMBER	.3 CHANGE IN INFORMATION
201	.5 _ CHANGE IN IN CHWATION

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FOR FDA LISE ONLY

PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your This form is authorized by Sections 510(b), (j) and 704 of the Federal Food, Drug, and Cosmetic 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 DISTRICT OFFICE: Los Angeles 6. Print all entries and make all corrections in red ink, if possible. Enter your phone violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p)) and can VALIDATED BY FDA: 21-DEC-2016 number in item 8.3 and the phone number of your actual location in item 4.1. Sign the result in a fine of up to \$1,000 or imprisonment up to one year or both, pursuant to Section 303(a) form and return to FDA. After validation, you will receive your Official Registration for the of the Act (Title 21, United States Code 33.3(a)). PRINTED BY FDA: 18-JAN-2017 ensuing year. 10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.) 9. TYPE OF OWNERSHIP ENTER ALL CHANGES IN RED INK AND CIRCLE. 4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, .1 SINGLE PROPRIETORSHIP .1 COMMUNITY (NON-HOSPITAL) BLOOD BANK state, country, and post office code) .2 PARTNERSHIP .2 HOSPITAL BLOOD BANK .3 CORPORATION profit .3 PLASMAPHERESIS CENTER .4 COOPERATIVE ASSOCIATION .4 PRODUCT TESTING LABORATORY San Diego Blood Bank a. \_\_\_\_ INDEPENDENT .5 FEDERAL (non-military) 12640 Sabre Springs Pkwy \_\_\_\_ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK .6 U.S. MILITARY Suite 109 .5 HOSPITAL TRANSFUSION SERVICE San Diego, CA 92128 .7 STATE a. — APPROVED FOR MEDICARE REIMBURSEMENT .8 COUNTY/MUNICIPAL/HOSPITAL AUTHORITY — NOT APPROVED FOR MEDICARE REIMBURSEMENT .9 OTHER (Specify): .6 COMPONENT PREPARATION FACILITY .7 COLLECTION FACILITY 4.1 PHONE 619-400-8254 .8 DISTRIBUTION CENTER U.S. LICENSE NUMBER OF PARENT FIRM .9 BROKER/WAREHOUSE 5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-.10 OTHER (Specify): as, previous names, and other firms co-located. If applicable, include registration number.) Sabre Springs Donor Center AUTOMATED PREPARE LEUKOCYTES IRRADIATED REDUCED COLLECT MANUAL APHERESIS DONOR STORE and 11. PRODUCTS DISTRIBUTI to OTHERS X ALLOGENEIC AUTOLOGOUS DIRECTED (.1) (.2)(.3)(.4) (.5)(.6)(.7)(.9)6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if WHOLE BLOOD х applicable, number and street, city, state, country, and post office code) 2 RED BLOOD CELLS (RBC) San Diego Blood Bank Х **RBC FROZEN** 3 ATTN: Helen A. Bixenman RBC DEGLYCEROLIZED 4 3636 Gateway Center Ave. Suite 100 RBC REJUVENATED San Diego, CA 92102 RBC REJUVENATED FROZEN 6 7 RBC REJUVENATED DEGLYCEROLIZED 8 CRYOPRECIPITATED AHF 7. U.S. AGENT (Include name, institution name if applicable, number and street, city, PLATELETS 9 Х х state, and zip code) LEUKOCYTES/GRANULOCYTES 10 PLASMA 11 х 12 PLASMA CRYOPRECIPITATE REDUCED FRESH FROZEN PLASMA 13 LIQUID PLASMA 14 THERAPEUTIC EXCHANGE PLASMA 15 16 SOURCE LEUKOCYTES 7.1 E-MAIL ADDRESS

SOURCE PLASMA

RECOVERED PLASMA

BLOOD BANK REAGENTS

BLOOD PRODUCTS FOR DIAGNOSTIC USE

17

19

20

21

8.3 PHONE 619-400-8254 8.4 DATE

FORM FDA 2830 (05/2015 ) PREVIOUS EDITION IS OBSOLETE

8.2 E-MAIL ADDRESS hbixenman@sandiegobloodbank.org

8. REPORTING OFFICIAL'S SIGNATURE

8.1 TYPED NAME Helen A. Bixenman

7.2 PHONE