U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code) 8. REPORTING OFFICIAL'S SIGNATURE 7.1 E-MAIL ADDRESS 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include Institution name if 5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration 8.3 PHONE 512-206-1134 8.1 TYPED NAME Wendy R. Bailey, QA Compliance Manager 7.2 PHONE applicable, number and street, city, state, country, and post office code) 4.1 PHONE 512-206-1266 4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, ENTER ALL CHANGES IN RED INK AND CIRCLE 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 8.2 E-MAIL ADDRESS state, country, and post office code) ensuing year. form and return to FDA. After validation, you will receive your Official Registration for the number in item 8.3 and the phone number of your actual location in item 4.1. Sign the Print all entries and make all corrections in red ink, if possible. Enter your phone We Are Blood 2132 North Mays Austin, TX 78756 4300 North Lamar Boulevard Round Rock, TX 78664 ATTN: Wendy R. Bailey, QA Compliance Manager We Are Blood Suite 900 We Are Blood PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING DEPARTMENT OF HEALTH AND HUMAN SERVICES wbailey@weareblood.org en uc 1-66.20 of the Act (Title 21, United States Code 33.3(a)) OTHER result in a fine of up to \$1,000 or imprisonment up to one year or both, pursuant to Section 303(a) violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p)) and can **BLOOD BANK REAGENTS BLOOD PRODUCTS FOR DIAGNOSTIC USE** RECOVERED PLASMA SOURCE PLASMA SOURCE LEUKOCYTES LIQUID PLASMA FRESH FROZEN PLASMA PLASMA CRYOPRECIPITATE REDUCED PLASMA LEUKOCYTES/GRANULOCYTES PLATELETS CRYOPRECIPITATED AHF RBC REJUVENATED DEGLYCEROLIZED RBC REJUVENATED RBC DEGLYCEROLIZED RED BLOOD CELLS (RBC) WHOLE BLOOD THERAPEUTIC EXCHANGE PLASMA RBC REJUVENATED FROZEN RBC FROZEN 11. PRODUCTS 9. TYPE OF OWNERSHIP ALLOGENEIC .8 COUNTY/MUNICIPAL/HOSPITAL AUTHORITY 6 U.S. MILITARY .5 FEDERAL (non-military) .3 CORPORATION profit .1 SINGLE PROPRIETORSHIP 9 OTHER (Specify): 4 COOPERATIVE ASSOCIATION 2 PARTNERSHIP AUTOLOGOUS 2. U.S. LICENSE NUMBER 1. REGISTRATION NUMBER FEI: 3004509482 DIRECTED non-profit V 6 ಸ 20 8 7 6 5 ದ ± la 1 COLLECT Ξ × MANUAL APHERESIS છ 10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.) 3. REASON FOR SUBMISSION 10 OTHER (Specify): .3 CHANGE IN INFORMATION .2 INITIAL REGISTRATION .1 ANNUAL REGISTRATION .8 DISTRIBUTION CENTER .6 COMPONENT PREPARA 5 HOSPITAL TRANSFUSION SERVICE .4 PRODUCT TESTING LABORATORY .1 COMMUNITY (NON-HOSPITAL) BLOOD BANK 9 BROKERWAREHOUSE 3 PLASMAPHERESIS CENTER 2 HOSPITAL BLOOD BANK AUTOMATED APHERESIS COMPONENT PREPARATION FACILITY હ × × INDEPENDENT APPROVED FOR MEDICARE REIMBURSEMENT ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK NOT APPROVED FOR MEDICARE REIMBURSEMENT PREPARE 3 REDUCED M 9 VALIDATED BY FDA: 22-FEB-2017 DISTRICT OFFICE: PRINTED BY FDA: IRRADIATED 9 U.S. LICENSE NUMBER OF PARENT FIRM FOR FDA USE ONLY DONOR S 22-FEB-2017 Dallas 韶 9 STORE and DISTRIBUTE to OTHERS 9