FORM APPROVED: OMB No. 0910-0052. Expiration Date: March 31, 2015. See page 3 for Burden Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. **REGISTRATION NUMBER**
FEI :
CFN :

2. **U.S. LICENSE NUMBER**

3. **REASON FOR SUBMISSION**
.1 ☐ ANNUAL REGISTRATION
.2 ☐ INITIAL REGISTRATION
.3 ☐ CHANGE IN INFORMATION

FOR FDA USE ONLY

DISTRICT OFFICE:

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.

ENTER ALL CHANGES IN RED INK AND CIRCLE.

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)).

4. **LEGAL NAME AND LOCATION** (Include legal name, number and street, city, state, country, and post office code.)

4.1 PHONE ( )

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.)

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

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
8.2 E-MAIL ADDRESS
8.3 PHONE ( ) 8.4 DATE

9. **TYPE OF OWNERSHIP**
.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):

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
.8 ☐ DISTRIBUTION CENTER
.9 ☐ BROKER/WAREHOUSE
.10 ☐ OTHER (Specify):
U.S. LICENSE NUMBER OF PARENT FIRM

11. **PRODUCTS**
☐ ALLOGENEIC ☐ AUTOLOGOUS ☐ DIRECTED

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

INSTRUCTIONS FOR COMPLETING BLOOD REGISTRATION FORM 2830

These instructions will help you complete FDA 2830. The FDA requires all blood establishments that collect, manufacture, prepare, store under controlled conditions for further distribution, or process blood and blood products to register under Title 21, CFR, Part 607. Hospital Transfusion Services certified under the Medicare program are exempt from registration (see 21 CFR 607.65(f)). We consider establishments that perform certain manufacturing steps to be Hospital Blood Banks, which are required to register. See instructions for Item 10.2 for these manufacturing steps.

Please review all pre-printed data for accuracy and completeness. Circle incorrect items in RED INK, and PRINT all corrections and additions.

Note the following: YOU MUST NOTIFY FDA WITHIN 5 DAYS IF YOU CHANGE LOCATION.

Item 2. U.S. LICENSE NUMBER-- The FDA Center for Biologics Evaluation and Research (CBER) issues U.S. Licenses under section 351 of the Public Health Service Act to firms that apply for licensure and otherwise qualify. Licenses are appropriate only for firms engaged in interstate commerce. Only Blood Banks, Plasmapheresis Centers, Product Testing Laboratories, and others are assigned unique license numbers. If your establishment is licensed, your U.S. License number appears in item 2 for your major manufacturing facilities. Establishments such as Component Preparation Facilities, Collection Facilities, and Distribution Centers that operate under the license of a parent establishment have the parent U.S. License number next to Item 10.7.

Item 4. LEGAL NAME AND LOCATION-- Provide the legal name (not the "doing-business-as" or other names in Item 5), street address, and telephone number of the actual location. Include the postal code (and, for U.S. firms, the 4-digit ZIP code extension). NOTE: If blood collection and laboratory facilities are separated, but register as one establishment because of their close proximity, use the laboratory address.

Item 5. OTHER NAMES USED AT THIS LOCATION--Provide any other name by which your facility is commonly known, including any name not shown in Item 4, that is or was used at this location. This includes trade, doing-business-as, and previous names, and names of unaffiliated corporations at the same location. If registered with FDA, include the registration number in parentheses.

Item 6. MAILING ADDRESS OF REPORTING OFFICIAL--Provide the reporting official's mailing address if it is different from the actual location of the establishment. Include the postal code (and, for U.S. firms, the 4-digit ZIP code extension).

Item 7. U.S. AGENT-- Non-U.S. establishments only: Provide your U.S. agent name, institution name if applicable, street address, e-mail address, and telephone number.

Item 8. REPORTING OFFICIAL'S SIGNATURE--The reporting official is the person appointed by the owner or operator to register the firm and answer all letters and inquiries about registration. Include the reporting official's e-mail address and telephone number.

Item 10. TYPE ESTABLISHMENT--Check all applicable boxes that describe your routine or autologous operations. If you check Hospital Transfusion Service (10.5) do not check any other block. If you operate as an auxiliary establishment (e.g., a donor center) for a Community or Hospital Blood Bank, check blocks 10.6 through 10.8 as applicable. If your parent blood bank is licensed, include the parent license number. NOTE: There is now a line for component brokers, independent distributors, and warehouses.

.1 Community (Non-hospital) Blood Bank--A commercial or non-profit blood collection/processing establishment, not located in a hospital, that may perform product testing and routinely distributes blood and/or blood products to one or more hospitals. We consider an independent blood bank located inside a hospital, but separately operated and owned, to be a Hospital Blood Bank (Item 10.2).

.2 Hospital Blood Bank--A hospital (or establishment located within a hospital) that routinely collects or processes Whole Blood or blood components. Components may be collected by apheresis or prepared from Whole Blood. Processing includes freezing, deglycerolizing, washing, irradiating, rejuvenating, or leukocyte-reducing Red Blood Cells. We include hospitals that perform autologous or directed collections in this category. Hospital Blood Banks usually perform product testing (such as blood grouping and hepatitis testing), as well as compatibility testing. We consider hospitals that solely prepare Red Blood Cells or Recovered Plasma, pool Platelets or Cryoprecipitated AHF for ease of transfusion, or issue bedside leukocyte-reduction filters with blood components to be Hospital Transfusion Services (Item 10.5). A hospital that collects Source Plasma under licensure should also check "Plasmapheresis Center."

.3 Plasmapheresis Center--An establishment licensed by the FDA/CBER that collects Source Plasma or Therapeutic Exchange Plasma for commercial distribution. If you also collect Whole Blood for a licensed establishment, check "Collection Facility" and include the license number of the parent firm. Hospitals that perform plasmapheresis for research purposes only or to prepare transfusion products such as Plasma or Platelets, Pheresis, should NOT check this box.

.4 Product Testing Laboratory--A separate establishment that performs routine blood and plasma donor testing. You must also answer Item 10.4a concerning type establishment.

.5 Hospital Transfusion Service--A hospital that performs compatibility testing (crossmatching) for blood or blood components but does NOT routinely collect allogeneic or autologous blood, or process Whole Blood into components (except Red Blood Cells and Recovered Plasma). We consider hospitals that freeze, deglycerolize, wash, irradiate, rejuvenate, or reduce the number of leukocytes from Red Blood Cells to be Hospital Blood Banks (Item 10.2). You must also answer Item 10.5a concerning Medicare program reimbursement.

.6 Component Preparation Facility--An intermediate processing establishment that prepares components from blood collected by a mobile or fixed collection site but does not perform product testing. If applicable, indicate the license number under which the component preparation facility operates. If you also collect or redistribute, check Item 10.7 or 10.8.

.7 Collection Facility-- An establishment that performs blood collections or apheresis, but does not test. If applicable, indicate the U.S. License number under which the collection facility operates. If you also redistribute the final product after it has been processed and returned to you by the blood bank, then check Distribution Center, Item 10.8.

.8 Distribution Center--An establishment that stores blood or blood products FOR TRANSFUSION under specific controlled conditions prior to shipping it to the final user. A transfusion service is not typically considered to be a "distribution center" since it holds the product over a relatively short period of time and does not intend to redistribute. If you are a transfusion service operating as a depot or distribution center for a blood bank, register as a Distribution Center and include the license number of the blood bank, if licensed.

.9 Broker/Warehouse-- A broker, distributor, or warehouse that stores and redistributes source material for further manufacture, such as Recovered Plasma, Source Plasma, and whole blood, red blood cells, or platelets for diagnostic product use.

.10 Other (specify)--This includes firms that manufacture fractionated blood derivatives, diagnostics, and other blood products, or independent establishments that irradiate blood products.

Item 11. PRODUCTS--Check all products that you manufacture in the appropriate columns. This includes allogeneic, autologous, and directed collections, or products prepared, tested, or stored for distribution to other firms. See the Product Definition section for information on products. Do not fill in shaded areas. You must list, in 11.21 "Other," any product you manufacture that is not specified in the product list. Do not list products you do not manufacture, but only hold for final use, such as albumin, reagents, immune globulins, etc.

Do not list any products you collect as a by-product of a therapeutic procedure and immediately destroy. Similarly, exclude products prepared under emergency conditions. We define an emergency as a situation that demands immediate action that has been suitably documented in writing by a responsible person. Do not list products that are pooled or divided into pediatric aliquots. A completed FDA 2657, "Drug Product Listing," or FDA 2892, "Medical Device Listing," must be submitted for any product not previously listed with FDA in order that an NDC Labeler Code may be assigned.

If you collect blood, indicate Allogeneic, Autologous, or Directed donor classifications. Allogeneic collections are intended for transfusion to other than the donor or a known recipient. Autologous collections are intended for transfusion at a later time to the donor. Directed collections are intended for transfusion to a known recipient.

(.1) Collect--refers to collection of whole blood or blood products for transfusion or further manufacturing into injectable or non-injectable products.

(.2) Manual Apheresis--refers to procedures such as plasmapheresis, plateletpheresis, and leukapheresis, in which unneeded portions of the whole blood are returned to the donor.

(.3) Automated Apheresis--refers to the collection of Red Blood Cells, Platelets, Leukocytes, Granulocytes, or Plasma by automated equipment.

INSTRUCTIONS FOR COMPLETING BLOOD REGISTRATION FORM 2830 (Continued)

(.4) Prepare--refers to functions such as component preparation from Whole Blood. For example, if you prepare Platelets from Whole Blood, check box 9(.4). If you collect Platelets by automated apheresis, check box 9(.3). Check box 9(.2) for Platelets collected by manual apheresis.

(.5) Leukocytes Reduced--refers to blood products processed to remove leukocytes before issue. Leukocyte-reduced products should meet the criteria for residual leukocyte count and product recovery described in FDA recommendations. Do not include products leukocyte reduced during transfusion.

(.6) Irradiated--refers to irradiation of blood products before transfusion. Check this only if you are performing the irradiation step, or have a contract manufacturing agreement for another establishment to perform the irradiation for you.

(.7) Donor Retested--refers to storage of products for a minimum of 112 days, until the donor returns for subsequent donation or testing, and all infectious disease markers are negative at the subsequent testing.

(.8) Test--refers to product testing such as blood grouping, syphilis, hepatitis, HIV, and protein electrophoresis, as well as compatibility testing (crossmatching). It does not include daily quality control tests of reagents.

(.9) Store and Distribute to Others--refers to storage of products under controlled conditions for distribution to other firms.

THE REPORTING OFFICIAL MUST SIGN AND DATE THIS FORM. After completion, send the form to:

Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-370)
ATTENTION: Blood Registration Coordinator
1401 Rockville Pike, 200N
Rockville, MD 20852-1448

After we update your registration form, we will send a validated form to the location shown for the registering establishment, and to you if your address is different. If you have questions, contact the Blood Registration Coordinator at 301-827-3546, or by e-mail at <bloodregis@cber.fda.gov>.

PRODUCT DEFINITION

.1 Whole Blood--All blood collected from human donors for transfusion to human recipients using an approved anticoagulant preservative solution.

.2 Red Blood Cells--Red Blood Cells remaining after separating plasma from human blood, or collected by apheresis.

.3 RBC Frozen--Red Blood Cells stored at ultra-low temperature in the presence of a cryoprotective agent, which may be preserved for long periods of time.

.4 RBC Deglycerolized--Red Blood Cells washed free of the glycerol in which they have been stored.

.5 RBC Rejuvenated--Red Blood Cells treated with a rejuvenating solution, such as pyruvate inosine, to restore cell integrity.

.6 RBC Rejuvenated Frozen--Red Blood Cells treated with a rejuvenating solution, then frozen and stored at ultra-low temperatures in the presence of a cryoprotective agent.

.7 RBC Rejuvenated Deglycerolized--Red Blood Cells treated with a rejuvenating solution, frozen using a cryoprotective agent, and then washed free of the rejuvenating solution and glycerol.

.8 Cryoprecipitated AHF--A preparation containing antihemophilic factor obtained from a single unit of plasma.

.9 Platelets--Platelets collected from a single donor and suspended in a specified volume of original plasma.

.10 Leukocytes/Granulocytes--White Blood Cells (leukocytes) collected from a single donor and suspended in a specific volume of original plasma intended for patient infusion.

.11 Plasma--The fluid portion of one unit of human blood intended for transfusion which, in a closed system, has been collected, stabilized against clotting, and separated from red cells within 26 days after phlebotomy (40 days when CPDA-1 is used as the anticoagulant) and stored at -18°C or colder.

.12 Plasma Cryoprecipitate Reduced--Plasma from which Cryoprecipitated AHF has been removed.

.13 Fresh Frozen Plasma--Single donor plasma prepared from Whole Blood within 8 hours of collection, or collected by automated apheresis, and stored at -18°C or colder.

.14 Liquid Plasma--Single donor plasma separated from red cells within 26 days after phlebotomy (40 days when CPDA-1 is used as the anticoagulant) and stored at 1-6°C.

.15 Therapeutic Exchange Plasma (TEP)--Plasma obtained from a patient who undergoes plasma exchange (also called therapeutic plasmapheresis). Do not list TEP that is destroyed immediately. TEP is intended as a source material for further manufacturing use, and may not be distributed without a license.

.16 Source Leukocytes--White Blood Cells intended as source material for further manufacturing use.

.17 Source Plasma--The fluid portion of human blood collected by plasmapheresis (except plasma derived by therapeutic plasma exchange) and intended as a source material for further manufacturing use. This includes source material intended for injectable and non-injectable products.

.18 Recovered Plasma--Plasma derived from single units of Whole Blood, Plasma, or as a by-product in the preparation of blood components from Whole Blood, for use in the manufacturing of licensed or unlicensed products.

.19 Blood Products for Diagnostic Use--Whole Blood, Red Blood Cells, or Platelets shipped for further manufacture into non-injectable products.

.20 Blood Bank Reagents-- Diagnostic substances manufactured for commercial distribution used to characterize and determine the acceptability of blood or products for transfusion purposes. These include reagent Red Blood Cells, blood grouping reagents, antibody to HBsAg, etc. A separate FDA 2892, "Medical Device Listing," should be submitted for each product when a product is initially listed.

.21 Other--Other products not listed above that you manufacture for commercial distribution. This includes fractionated blood derivatives such as immune globulins, albumin, etc. Do not list these products if you do not manufacture them. When submitting an initial product listing, list each product individually on the FDA 2657, "Drug Product Listing".

February, 2003

Paperwork Reduction Act Statement